ORIGINAL

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF THE ADMINISTRATIVE LAW JUDGES
Washington, D.C.

In the Matter of **ECM BIOFILMS, INC.,** **a corporation, also d/b/a** **Enviroplastics International,** **Respondent.**	**Docket No. 9358** **PUBLIC**

RESPONDENT ECM BIOFILMS' PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW, & POST-TRIAL BRIEF

Jonathan W. Emord, Esq.
Emord & Associates, P.C.
11808 Wolf Run Lane
Clifton, VA 20124
Ph: 202-466-6937
Fx: 202-466-6938
Em: jemord@emord.com

Peter A. Arhangelsky, Esq.
Eric J. Awerbuch, Esq.
Bethany R. Kennedy, Esq.
Joshua Furman
Emord & Associates, P.C.
3210 S. Gilbert Road, Ste 4
Chandler, AZ 85286
Ph: 202-466-6937
Fx: 602-393-4361
Em: parhangelsky@emord.com, eawerbuch@emord.com,
bkennedy@emord.com

Dated: September 25, 2014

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF THE ADMINISTRATIVE LAW JUDGES
Washington, D.C.

In the Matter of **ECM BioFilms, Inc.,** **a corporation, also d/b/a** **Enviroplastics International,** **Respondent.**	**Docket No. 9358** **PUBLIC**

RESPONDENT ECM BIOFILMS' PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

Jonathan W. Emord, Esq.
Emord & Associates, P.C.
11808 Wolf Rune Lane
Clifton, VA 20124
Ph: 202-466-6937
Fx: 202-466-6938
Em: jemord@emord.com

Peter A. Arhangelsky, Esq.
Eric J. Awerbuch, Esq.
Bethany R. Kennedy, Esq.
Joshua Furman
Emord & Associates, P.C.
3210 S. Gilbert Road, Ste 4
Chandler, AZ 85286
Ph: 202-466-6937
Fx: 602-393-4361
Em: parhangelsky@emord.com, eawerbuch@emord.com,
bkennedy@emord.com

TABLE OF CONTENTS

RESPONDENT ECM BIOFILMS' PROPOSED FINDINGS OF FACT

I. SUMMARY OF COMPLAINT, ANSWER AND PROCEDURAL BACKGROUND

A. FTC's Complaint

1. The Federal Trade Commission ("FTC") issued its Complaint against ECM BioFilms, Inc. ("Respondent" or "ECM") on October 18, 2013. (*See* Comp.).

2. The Complaint challenges ECM's advertising of its plastics additive, MasterBatch Pellets ("ECM Additives"), the formula for which is a trade secret. (Comp. ¶ 2).

3. The FTC alleges that Respondent disseminated or caused to be disseminated printed advertisements, website advertisements, certifications and other promotional materials to distributors, customers, and end-use consumers. (Comp. ¶ 4).

4. The FTC alleges that these materials make false and/or misleading representations. (Comp. ¶ 11).

5. Specifically, the FTC complains of four claims: 1) ECM Plastics are biodegradable; 2) ECM Plastics are biodegradable in a landfill; 3) ECM Plastics biodegrade in a stated qualified timeframe (nine months to five years OR greater than one year); and 4) ECM Plastics have been shown to be biodegradable, biodegradable in a landfill, or biodegradable in a stated qualified timeframe under various scientific tests, including, but not limited to, ASTM D5511. (Comp. ¶ 9).

6. The FTC defines the term "biodegradable" to mean "will completely break down and decompose into elements found in nature within a reasonably short period of time after customary disposal." (Comp. ¶ 9(A)).

7. The FTC defines a "reasonably short period of time" to be "one year or less." (Comp.¶¶ 4(A), 9(A)(i)).

8. The FTC refutes the validity of all four alleged ECM claims. (Comp. ¶ 10).

9. The FTC alleges that at the time ECM made the above representations, ECM did not possess and rely on a reasonable basis that substantiated the representations. (Comp. ¶ 13).

10. Complaint Counsel alleges that Respondent distributed promotional materials to its customers and independent distributors, and in so doing, provided them with the means and instrumentalities for the commission of deceptive acts or practices in violation of section 5(a) of the FTCA. (Comp. ¶ 14–15).

B. ECM's Answer

11. Respondent filed an answer on November 14, 2013. (*See* Answer).

12. In its Answer, Respondent explains that the Complaint fails to state a claim upon which relief can be granted under Section 5 of the FTC Act, 15 U.S.C. § 45. (Answer at 11).

13. Respondent states that the requested relief, if granted, would not be in the public interest. (Answer at 12).

14. Respondent further states that any alleged deception of the end-use consumer is caused by third parties, i.e. downstream plastics manufacturers and suppliers who market directly to end-use consumers. (Answer at 11).

15. Respondent states that it acted in good faith in all of its marketing practices and took affirmative steps to comply with apparent FTC advertising requirements after the FTC revised its Green Guides effective October 2012. (Answer at 12).

16. Respondent also states that there is no danger of recurrence of any of the alleged violations and the requested relief is not reasonably related to ECM's alleged violations. (Answer at 13).

17. Respondent further states that the advertising claims excerpted by the FTC in its Complaint are not material to the purchasing decisions of ECM customers. (Answer at 13).

18. Respondent states that the Complaint ordering paragraphs, if adopted, violate ECM's First Amendment right to communicate truthful commercial speech, and as such, the FTC lacks authority to impose the requested relief. (Answer at 13).

19. Respondent also states that the FTC's allegations are predicated on arbitrary and capricious regulatory policies, particularly the One Year Rule, that are illogical, contrary to scientific evidence, and not based on substantial evidence. (Answer at 14).

20. Respondent further states that the FTC violates the APA by arbitrarily and capriciously enforcing its 2012 revisions to the Green Guides to commercial speech that predated those same guides. (Answer at 15).

21. Respondent states that the Commission violates ECM's right to Due Process under the Fifth Amendment to the United States Constitution by abrogating the Separation of Functions Doctrine. (Answer at 15).

22. Respondent denies any allegation to the extent that it depends on the FTC's definition of "biodegradable." (*See* Answer).

23. Respondent states that it has always qualified its claims to provide its customers accurate and non-misleading information concerning the nature and characteristics of the Plastic containing the ECM additive. (Answer ¶ 9(A)).

24. ECM admits that it has claimed that the Plastic containing the ECM additive causes plastics to degrade through biological means, but denies that it has made unqualified plastic elimination claims in advertising concerning the Plastic containing the ECM additive in landfills. (Answer ¶ 9(B)).

25. ECM further states that its advertising plainly explains that the rate of plastic degradation is dependent on ambient environmental conditions. (Answer ¶ 9(B)).

26. Respondent denies that its biodegradable claim is deceptive, false, or misleading in any respect. (Answer ¶ 9(B)).

27. Respondent asserts that it has proven through competent and reliable testing that plastics manufactured with the Plastic containing the ECM additive will fully biodegrade through biological means when exposed to micro-organisms commonly present in the outdoor environment, including in landfills. (Answer ¶ 9(B)).

C. Procedural Background

28. Respondent, a small corporation with only six employees, has endured an unusually costly and burdensome discovery process throughout this litigation. (Sullivan, Tr. 699; Sinclair, Tr. 860).

29. Complaint Counsel's discovery requests were without limitation, seeking all files related to the "ECM additive," which included virtually every document in ECM's possession, custody or control, without time limitation. (Complaint Counsel's First Set of Requests for Product of Documents; Complaint Counsel's Second Set of Requests for Production of Documents; Complaint Counsel's Third Set of Requests for Production of Documents; Complaint Counsel's Forth Set of Requests Pursuant to Rule 3.37).

30. Rather than incur the expense of costly motion practice to oppose the overbroad requests, ECM reluctantly complied and turned over more than 100,000 pages of email communications with, and data base summations concerning communications with, customers. (Sinclair, Tr. 860; *see e.g.*, RX 120 (Bates stamped as "ECM

114860," indicating that it was the 114,860th page disclosed by ECM to Complaint Counsel).

31. The parties performed 29 depositions in this case with Complaint Counsel taking 4 depositions of ECM employees and 21 depositions of non-parties. (CCX 799–CCX 805; CCX 808–813; CCX 815–822; CCX 943; CCX 1075; RX 841–RX 843; RX 851; RX 858; RX 970).

32. Complaint Counsel's extensive use of discovery forced Respondent to appear unrepresented in 8 depositions and have counsel available only telephonically in 6 depositions. (CCX 800; CCX 803; CCX 801; CCX 810; CCX 811; CCX 812; CCX 817; CCX 822; CCX 802; CCX 804; CCX 808; CCX 809; CCX 815; CCX 821).

33. The final pre-hearing conference was held on July 29, 2014, with trial commencing on August 5, 2014.

34. Over 2,000 exhibits were designated prior to the hearing. (JX-1-A).

35. Respondents submitted into evidence thirty-three (33) scientific studies supporting its biodegradability claim.

36. The testimonial portion of the trial concluded on August 29, 2014 after 15 days of trial testimony.

37. The hearing record was closed on September 4, 2014, pursuant to Commission Rule 3.44(c), by Order dated August 29, 2014. (Tr. 3002–02),

38. On September 25, 2014, 2014, the parties filed concurrent post-trial briefs, proposed findings of fact, and findings of law.

D. Evidence Before This Court

These findings of fact are based on the exhibits properly admitted into evidence, the transcripts of testimony at trial, and the briefs submitted by the parties. References to the record are abbreviated as follows:

CCX- Complaint Counsel's Exhibit

RX- Respondent's Exhibit

Tr.- Transcript of Testimony before the ALJ

Dep.- Transcript of witness deposition

JX-3- Joint Stipulations of Law and Facts

II. BACKGROUND OF ECM BIOFILMS, INC.

39. ECM BioFilms, Inc. is an Ohio-based corporation started by Patrick Riley of Micro-Tech Research, Inc. in 1998. (Sinclair, Tr. 746, 756–57).

40. Micro-Tech was found in 1995, and produced a biodegradable MasterBatch pellet that renders plastics resins (e.g., polystyrene, polyethylene, and polypropylene) biodegradable. (CCX 818 (Sinclair, Dep. at 19)).

41. ECM's product is the oldest product on the market, and is a successful cost-effective solution for companies looking to reduce long-term environmental impact. (CCX 818 (Sinclair, Dep. at 120); CCX 820 (Sullivan, Dep. at 56–57); CCX 445)).

42. Robert Sinclair assumed leadership of ECM Biofilms in 2000. (Sinclair, Tr. 757).

43. Patrick Riley invented the ECM additive among other inventions. (Sinclair, Tr. 747–48).

44. Mr. Riley spent years developing the additive. (Sinclair, Tr. 748).

45. Mr. Riley tested the additive in Petri dishes, and exposed it to inoculum in his own experiments. (Sinclair, Tr. 748).

46. Mr. Riley tested products in experiments conducted at the University of Akron and at a company called Organic Waste Systems. (Sinclair, Tr. 748–49).

47. Mr. Riley also worked with Timothy Barber, then a principal scientist for a company called ChemRisk, to test the ECM additive. (Sinclair, Tr. 749).

48. During development of the additive, Mr. Riley also worked with Morton Litt, Professor of Macromolecular Biology at Case Western Reserve University. (Sinclair, Tr. 749).

49. Mr. Sinclair understood from Patrick Riley that the additive had been tested numerous times, in numerous places, and would cause conventional plastics to biodegrade in nine months to five years in most circumstances. (Sinclair, Tr. 754–55).

50. Mr. Sinclair was also understood that both Timothy Barber and Professor Litt believed the additive worked. (Sinclair, Tr. 753–54).

51. Mr. Sinclair and Mr. Riley each performed home testing of ECM plastics. (Sinclair, Tr. 755–56).

52. Those tests included aerobic testing: burying the plastic in gardens and other places, and then digging them up and observing the level of biodegradation. (Sinclair, Tr. 755).

53. Mr. Sinclair and Mr. Riley also performed aerobic and anaerobic testing in sealed drums. (Sinclair, Tr. 755–56).

54. In all of those tests, Mr. Sinclair and Mr. Riley observed visual indications of partial or complete biodegradation within nine months to five years. (Sinclair, Tr. 756).

55. Mr. Sinclair received test data from Micro-Tech, including studies demonstrating the efficacy of the product, and claim language that had been used with the product in commerce. (RX 551; RX 260; RX 263; RX 264; RX 265; RX 269; CCX 241; CCX 799 (Barber, Dep. 135, 138–141, 266)).

56. Dr. Barber did work while at McClaren/Hart for Microtech testing the ECM additive. (Barber, Tr. 2012).

57. Dr. Barber analyzed the findings of several tests performed on the Plastic containing the ECM additive, and drafted a report containing his findings. (Barber, Tr. 2012–14).

58. Those tests included biodegradation tests conducted in a laboratory setting, as well as post-degradation testing from a toxicity perspective. (Barber, Tr. 2013).

59. Dr. Barber's report was based on testing performed by Organic Waste Systems. (Barber, Tr. 2014).

60. Dr. Barber's report was reviewed by another, disinterested McClaren/Hart scientist and received no criticism. (Barber, Tr. 2022–23).

61. The McClaren/Hart report states that "the results of the aerobic degradation tests indicate that, in time, plastics produced using ECM pellets will biodegrade in aerobic conditions." (Barber, Tr. 2024).

62. That conclusion was based on the Organic Waste Systems laboratory results that showed the ECM material biodegraded under the aerobic test conditions performed. (Barber, Tr. 2025).

63. The McClaren/Hart report further states that based on the Organic Waste Systems tests, ECM plastics should break down under anaerobic conditions as well, although at a slower rate than 100 percent ECM pellets. (Barber, Tr. 2026).

64. Although the McClaren/Hart report often uses the phrase "degradation," that was merely a short hand for "biodegradation." (Barber, Tr. 2027).

65. Dr. Barber understands "inherent biodegradability" to mean:

> Is the material itself biodegradable and would it biodegrade completely at the -- at some point in time, given the proper conditions to support biological activity, including microbes, water, pH, nutrients, all the things necessary to support biological activity.

(Barber, Tr. 2027).

66. Dr. Barber conveyed the report and its content to Patrick Riley, then President of Microtech (ECM). (Barber, Tr. 2026).

67. On average, ECM has employed six employees. (CCX 819 (Sinclair, Dep. 327–28)).

68. Those employees include Robert Sinclair (President and CEO), Kenneth Sullivan (CFO), and one or two administrative employees and one or two sales people. (Sullivan, Tr. 699).

69. Mr. Sinclair is primarily responsible for communicating with clients concerning ECM's technology. (Sullivan, Tr. 699).

III. WITNESSES

A. ECM's Fact Witnesses

1. Robert Sinclair

70. ECM called Robert Sinclair, President of ECM, Biofilms to testify as a fact witness regarding ECM's claims, marketing methods, biodegradability research, and customer characteristics (Sinclair, Tr. 745–797).

71. Mr. Sinclair is a minority shareholder (12%) in ECM. (Sinclair, Tr. 745).

72. Mr. Sinclair is also the director and CEO of ECM. (Sinclair, Tr. 745).

73. Mr. Sinclair manages all daily operations of the company. (Sinclair, Tr. 745).

74. Mr. Sinclair earned his J.D. from Case Western Reserve University Law School, and his undergraduate degree from Dartmouth College. (Sinclair, Tr. 746).

75. Mr. Sinclair, although not a scientist, has familiarity with scientific issues and experiments. (Sinclair, Tr. 760).

76. Mr. Sinclair took many biology sciences classes in college, developed resistant strains of bacteria for projects, and taught science for six years in the Cleveland and East Cleveland public school systems. (Sinclair, Tr. 760).

77. Mr. Sinclair practiced law until he became President of ECM. (Sinclair, Tr. 746).

78. Mr. Sinclair became involved with ECM in 1997 after learning about the Plastic containing the ECM additive and company from Rob DeMarco, and buying 1% of the company after speaking with Patrick Riley. (Sinclair, Tr. 746–47, 747–48).

79. Mr. Sinclair was deposed in this matter on February 18, 2014 and February 19, 2014. (CCX 818–CCX 819).

80. Mr. Sinclair is a member of the ASTM D20 committee, which is the committee on plastics. (Sinclair, Tr. 778).

81. Mr. Sinclair is the chairman of the ASTM D20.92 subcommittee on plastic terminology. (Sinclair, Tr. 778).

82. Mr. Sinclair is also on the ASTM D20.96 subcommittee on bio-based and biodegradable plastics. (Sinclair, Tr. 778).

83. Mr. Sinclair is on the ASTM D20.95 subcommittee on plastic recyclability. (Sinclair, Tr. 778–79).

84. Mr. Sinclair is also on the ASTM E60 and ASTM E50 committees on sustainability and other environmental issues. (Sinclair, Tr. 779).

85. As a member of numerous ASTM committees and subcommittees, Mr. Sinclair is familiar with many current ASTM standards, as well as proposed ASTM standards. (Sinclair, Tr. 779).

2. Kenneth Sullivan

86. ECM called Kenneth Charles Sullivan, Jr., CFO of ECM Biofilms, to testify as a fact witness. (Sullivan, Tr. 690).

87. Mr. Sullivan has been the CFO of ECM since May of 2009. (Sullivan, Tr. 690–91).

88. Mr. Sullivan is responsible for all the accounting, finance and treasury functions at ECM. (Sullivan, Tr. 691).

89. Mr. Sullivan also deals with ECM's 49 shareholders, the employee benefits plan, office administrative staff, and any other functions not associated with sales or technical issues. (Sullivan, Tr. 691).

90. Mr. Sullivan is a CPA and has worked in a financial capacity with multiple companies since 1987. (Sullivan, Tr. 691–92).

91. Mr. Sullivan was deposed in this matter on February 20, 2014. (CCX 820 (Sullivan, Dep. at 1)).

3. Timothy Barber

92. ECM called Dr. Timothy Barber as a fact witness to testify regarding ECM's early research. (Barber, Tr. 2003–04).

93. Dr. Barber has a B.S. in chemistry, with a focus in organic chemistry, from State University of New York at Binghamton. (Barber, Tr. 2004).

94. Dr. Barber obtained a Ph.D. in marine science with a specialization in chemistry from the University of South Florida. (Barber, Tr. 2005).

95. Dr. Barber wrote a dissertation on the biogeochemistry of low-molecular-weight hydrocarbons in wetland environments. (Barber, Tr. 2005).

96. Dr. Barber worked at the Florida Marine Research Institute as an analyst and then Entix as a senior chemist before taking a position with McLaren/Hart-ChemRisk in Cleveland, Ohio. (Barber, Tr. 2005–07).

97. At the Florida Marine Research Institute, Dr. Barber's responsibilities included collecting data, analyzing data, developing reports, and conducting laboratory work. (Barber, Tr. 2006).

98. At Entix, Dr. Barber's responsibilities included analyzing data, writing reports, and conducting fieldwork. (Barber, Tr. 2006).

99. McClaren/Hart, which no longer exists, was an environmental consultancy that worked primarily for private industry. (Barber, Tr. 2007).

100. McLaren/Hart employed approximately 350–500 people throughout the United States in about 15 different offices. (Barbet, Tr. 2006–07).

101. Dr. Barber was a consultant at McClaren/Hart assisting companies with pollution problems, developing work plans, collecting data, analyzing that information and writing reports. (Barber, Tr. 2007).

102. After leaving McClaren/Hart, Dr. Barber continued to work in the field of environmental contamination and ecological risk assessment for Geraghty & Miller (now Arcadis) and Environ International Corporation. (Barber, Tr. 20–09).

103. At Geraghty & Miller Dr. Barber was a principal scientist. (Barber, Tr. 2008).

104. Dr. Barber is presently employed at Environ International Corporation as a principal scientist and office manager. (Barber, Tr. 2008–09).

105. Dr. Barber collaborates with other Environ scientists in the conduct of his research work. (Barbet, Tr. 2010).

106. Dr. Barber was the instructor for the chemical oceanography laboratory at the University of South Florida and an ecological risk assessment course at that same university. (Barber, Tr. 2010–11).

107. Dr. Barber taught a one-day seminar to the Ohio EPA on forensic chemistry. (Barber, Tr. 2011).

108. Dr. Barber has written approximately thirty (30) peer-reviewed articles on various topics related to anthropogenic or manmade chemicals in the environment, potential toxicity associated with those, as well as fate and transport, persistence, bioaccumulation and ecological risks of those chemicals. (Barber, Tr. 2011).

109. Dr. Barber is a member of the American Chemical Society, the Environmental Toxicology and Chemistry Organization, the International Society of Ecological Economics, and the International Society of Environmental Forensics. (Barber, Tr. 2012).

110. Dr. Barber was deposed in this matter on March 7, 2014. (RX 870 (Barber, Dep. at 1)).

4. Thomas Poth

111. ECM called Thomas Poth to testify as a fact witness regarding the testing done on the ECM additive and ECM plastics by Eden Laboratories. (Poth, Tr. 1434, 1442).

112. Mr. Poth was deposed in this matter on May 19, 2014. (RX 876 (Poth, Dep. at 1)).

113. Mr. Poth completed the course requirements for an undergraduate degree from New Mexico Institute of Mining and Technology in chemistry and environmental engineering. (Poth, Tr. 1435–36).

114. Mr. Poth also took numerous courses on hazardous waste management and radioactive waste management at the graduate level, but did not receive a degree. (Poth, Tr. 1435).

115. Mr. Poth owns Eden Research Laboratories (Eden Labs), formerly Zia Environmental Laboratories. (Poth, Tr. 1437).

116. Mr. Poth is also the laboratory director at Eden. (Poth, Tr. 1437).

117. Before starting Eden Labs, Mr. Poth managed a laboratory called Assaigai Laboratory in Albuquerque, New Mexico. (Poth, Tr. 1438).

118. Mr. Poth was then transferred to West Texas to manage another laboratory in the Midland area. (Poth, Tr. 1438).

119. As laboratory manager for both the Assaigai and Texas labs, Mr. Poth oversaw sales, marketing, and laboratory testing. (Poth, Tr. 1438).

120. Mr. Poth then ran the science and engineering design department for RW Technologies, a company that developed water treatment systems using cutting-edge technology. (Poth, Tr. 1439).

121. This position required familiarity with environmental testing, among other skills. (Poth, Tr. 1440).

122. Mr. Poth and Eden Laboratories employ two full-time employees, and two part-time employees. (Poth, Tr. 1440).

123. Other than Mr. Poth, Eden's other full-time employee is Brian Esau, who assists in project design and implementation. (Poth, Tr. 1440–41).

124. Mr. Esau has an undergraduate degree and a Ph.D. in biochemistry. (Poth, Tr. 144–41).

125. Mr. Esau worked for Oak Ridge National Laboratory doing cancer research prior to his employment at Eden Laboratories. (Poth, Tr. 1443).

126. Eden Laboratories works with businesses such as Adidas Group, Reebok, Pactiv, Saucony, and Georgia Pacific, and also works with smaller companies as well. (Poth, Tr. 1443).

127. Eden Laboratories has performed biodegradability testing of plastic products such as plastic bags and drink bottles since 2010. (Poth, Tr. 1444–45).

128. Eden Laboratories offers other environmental services, such as digester design for treatment of waste streams, solid waste management design, and water treatment system design. (Poth, Tr. 1445).

129. Approximately 50% of Eden Laboratories' current business is biodegradability testing. (Poth, Tr. 1445).

130. In the past, nearly 75% of Eden Laboratories' business was biodegradability testing. (Poth, Tr. 1445).

5. Alan Johnson

131. ECM called Alan Charles Johnson to testify as a fact witness regarding testing that was done by Northeast Laboratories. (Johnson, Tr. 1553).

132. Mr. Johnson has been working at Northeast Laboratories since 1977. (Johnson, Tr. 1554).

133. Mr. Johnson is the laboratory director, and he is responsible for overseeing all laboratory operations. (Johnson, Tr. 1554).

134. Before starting Northeast Laboratories, Mr. Johnson earned a bachelor's degree with a major in biology and a minor in chemistry from the University of Connecticut. (Johnson, Tr. 1554–55).

135. Mr. Johnson also took graduate level coursework for a master's degree in microbiology but did not complete the program. (Johnson, Tr. 1555).

136. Mr. Johnson first worked as an analytical technician for Dairy Control Service Laboratory. (Johnson, Tr. 1555).

137. Mr. Johnson then went to work at Northeast Laboratories, eventually purchasing it. (Johnson, Tr. 1555–56).

138. Mr. Johnson and Northeast Laboratories have fourteen (14) employees, working in different disciplines, including biodegradation, wastewater, and microbiology. (Johnson, Tr. 1556–57).

139. Northeast Laboratories has two major branches: chemistry and microbiology. (Johnson, Tr. 1557).

140. Northeast Laboratories is EPA, FDA, USDA, CDC and State of Connecticut certified. (Johnson, Tr. 1558).

141. Those certifications authorize the lab to test pharmaceutical chemistry, wastewater, and pharmaceutical, food and environmental microbiology. (Johnson, Tr. 1558–59).

142. Generally, all of Northeast Laboratories' certifications are subject to inspections and proficiency testing. (Johnson, Tr. 1559).

143. Northeast Laboratories has received good reports after being audited by the State of Connecticut and the USDA this past year. (Johnson, Tr. 1559–60).

144. Northeast Laboratories conducts biodegradation testing, and began doing so in 2005. (Johnson, Tr. 1560).

145. The chemistry division of the lab assists biodegradability testing by performing titrations, instrumental work, and report writing. (Johnson, Tr. 1560–61).

146. Mr. Johnson oversees all biodegradability testing, and often does some of the work himself. (Johnson, Tr. 1561).

147. Northeast Laboratories performs ASTM D5511 and ASTM D5538 biodegradability testing. (Johnson, Tr. 1561).

148. Dr. William Ullman had a Ph.D. in microbiology and ran the biodegradability at Northeast Laboratories program from its inception in 2005, until his death in 2011. (Johnson, Tr. 1562–63).

149. Prior to purchasing Northeast Laboratories, Dr. Ullman was the director of the State of Connecticut Public Health Laboratory.

150. Dr. William Ullman trained Alyssa Ullman, a chemist for Northeast Laboratories, in the discipline. (Johnson, Tr. 1562–63).

B. ECM's Expert Witnesses

1. Dr. Ranajit Sahu

151. ECM called Dr. Ranajit Sahu, an expert in environmental and applied sciences. (Sahu, Tr. 1733–34; RX 855 (Sahu, Rep. at 5–6)).

152. Dr. Sahu earned his undergraduate degree in mechanical engineering from the Indian Institute of Technology. (Sahu, Tr. 1730–31).

153. The foundational coursework in this degree program involved chemistry, physical chemistry, and organic chemistry. (Sahu, Tr. 1732).

154. The advanced coursework in this degree program involved the study of metals and nonmetals, including plastics and polymers, and the manufacturing processes associated with these materials. (Sahu, Tr. 1732).

155. Dr. Sahu earned a master's and a Ph.D. in combustion from the California Institute of Technology. (Sahu, Tr. 1732).

156. Within the coursework of these post-graduate programs, Dr. Sahu studied polymer science, specifically the applicability of organic chemistry and chemical engineering, and the manufacturing of polymers into useful articles. (Sahu, Tr. 1733–34).

157. Dr. Sahu is a Qualified Environmental Professional (QEP) certified by the Air and Waste Management Association. (Sahu, Tr. 1748).

158. Dr. Sahu is a Certified Environmental Manager (CEM) certified by the State of Nevada. (Sahu, Tr. 1758).

159. Dr. Sahu first worked as a research development engineer at the Heat Transfer Research Institute and shortly thereafter at Kinetics Technology International. (Sahu, Tr. 1734).

160. In those capacities, Dr. Sahu designed equipment for use in the petrochemical industry. (Sahu, Tr. 1734).

161. Dr. Sahu then worked for Parsons Corp., a large engineering and architectural firm, where he performed environmental consulting often in the area of solid waste disposal in landfills, incinerators, and other disposal methods. (Sahu, Tr. 1735–36).

162. At Parsons Corp., Dr. Sahu managed a testing group, which conducted field-testing, laboratory testing, third party laboratory analysis, and data evaluation. (Sahu, Tr. 1736–37).

163. Since leaving Parsons Corp. in December 1999, Dr. Sahu has been an independent consultant, providing a variety of consulting services in a wide range of fields. (Sahu, Tr. 1737).

164. Dr. Sahu has over twenty years of experience in the field of chemical engineering, spanning from undergraduate studies through post-graduate employment at Parsons Corp. and as an independent consultant. (Sahu, Tr. 1738).

165. More specifically, Dr. Sahu has extensive experience in the field of polymer science. (Sahu, Tr. 1738–39).

166. Dr. Sahu spent three or four years as an independent consultant working with various bathroom fixture manufacturers to assess the degradation and manufacturing waste of their polystyrene and styrene-based products. (Sahu, Tr. 1739–40).

167. Dr. Sahu has also worked extensively in the field of polymer material properties, structure, composition and manufacture as an independent consultant with fuel industry consortia. (Sahu, Tr. 1740–41).

168. Dr. Sahu has conducted multiple projects dealing with waste containment in landfills, including MSW landfills. (Sahu, Tr. 1741–42).

169. Dr. Sahu has worked on multiple projects involving MSW landfill gas extraction, treatment, and measurement. (Sahu, Tr. 1742–44).

170. Dr. Sahu's work with MSW landfills has also included leachate collection. (Sahu, Tr. 1744).

171. Dr. Sahu currently works with a small development company managing a major project involving the siting, construction and closure of a four million cubic yard landfill. (Sahu, Tr. 1744–45).

172. As project manager and the principal in charge, Dr. Sahu designed every aspect of the landfill construction plan, supervised construction, and oversaw storm water management and leachate disposal. (Sahu, Tr. 1745).

173. Dr. Sahu has worked with municipalities, states, and the U.S. EPA. (Sahu, Tr. 1746).

174. Dr. Sahu has held various adjunct teaching positions with a number of universities in Southern California. (Sahu, Tr. 1746–47).

175. Dr. Sahu has been retained and qualified as an expert witness in environmental matters in multiple administrative proceedings and several state and federal judicial proceedings. (Sahu, Tr. 1747).

176. Dr. Sahu has been a member of the ASTM for three or four years, and currently serves on numerous committees. (Sahu, Tr. 1750).

177. Dr. Sahu was heavily involved with the ASTM on a project regarding the introduction of ethanol into the fuel mix. (Sahu, Tr. 1750).

178. In that capacity, Dr. Sahu advised the ASTM on the interaction of the fuel mix with plastics and polymers in fuel systems. (Sahu, Tr. 1750).

179. Due to this involvement and his work as an independent consultant, Dr. Sahu is very familiar with a wide range of ASTM standards and protocols. (Sahu, Tr. 1750–51).

180. Dr. Sahu authored and submitted an expert report in this matter on June 18, 2014. (Sahu, Tr. 1737; RX 855 (Sahu, Rep. at 1)).

181. Dr. Sahu was deposed in this matter on June 30, 2014. (RX 842 (Sahu, Dep. at 1)).

2. Dr. Morton Barlaz

182. ECM called Dr. Morton Barlaz, as an expert witness in biodegradation in MSW landfills. (Barlaz, Tr. 2166; RX 853 (Barlaz, Rep. at 27)).

183. Dr. Barlaz authored an expert report in this matter on June 15, 2014. (Barlaz, Tr. 2170); RX 853 (Barlaz, Rep. at 3)).

184. Dr. Barlaz was deposed in this matter on July 14, 2014. (RX 864 (Barlaz, Dep. at 1)).

185. Dr. Barlaz is professor and head of the Department of Civil Construction and Environmental Engineering at North Carolina State University. (Barlaz, Tr. 2167).

186. He runs a research program for the University in the area of solid waste management, and more specifically, biodegradation, decomposition, chemical and biological reactions in landfills, and the application of life cycle analysis to solid waste management systems. (Barlaz, Tr. 2168).

187. Dr. Barlaz has an undergraduate degree in chemical engineering from the University of Michigan and a master's and Ph.D. in civil and environmental engineering from the University of Wisconsin. (Barlaz, Tr. 2168).

188. Dr. Barlaz's Ph.D. focused on the microbiology of solid waste decomposition in landfills. (Barlaz, Tr. 2168).

189. Dr. Barlaz has published approximately 115 peer-reviewed publications and one-half to two-thirds of those are associated with some aspect of biodegradation. (Barlaz, Tr. 2169–70).

190. In his research program at North Carolina State University, Dr. Barlaz has conducted numerous tests on the biodegradation of various components of municipal solid waste. (Barlaz, Tr. 2071).

191. Dr. Barlaz has performed anaerobic biodegradability tests at reactor scale, vessels from one-half to two and a half gallons, measuring methane generation from municipal solid waste or specific components of municipal solid waste. (Barlaz, Tr. 2171).

192. Dr. Barlaz has also performed biochemical methane potential tests, which are tests of anaerobic biodegradability. (Barlaz, Tr. 2171–72).

193. Dr. Barlaz has performed qualitative testing of anaerobic biodegradability in fifty-five (55) gallon drums. (Barlaz, Tr. 2172).

194. Dr. Barlaz is not only familiar with the ASTM and their protocols, but has drafted a protocol for radiolabel testing of biodegradability that was ultimately adopted by the ASTM. (Barlaz, Tr. 2172).

195. Dr. Barlaz recently completed a project funded by the Plastics Environmental Council to evaluate the effect of different inocula on biodegradation rates for the purpose of developing a protocol for biodegradability testing that is more flexible than the ASTM 5511 protocol. (Barlaz, Tr. 2172–73).

196. Complaint Counsel's expert, Dr. Tolaymat, recognizes Dr. Barlaz as an authority in the field of biodegradability of municipal solid waste and landfill gas. (Tolaymat, Tr. 156, 184, 233).

197. Dr. Tolaymat has consulted Dr. Barlaz on a number of questions concerning landfill biodegradation. (Tolaymat, Tr. 233).

198. When asked if he has ever asked Dr. Barlaz to comment on his work, Dr. Tolaymat responded "of course." (Tolaymat, Tr. 234).

199. Dr. Barlaz has reviewed Dr. Tolaymat's work product and Dr. Tolaymat has accepted a number of his recommendations for his work. (Tolaymat, Tr. 234).

200. Dr. Tolaymat co-authored an article that defined "bioreactor landfill" the same way as Dr. Barlaz does. (Tolaymat, Tr. 337–38; RX 899; RX 900; RX 901).

3. Dr. Ryan Burnette

201. ECM called Dr. Ryan Nelson Burnette as an expert in microbiology, biochemistry and anaerobic microorganisms. (Burnette, Tr. 2364–65; RX 854 (Burnette, Rep.)).

202. Dr. Burnette earned his undergraduate degree in biochemistry and two minors in chemistry and environmental sciences from Virginia Polytechnic Institute and State University. (Burnette, Tr. 2360).

203. Dr. Burnette's undergraduate coursework included organic chemistry, general biochemistry, microbiology, molecular biology, genetics, enzymology, and enzyme kinetics. (Burnette, Tr. 2361).

204. Dr. Burnette also earned a Ph.D. in biochemistry and molecular biology from Virginia Polytechnic Institute and State University. (Burnette, Tr. 2361).

205. Dr. Burnette's doctoral dissertation focused on signal transduction via enzymatic pathways with response to environmental stimulus, how organisms respond to their environment, the signaling cascades, the small molecules, the enzymes involved in that signal transduction pathway, applied across a variety of organisms. (Burnette, Tr. 2361).

206. Dr. Burnette studied within the Department of Biochemistry which studies anaerobic microbiology and general biochemistry. (Burnette, Tr. 2363).

207. Dr. Burnette was also a National Institute of Health Fellow at Vanderbilt University School of Medicine where he studied signal transduction and enzyme pathways. (Burnette, Tr. 2364).

208. Dr. Burnette has taught biochemistry, molecular biology, microbiology and genetics at the undergraduate, masters and doctoral levels, as well as to medical students. (Burnette, Tr. 2364–65).

209. Dr. Burnette has worked with numerous pre-eminent microbiologists in the field of anaerobic microbiology. (Burnette, Tr. 2365).

210. Much of Dr. Burnette's own research involves anaerobic microorganisms. (Burnette, Tr. 2365–66).

211. Dr. Burnette worked for Hatcher-Sayre, Inc., an environmental consulting firm, as an environmental scientist testing soil samples, landfills, groundwater, and water. (Burnette, Tr. 2366).

212. Dr. Burnette is currently the Vice President of the Biological Safety Division at WIRB-Copernicus Group (WCG), a clinical services organization that provides support to a variety of biopharmaceutical and academic research programs. (Burnette, Tr. 2367).

213. Dr. Burnette and the WCG assist customers with the design of laboratories, containment, disinfection, decontamination, and infection prevention. (Burnette, Tr. 2367–68).

214. WCG's clients include major biopharmaceutical firms, academic research institutions, and government entities such as the CDC. (Burnette, Tr. 2368).

215. Dr. Burnette authored and submitted an expert report in this matter. (Burnette, Tr. 2370; RX 854 (Burnette, Rep.)).

216. Dr. Burnette was deposed in this matter on July 2, 2014. (CCX 1075 (Burnette, Dep. at 1)).

4. Dr. David Stewart

217. ECM called Dr. David Wayne Stewart, as a survey expert, to present the method and findings of his own study and opine on the validity of Complaint Counsel's surveys and conclusions. (Stewart, Tr. 2491).

218. Dr. Stewart is currently the President's Professor of Marketing and Business Law at Loyola Marymount University. (Stewart, Tr. 2492).

219. Dr. Stewart received an undergraduate degree in psychology from the University of Louisiana at Monroe, then Northeast Louisiana University. (Stewart, Tr. 2494).

220. Dr. Stewart also earned a master's degree in general psychology from Baylor University and a Ph.D. in personality and social psychology from Baylor University. (Stewart, Tr. 2495).

221. Dr. Stewart currently teaches advertising and promotion management, marketing strategy, and the introductory MBA marketing course at Loyola Marymount. (Stewart, Tr. 2496).

222. Prior to holding his current position, from July 2007 through July 2011, Dr. Stewart was Dean of the School of Business at the University of California at Riverside. (Stewart, Tr. 2496).

223. Dr. Stewart has also served as the Robert E. Brooker Professor of Marketing and Chairman of the Department of Marketing in the Marshall School of Business at the University of Southern California. (Burnette, Tr. 2497).

224. Prior to these positions, Dr. Stewart served as the Senior Associate Dean of the Owen Graduate School of Management at Vanderbilt, and was a member of the faculty in the psychology department and business school at Jacksonville State University in Jacksonville, Alabama. (Stewart, Tr. 2498).

225. Dr. Stewart has taught extensively in the field of conduct and methodology of surveys, teaching marketing research at the undergraduate, graduate, and doctoral levels. (Stewart, Tr. 2498).

226. He has also taught courses on research methodology, psychometrics, and experimental design. (Stewart, Tr. 2499).

227. Prior to his work in education, Dr. Stewart was a research manager for Needham, Harper & Steers Advertising in Chicago (now DDB). (Stewart, Tr. 2499).

228. In that capacity, Dr. Stewart provided internal consultation services on research design, conducted an annual omnibus lifestyle survey of consumers in the United

States, and tested creative content prior to its presentation to clients. (Stewart, Tr. 2499–2500).

229. Dr. Stewart has served as the Editor of both the Journal of Marketing and the Journal of the Academy of Marketing Science. (Stewart, Tr. 2500).

230. He is currently serving as the Editor of the Journal of Public Policy and Marketing. (Stewart, Tr. 2500).

231. Approximately half of the papers submitted to those three journals use survey methodology as a basis for empirical presentation. (Stewart, Tr. 2500).

232. As Editor, Dr. Stewart has reviewed those papers and the survey methodology used in their preparation. (Stewart, Tr. 2500–01).

233. Dr. Stewart has published in excess of 200 peer reviewed journals, proceedings volumes, and book chapters, over half of which contained survey research. (Stewart, Tr. 2501).

234. Dr. Stewart has been awarded numerous awards, including the American Academy of Advertising's Outstanding Contribution to Advertising Research Award, the Academy of Marketing Science's Cutco/Vector Distinguished Marketing Educator Award, and the Society for Marketing Advances's Elsevier Distinguished Marketing Contribution Award. (Stewart, Tr. 2501).

235. Dr. Stewart is a member of the following academic and trade associations:

- The American Marketing Association
- The American Statistical Association
- INFORMS (management science professional organization)
- The Association for Consumer Research
- The Society for Consumer Psychology
- The Classification Society
- The Society for Personality and Social Psychology
- The Academy of Management

(Stewart, Tr. 2501–02).

236. Dr. Stewart is a past president of the Society for Consumer Psychology. (Stewart, Tr. 2502).

237. Dr. Stewart is a past president of the Academic Council for the American Marketing Association. (Stewart, Tr. 2502)

238. He has also served on the American Marketing Association's board of directors and as its vice president of finance. (Stewart, Tr. 2502–03).

239. Dr. Stewart has chaired the research committee of the American Academy of Advertising. (Stewart, Tr. 2503).

240. Dr. Stewart has also served as representative to the council of the American Psychological Association on behalf of the Society for Consumer Research. (Stewart, Tr. 2503).

241. In the 1990's, Dr. Stewart served two, three year terms as a member of the joint professional advisory committee to the United States Census, and in that role advised the Census Bureau in the design of its various data collection activities, including the census. (Stewart, Tr. 2503–04).

242. In 2009, Dr. Stewart served as part of a panel of academics that evaluated the marketing plan for the 2010 decennial census, and submitted their report to Congress. (Stewart, Tr. 2504).

243. He is a past appointee of the Secretary of Commerce to the Southern California Direct Export Council which facilitates the export of American goods and services to international markets. (Stewart, Tr. 2504).

244. The FTC Complaint Counsel emailed Dr. Stewart and expressed interest in him serving as Complaint Counsel's expert witness in this matter; however, he had already been retained by ECM. (Stewart, Tr. 2504–05).

245. Dr. Stewart has served as an expert witness for the FTC multiple times. (Stewart, Tr. 2505).

246. In the late 1980's, Dr. Stewart designed and implemented a survey for the FTC in connection with a deceptive advertising case against Kraft. (Stewart, Tr. 2505).

247. In the Kraft decision, Dr. Stewart's survey was credited by the ALJ and cited by the full commission as supportive of its decision. (Stewart, Tr. 2506).

248. Dr. Stewart was retained as an expert by the FTC in a matter involving Novartis. (Stewart, Tr. 2507).

249. Dr. Stewart was also an FTC expert in the POM Wonderful matter. (Stewart, Tr. 2507).

250. Dr. Stewart was retained as an expert by the FTC in matters against QVC, Neurologic Labs, and John Beck. (Stewart, Tr. 2507–08).

251. Dr. Stewart has also been retained by various Respondents in cases brought by the FTC, including Pantron, Schering, and Guaranty Life. (Stewart, Tr. 2507–08).

252. In most of the cases Dr. Stewart opined on surveys; in approximately half of those cases Dr. Stewart designed a survey, and in many of those cases Dr. Stewart gave rebuttal testimony concerning the opposing party's surveys. (Stewart, Tr. 2508:18-2509:3).

253. Dr. Stewart is unaware of a single instance in which his testimony or survey was not credited by either the ALJ or the Commission. (Stewart, Tr. 2509).

254. Dr. Stewart has served as a survey expert in federal court "a couple of dozen times" and in none of those cases has his survey been deemed to be unreliable or not credited by the court. (Stewart, Tr. 2520–21).

255. Dr. Stewart prepared and submitted an expert report in this matter on June 17, 2013. (Stewart, Tr. 2492; RX 856 (Stewart, Rep. at 1)).

C. Complaint Counsel's Fact Witnesses

256. Between February 18, 2014 and May 30, 2014, Complaint Counsel performed sixteen (16) fact depositions of testing laboratories and ECM customers all over the country, including Hawaii, California, New York, Ohio, and the District of Columbia. (CCX 799–CCX 805; CCX 809–812; CCX 815; CCX 817; CCX 821–CCX 823).

257. Complaint Counsel called no (0) fact witnesses at trial. (Tr. 259).

258. Respondent was unrepresented, or had counsel appear telephonically, at 14 fact witness depositions. (CCX 800; CCX 803; CCX 801; CCX 810; CCX 811; CCX 812; CCX 817; CCX 822; CCX 802; CCX 804; CCX 808; CCX 809; CCX 815; CCX 821).

D. Complaint Counsel's Expert Witnesses

1. Thabet Tolaymat

259. Complaint Counsel called Dr. Thabet Tolaymat as their landfill expert. (Tolaymat, Tr. 112–358).

260. Dr. Tolaymat authored an expert report dated June 4, 2014. (CCX 893 (Tolaymat, Rep. at 1)).

261. In his report, Dr. Tolaymat opined on the scientific reliability and the applicability of ECM's biodegradability testing. (CCX 893 (Tolaymat, Rep.)).

262. In his report, Dr. Tolaymat criticized tests relied upon by ECM for failing to simulate actual conditions in an MSW landfill, and discounts the testing results in their entirety on that basis. (CCX 893 (Tolaymat, Rep. 1)).

263. Dr. Tolaymat drew his conclusions without any knowledge of the bacterial communities present in MSW landfills or the testing environment. (Tolaymat, Tr. 265–267).

264. Dr. Tolaymat was deposed on June 24, 2014. (CCX 851 (Tolaymat, Dep. at 1)).

2. Stephen McCarthy

265. Complaint Counsel called Dr. Stephen McCarthy as their primary expert witness in the areas of general biodegradation, biodegradability of plastics and biodegradability testing methodologies. (McCarthy, Tr. 359-480).

266. Dr. McCarthy authored an expert report on June 4, 2014. (CCX 891 (McCarthy, Rep. at 1)).

267. In his report, Dr. McCarthy opined that all thirty-three of ECM's positive biodegradation tests were flawed, that the flaws invalidate any findings of biodegradation, and to the extent that many of the tests indicate the occurrence of biodegradation, that data is the result of a so-called "priming effect." (CCX 891 (McCarthy, Rep. at 7–8)).

268. Dr. McCarthy stands to profit personally from FTC rejection of the biodegradability of ECM plastics and the entire biodegradable plastic additive industry. (McCarthy, Tr. 523–524).

269. Complaint Counsel wrote the definition of the term "biodegradable" contained in footnote 1 of Dr. McCarthy's expert report. (RX 841 (McCarthy, Dep. at 20)).

270. That definition reads:

> [B]iodegradable means that the entire treated plastic will completely break down and return to nature (*i.e.* decompose into elements found in nature) within one year after customary disposal (*i.e.* incinerator, landfill, or recycling).
>
> (CCX 891 (McCarthy, Rep. at 5 n. 1)).

271. Dr. McCarthy tailored his definition of "biodegradable" to comport with Complaint Counsel's definition despite Dr. McCarthy's use of conflicting definitions in prior research and publication. (McCarthy, Tr. 485–88, 494).

272. Dr. McCarthy wrote the following sentence contained in footnote 1 of his expert report: "I use this definition and the scientific definition of biodegradable interchangeably in this Expert Report, because there is no substantive difference between the two that affects my analysis or my opinions." (McCarthy, Tr. 487; CCX 891 (McCarthy, Rep. at 5 n. 1)).

273. Dr. McCarthy was unable to identify a single instance in the peer-reviewed literature in which the definition of "biodegradable" contained in his Expert Report at footnote 1 is recited. (McCarthy, Tr. 493–94).

274. During cross-examination concerning his reliance on the term "biodegradable" contained in footnote 1 of his expert report, Dr. McCarthy stated that he "would like to change that." (McCarthy, Tr. 496).

3. Shane Frederick

275. Complaint Counsel called Dr. Shane Frederick as their survey expert. (Frederick, Tr. 1025–1181).

276. Dr. Frederick produced an expert report on June 4, 2014. (CCX 890 (Frederick, Rep. at 1)).

277. In this report, Dr. Frederick opined that:

i. Roughly half of all consumers believe that products with an unqualified "biodegradable" claim will biodegrade in one year or less.

ii. A substantial minority (20-30%) of consumers believe that a plastic product bearing an unqualified "biodegradable" claim will biodegrade within a year.

iii. If a plastic package bears the claim that it biodegrades in "some period greater than a year," 29% of consumers assume it will biodegrade in two years or less, and 54% assume it will biodegrade in five years or less.

iv. Consumers infer similar periods of biodegradation whether the qualified claim states "in some period greater than a year" or "nine months to five years."

(CCX 890 (Frederick, Rep. at 1)).

Dr. Frederick based those conclusions in part on studies he regards as flawed and invalid, referred to as the APCO study and the Synovate study. (Stewart, Tr. 2618; Frederick, Tr. 1042–43, 1045, 1047; CCX 890 (Frederick, Rep. at 7–16, 20)).

278. Dr. Frederick further based his conclusions on his own Google survey. (Stewart, Tr. 2614–18; Frederick, Tr. 1060).

279. Moreover, Dr. Frederick conducted his Google survey with the intention of correcting the flaws he admits pervade the APCO study, while maintaining the flawed conclusion in the APCO study. (Stewart, Tr. 2616, 2618–19).

280. Dr. Frederick was deposed in this matter on June 23, 2014. (RX 858 (Frederick, Dep. at 1)).

4. Frederick Michel

281. Dr. Frederick C. Michel, Jr. was called to rebut the testimony of two ECM expert witnesses, Dr. Sahu and Dr. Burnette. (Michel, Tr. 2839).

282. Dr. Michel was deposed in this matter on July 31, 2014. (RX 970 (Michel, Dep. at 1)).

283. Dr. Michel prepared a rebuttal report purportedly based on Dr. Burnette's and Dr. Sahu's expert reports. (Michel, Tr. 2839; CCX 895 (Michel, Rebuttal Rep.)).

284. Dr. Michel also provided his Curriculum Vitae. (Michel, Tr. 2840; CCX 896).

285. Dr. Michel serves as editor of the Compost Science & Utilization Journal, and attends U.S. Composting Council meetings. (Michel, Tr. 2834, 2837).

286. Dr. Michel is the head of the compost research group for Ohio Agricultural Research and Development Center-Food, Agricultural, and Biological Engineering ("OARDC-FABE"). (Michel, Tr. 2918).

287. Dr. Michel was the coeditor for proceedings at the 2002 Symposium on Composting and Compost Utilization. (Michel, Tr. 2918).

288. Dr. Michel was also the section editor for Test Methods for the Examination of Composting and Compost (TMECC). (Michel, Tr. 2918–19).

289. Dr. Michel is a paid consultant for AllTreat Organic Composting. (Michel, Tr. 2919).

290. Dr. Michel is a consultant for DuPont, a member of the Biodegradable Products Institute (BPI). (Michel, Tr. 2919–20; RX 169).

291. DuPont also provided Dr. Michel with grant money. (Michel, Tr. 2920).

292. Dr. Michel is a paid consultant for Indian Summer Composting. (Michel, Tr. 2920).

293. Dr. Michel has consulted for the U.S. Composting Council for "six or seven years." (Michel, Tr. 2920–21).

294. Dr. Michel also consulted for Amylex and International Paper, companies that sell compostable products, and receives grant money for Ohio State University in return. (Michel, Tr. 2921–22).

295. The composting industry generally, and compostable plastics specifically, directly compete with ECM and other companies within the biodegradable plastics industry. (Sullivan, Tr. 696–697; Sinclair, Tr. 775–777).

IV. ECM'S CUSTOMERS

A. ECM's Customers Are All Sophisticated Plastic Manufacturers That Do Not Base Their Purchasing Decisions Of The ECM Additive On Any Rate Claim—Whether Implied Or Explicit—Made By ECM

296. ECM's promotional and marketing information is exchanged through detailed business transactions with sophisticated corporations, to wit, plastics manufacturers. (Sinclair, Tr. 761–67).

297. ECM does not sell the Plastic containing the ECM additive to end use consumers, only to plastics manufacturers. (Sinclair, Tr. 758–59, 764–67; Sullivan, Tr. 703–04, 707).

298. The Plastic containing the ECM additive is not usable by a consumer, only by plastics manufacturers who manufacture plastics with the Plastic containing the ECM additive included as an additive. (Sinclair, Tr. 759).

299. To be effectual, the additive must be manufactured in strict accordance with ECM manufacturing specifications. (Sinclair, Tr. 787–790).

300. ECM's advertising budget is less than $12,000 per year, which is mainly devoted to website maintenance. (Sullivan, Tr. 700).

301. ECM does not have a nationwide advertising plan. (Sullivan, Tr. 700–01).

302. ECM does not purchase ads in trade magazines. (Sullivan, Tr. 701).

303. ECM does not purchase any consumer-type advertising. (Sullivan, Tr. 701).

304. ECM markets its technology through sales meetings, published material (e.g., brochures), and networking functions. (Sullivan, Tr. 735).

305. ECM may acquire customer leads from a personal contact by Tom Nealis at a trade show, but that is rare. (Sullivan, Tr. 701).

306. A common way that ECM acquires customer leads is through website inquiries by plastics manufacturers or distributors. (Sullivan, Tr. 701–02).

307. ECM's sales are complex business transactions that take months or years to complete, in contrast with retail sales to end-consumers. (Sullivan, Tr. 703–04).

308. In the first instance, ECM offered its "9 month to 5 year" degradable claim not as a performance claim, but as a means to distinguish its technology from competing technologies claiming to satisfy short-term compostability standards. (Sinclair, Tr. 768; Sullivan, Tr. 711).

309. ECM's customers were aware of the FTC's requirements in the Green Guides, and they tailored their advertising content according to those policies. (RX 35–RX 77; RX 871 (Blood, Dep. 193:10–21)).

310. ECM always explained the actual rate of biodegradation for each specific plastic to customers as being an approximation that was, of course, subject to numerous disposal conditions. (Sinclair, Tr. 769).

311. ECM explained to customers that it had seen products biodegrade in less than nine months in some conditions, however, conditions in an extremely dry or cold climate might result in biodegradation in far more than five years. (Sinclair, Tr. 769–70).

312. The time frame was always expressed as a general time frame based on anecdotal experience and on the testing that ECM had performed by third party laboratories. (Sinclair, Tr. 770).

313. The FTC revised its Green Guides to prohibit unqualified biodegradable claims without suitable qualifications in 2012. (RX 347).

314. ECM stopped using the nine months to five year time frame approximately three years ago after the revision of the Green Guides was released. (Sinclair, Tr. 769–70).

315. Mr. Sinclair felt that the literal interpretation of ECM's timeframe claims was more of an obstacle than a benefit, and ECM discontinued making such claims. (Sinclair, Tr. 770).

316. Once the most recent revision of the Green Guides required a product to fully biodegrade within one year to make an unqualified "biodegradable" claim, ECM determined that it had to qualify its claim to satisfy the FTC regulation. (Sinclair, Tr. 771)

317. From that point on, ECM has stated that its plastics infused with the ECM additive would biodegrade in some timeframe greater than one year. (Sinclair, Tr. 771).

318. ECM has no intention of ever making the nine month to five year claim again. (Sinclair, Tr. 771).

319. Almost invariably, the end-customer is provided with a naked "biodegradable" claim, which is the only claim ECM has in its certificate of biodegradability. (RX 00; RX 02; RX 03; RX 14; RX 15; RX 16; RX 17; RX 22; RX 26; RX 28; RX 29; RX 30; RX 315; CCX-30 ; CCX-31; CCX 32; CCX 36; CCX 39; CCX 43; CCX 46; CCX 47; CCX 49; CCX 50; CCX 52; CCX 59; CCX 60; CCX 63' CCX 64; CCX 65; CCX 66; CCX 79; CCX 97; CCX 98; CCX 99; CCX 100; CCX 101; CCX 103;CCX 104; CCX 107; CCX 109–CCX 133; CCX 135; CCX 136; CCX 138; CCX 139; CCX 140; CCX 142–CCX 151).

320. In its Certificate of Biodegradability, which is given to every customer that confirms that it will make its plastic in accordance with ECM's manufacturing specifications, the following definition is given by ECM to its customers of "biodegradation:"

> A degradable plastic is defined (ASTM D883-12) as a plastic that is designed to undergo a significant change in its chemical structure under specific environmental conditions resulting in a loss of some properties that may vary as measured by standard test methods appropriate to the plastic and the application in a period of time that determines its classification. A Biodegradable Plastic is defined as a degradable plastic in which the degradation results from the action of naturally occurring microorganisms such as bacteria, fungi, and algae.

(CCX 14; Sinclair, Tr. 784).

321. ECM customers are not concerned with the rate of biodegradability. (Sinclair, Tr. 770).

322. The ECM additive is sold in a highly competitive market. (Sinclair, Tr. 775).

323. ECM's competitors include other additive companies, replacement resin companies, and oxo-degradable companies. (Sinclair, Tr. 775–77).

324. ECM has direct competitors who produce similar additives, invented after ECM's, such as Biotech and Ecoplast. (Sinclair, Tr. 776–77).

325. There are competing technologies available, such as "bioplastics" which are biodegradable plastic polymers or resins derived from biological substances instead of petroleum. (Sahu, Tr. 1758; RX 748; RX 678).

326. Bioplastic can be either non-biodegradable, such as bio-based polyethylene, or they can be biodegradable, such as polyhydroxyaldehyde. (RX 748)

327. Many of the bioplastic technologies will produce an end-product that biodegrades more rapidly or readily than plastics made with the ECM additive in an industrial composting operation. (RX 725; RX 178).

328. However, bioplastic technologies come at a substantial cost, (Sullivan, Tr. 697; Sinclair, Tr. 768; RX 335), and bioplastics are ordinarily not suitable for strong plastics that are meant for applications that require endurance and lack of malleability. (Sahu, Tr. 1821–24).

329. ECM customers purchase the ECM additive in part because it provides them with a biodegradable product without many of the drawbacks that come with using ECM's competitors' technologies. (Sinclair, Tr. 774–75).

330. ECM offers a cost-effective means to achieve biodegradable plastics. (Sullivan, Tr. 697; RX 335).

331. ECM Customers are interested in a "biodegradable" product that can work with their manufacturing systems, because the plastic has to serve a function foremost. (Sullivan, Tr. 709; RX 111).

332. Replacement resin companies, such as Metabolix, provide a biodegradable or compostable plastics solution, but it requires a complete replacement of the resin. (Sinclair, Tr. 776).

333. Companies choosing to invest in most bioplastics must change their entire manufacturing process to accommodate the use of the new natural resins. (Sullivan, Tr. 696; RX 520).

334. ECM customers have complained to Mr. Sinclair that oxo-degradable or oxo-biodegradable products have disintegrated in the warehouse on a hot summer day. (Sinclair, Tr. 775).

335. Additional additives are needed to stabilize the Bioplastics during the manufacturing process for the intended use of the end product. (RX 520).

336. Complaint Counsel's expert Frederick Michel admits that the bio-based polymers are almost always significantly more expensive than ECM's additive. (Michel, Tr. 2977–78; RX 520).

337. Because the ECM additive can render a plastic biodegradable with load rates of just over 1% by weight, plastics manufacturers are not required to make substantial changes to their manufacturing processes to accommodate the additive, which, when properly manufactured, is included in the plastic in much the same way a colorant or plasticizer is diffused throughout plastic, thus ensuring uniform distribution in every part of the plastic. (Sullivan, Tr. 697; RX 326; RX 520).

338. ECM's additive technology has a much smaller impact on manufacturers' cost basis than bioplastic alternatives. (Sullivan, Tr. 697:6-22; RX 520).

339. With ECM's technology, the biodegradable component is an option manufacturers can implement, thus helping the environment, where they would otherwise not have the resources or financial incentive to invest in different, more expensive competing technologies. (RX 520; CCX 809 (Sandry, Dep. at 14–15)).

340. ECM's customers are primarily concerned with the balance between biodegradable effectiveness and product performance (i.e., tensile strength, shelf-life, etc.) after the ECM additive is included. (CCX 811 (Hong, Dep. at 44); RX 13; RX 33).

341. ECM tells its customers that adding the ECM additive to their plastics will render their products biodegradable without negatively affecting product performance. (Sinclair, Tr. 767).

342. ECM plastics do not lose physical properties as a result of the additive infusion like oxo-degradable or oxo-biodegradable plastics. (Sinclair, Tr. 775).

343. ECM explains that shelf-life and usable-life will not be negatively affected by infusion of the ECM additive. (Sinclair, Tr. 767; RX 13).

344. The fact that the addition of the ECM additive does not impact shelf-life and usable-life of the plastic products distinguishes ECM from many of its competitors. (Sinclair, Tr. 767; RX 13).

345. The ECM additive is a cost-effective biodegradability solution for plastic manufacturers that will not reduce shelf life, product durability, or recyclability. (Sinclair, Tr. 767–68; RX 33).

346. Bioplastics are often suitable only for certain limited uses in the market. (RX 335).

347. Oxo-degradable plastic additives have not been shown to biodegrade under realistic conditions, but they have been shown to fall apart on the shelf. (Sinclair, Tr. 776:12-23).

348. ECM plastics are recyclable to the extent the plastic would be recyclable without the addition of the ECM additive. (Sinclair, Tr. 767).

349. In most cases, ECM's potential customer contacts ECM directly. (Sinclair, Tr. 761).

350. ECM employs a sales manager, Tom Nealis. (Sullivan, Tr. 698–700).

351. However, ECM employs no active sales force. (Sullivan, Tr. 699).

352. A potential customer will be put in contact with Tom Nealis, director of sales, and he will provide the potential customer with pricing, sales literature and any other initial information that customer requires. (Sinclair, Tr. 761).

353. Mr. Sinclair will often work with the marketing and sales people to educate them on the new product. (Sinclair, Tr. 763–64).

354. Mr. Nealis will often correspond with potential customers to answer any questions that they may have about the product and provide them with test reports. (CCX 813 (Nealis, Dep. at 49; RX 13)).

355. ECM customers ordinarily test ECM's product in manufacture, often perform biodegradability testing on plastics made with the ECM additive, and evaluate testing performed on ECM's product before deciding to incorporate the product into plastics that are sold to downstream purchasers and ultimately made available to consumers. (Sinclair, Tr. 761–63; Sullivan, Tr. 704–05).

356. Most ECM customers put their marketing department to the task of developing claims. (Sinclair, Tr. 763).

357. No customer has ever asked Mr. Nealis to provide a narrower timeframe than some period greater than a year. (CCX 813 (Nealis, Dep. at 111)).

358. No customer has ever asked ECM what some period greater than a year means. (CCX 813 (Nealis, Dep. at 112).

359. ECM customers are not concerned with the rate of biodegradation; rather, their concern is that plastics made with the ECM additive will biodegrade when discarded into the environment. (Sinclair, Tr. 774).

360. ECM has no storefront or brick and mortar office. (Sinclair, Tr. 765–66).

361. Customers place orders directly with the ECM customer service team, and the product is shipped directly from the ECM manufacturing site in Carpentersville, Illinois. (Sinclair, Tr. 765).

362. Prior to processing an order, ECM double-checks that the company understands the proper loading rate is one percent (1%) by weight. (Sinclair, Tr. 765).

363. ECM provides its customers with precise and tailored manufacturing instructions to ensure that the product made with the additive is distributed throughout the plastic and that the additive is not scorched. (Sinclair, Tr. 762, 783, 787–90).

364. ECM sells only the MasterBatch Pellet and no other products. (Sinclair, Tr. 766).

365. Most sales of the ECM additive are completed over the phone and followed-up with a confirmation fax or e-mail. (Sinclair, Tr. 766; RX 23).

366. When Judge Chappell asked Mr. Sinclair "can the product be purchased over the internet?" Mr. Sinclair responded, "no." (Sinclair, Tr. 766).

367. The ECM website merely provides a standard web inquiry form that is automatically emailed to the ECM sales team and Mr. Sinclair. (RX 139).

368. ECM customers are plastics manufacturers who sell to multiple other, second-layer manufacturers. (Sinclair, Tr. 707–08; RX 471).

369. ECM targets its marketing message to plastic product manufacturers. (Sinclair, Tr. 787).

370. ECM-infused plastics often pass through at least two levels in the supply chain before ever reaching a so-called "end-user." (Sinclair, Tr. 785–86; CCX 811 (Hong, Dep. at 10–11, 112)).

371. It can be very difficult to determine who the "end-use consumer" is. (Sinclair, Tr. 786).

372. ECM doesn't know and cannot control how its customers label or advertise their products. (Sinclair, Tr. 786–87).

373. Rarely, an ECM customer will ask Mr. Sinclair what he thinks about their anticipated labeling language, and Mr. Sinclair will provide his opinion or feedback. (Sinclair, Tr. 787; RX 90; RX 117).

374. Mr. Sinclair does not know of any ECM customer who believes that ECM plastics completely decompose into elements found in nature within one year of customary disposal. (Sinclair, Tr. 785).

375. ECM used to say that its additive would cause plastics to biodegrade in nine months to five years. (Sinclair, Tr. 768).

376. ECM stopped saying that the time frame for biodegradation of plastic containing the ECM additive is nine months to five year claim about three years ago. (Sinclair, Tr. 770, 975-76).

377. ECM updated its website to include the following explanation:

> The basic concept is that biodegradation is a natural process that occurs around the world but at various speeds due to various conditions. Plastics with our additives behave like sticks, branches or trunks of trees. Due to this fact, we do not guarantee any particular time because the time depends on the same factors that the biodegradation of woods and most other organic materials on earth depend – ambient biota and other environmental conditions. Under specific composting conditions with additional accelerants sprayed on them, some customers have reported biodegradation in as little as a couple of months. Under the more usual, commercial composting conditions using high heat processes, a time frame of around some period greater than a year is a reasonable expectation.

(RX 681, at 61)

378. ECM's website further explains: "It is not a 'poof, it's gone' system but simply makes the plastic product biodegrade as if it were a stick or a branch off a tree rather than 'sticking around' for hundreds of years." (RX 681, at 61).

379. ECM distributors have explained to downstream manufacturers that the time it takes for an ECM plastic to fully biodegrade will depend on various factors. (RX 08).

380. Following the revisions to the Green Guides, ECM dispatched a truthful and non-misleading email to all of its customers explaining the FTC's requirements concerning biodegradable claims. (RX 35–RX 77).

381. This email to ECM's customers stated:

> If you have evidence that your products with our additives will fully biodegrade in one year or less in the environment where it will be customarily disposed you may still make an unqualified claim of "biodegradable" for those products. But for most of our customers' plastic products with our additives whose customary disposal is in a landfill, they will not be able to use that unqualified claim.
>
> (RX 35–RX 77).

382. This email continued by discussing the benefits of ECM's product: "Municipal Solid Waste that biodegrades **slowly but surely over periods from a few years to tens of years** provides the (sic) [landfill gases] that is captured, processed and sold to the public renewable energy or even new chemical source. This is the end-of-life scenario that has made plastic products **with our additives** so ever-increasingly popular." (RX 35–RX 77).

383. ECM's customers are sophisticated. (Sinclair, Tr. 904).

384. Mr. Sinclair often provides potential customers with information and answers their questions as well. (RX 93; RX 110; RX 122).

385. ECM's customers are primarily companies that manufacture plastic or companies that have plastic manufactured for them, and some distributors who sell the additive to plastic manufacturers. (Sullivan, Tr. 695–96, Sinclair, Tr. 758–59).

386. ECM sells an industrial product that is not sold to consumers. (Sullivan, Tr. 696; Sinclair, Tr. 759).

387. The ECM customer is primarily interested in the ECM Additive because it provides a cost-effective method to produce a biodegradable product in the modern, environmentally friendly market. (Sullivan, Tr. 696).

388. Most ECM customers are long term, repeat purchasers. (Sullivan, Tr. 705–06).

389. ECM does not sell to consumers. (Sullivan, Tr. 707).

390. ECM does not target end-use consumers in advertising, of which it has none, or marketing. (Sullivan, Tr. 707).

391. ECM customers are sophisticated industrial consumers with years of plastics manufacturing or distributing experience. (Sullivan, Tr. 709; Barber, Tr. 2029).

392. ECM customers will often ask sophisticated questions about product performance. (RX 13; RX 126–RX 135).

393. ECM customers have already designed a product that contains additives for color, ultraviolet light, flame retardant, etc., and they conduct significant investigation and research before making a change in this process. (Sullivan, Tr. 710).

394. ECM customers are often much larger companies than ECM. (Sullivan, Tr. 709).

395. ECM customers are primarily concerned with how their product will perform (i.e. maintain its other attributes) after the addition of the ECM additive. (Sullivan, Tr. 709).

396. Plastics companies purchase ECM additive in either sixty-five kilogram (65kg) drums or five hundred kilogram (500kg) pallet boxes. (Sinclair, Tr. 764–65).

397. ECM's customers are sophisticated and knowledgeable. (Sinclair, Tr. 773–74; RX 132).

398. Plastics manufacturers must make complex, informed choices about which resins or plastics to choose to create the appropriate combination of characteristics for the product's purpose. (Sinclair, Tr. 773–74).

399. Plastic's manufacturers must also make decisions about machinery, additives, coloring and molds. (Sinclair, Tr. 774).

400. Plastic manufacturing is a very sophisticated and complex process, and ECM's customers are well versed in the investigative steps necessary to make the right decisions. (Sinclair, Tr. 774; RX 131; RX 132).

401. Most ECM customers perform product performance testing on their finished ECM-infused plastic before ordering product. (Sullivan, Tr. 704; RX 413; RX 412; RX 108; RX 109; RX 130; RX 132).

402. ECM also encourages biodegradability testing by its customers if they have concerns about their ability to support their intended claims. (Sullivan, Tr. 706).

403. ECM invites independent testing of its product and usually provides two kilograms of MasterBatch Pellets for free to a prospective customer for testing, and beyond that will sell quantities for further testing. (Sullivan, Tr. 705).

404. A prospective customer often performs product testing (including performance testing) before deciding whether the Plastic containing the ECM additive is a fit. (Sullivan, Tr. 704; RX 130; RX 132).

405. FP International, an ECM customer, tested its ECM plastic product for biodegradability. (Barber, Tr. 2029).

406. Eden Laboratories has performed biodegradability testing for ECM customers. (Poth, Tr. 1481).

407. Northeast Laboratories has conducted testing on plastics infused with the ECM additive for ECM customers. (Johnson, Tr. 1577).

408. ECM customers will always perform functionality and qualitative testing comparing the ECM plastic with their original product. (Sinclair, Tr. 762–63; RX 31).

409. Functionality and qualitative tests will determine whether the Plastic containing the ECM additive is functioning up to the necessary specifications and there has been no specification deterioration. (Sinclair, Tr. 763).

410. Many ECM customers will also perform biodegradability testing, either by a third party laboratory or using in-house methods. (Sinclair, Tr. 763).

411. Many ECM customers do their own biodegradability testing on the ECM additive. (Sinclair, Tr. 772).

412. Some ECM customers actively review ECM's competition, and even test competing products to determine if ECM is the best fit from a performance and biodegradation perspective. (RX 159).

413. The sales process to purchase the ECM additive is long and involved. (Sinclair, Tr. 764).

414. On average, a first-time sale, from initial contact to product purchase of the Plastic containing the ECM additive, takes six months to a year, and may sometimes take several years. (Sinclair, Tr. 767).

415. Most of ECM's customers have in-house counsel and often hire outside counsel. (Sinclair, Tr. 771).

416. Most of ECM's customers have scientists of varying disciplines working for them. (Sinclair, Tr. 772).

417. Most of ECM's customers either employ plastics engineers or are owned by a plastic engineer. (Sinclair, Tr. 772).

418. Many ECM customers employ scientists or engineers in charge of product development. (Barber, Tr. 2028–29; RX 136).

419. Even ECM distributors explained to downstream manufacturers that the time it takes for an ECM plastic to fully biodegrade will depend on various factors. (RX 08).

420. ECM regularly corresponds with customers by email or phone to provide them with any information they require. (RX 113, RX 115; RX 117-118; RX 126-129; RX 132-135).

421. Both direct customers and down-stream customers regularly inquire about the effect that various environmental conditions have on the biodegradability of ECM plastics. (RX 127-128; RX 132).

422. ECM has kept customers informed of research developments within the field of biodegradable plastic additives in the landfill environment. (RX 89; RX 118).

423. ECM customers will often ask sophisticated questions about product performance. (RX 13).

424. Some ECM customers are large enough to have entire regulatory departments. (RX 97).

425. ECM customers keep abreast of changes in regulatory requirements and certifications. (RX 98; RX 116; RX 119).

426. ECM customers often inquire into ECM's choices regarding testing methodology, results of tests, and extrapolation of results. (RX 122; RX 132).

427. BioPVC, an ECM customer, also had biodegradability and ecotoxicology testing done on its product. (RX 120; RX 121).

428. For many ECM customers, deciding whether to test a product for biodegradability is just another operational decision. (RX 24).

429. This often includes providing customers with scientific information and test data. (RX 88; RX 101; RX 122; RX 136).

430. Even down-stream customers that do not interact directly with ECM have scientists on staff. (RX 102).

431. The evidence suggests that ECM customers are, in fact, only concerned with marketing a "biodegradable" claim and, so, they considered ECM's statements concerning the "rate" of biodegradation only to the extent those claims were apparently mandated by regulatory bodies such as the FTC. (Sinclair, Tr. 770–771, 775; RX 105; RX 107; RX 112–113; RX 117; RX 140; RX 871 (Blood, Dep. at 193)).

432. Mr. Sinclair often provides potential customers with information and answers their questions as well. (RX 93; RX 110; RX 122).

B. Deposition Testimony Confirms that ECM's Customers are Sophisticated Plastic Manufacturers

433. Robert Ringley is the vice president of BER Plastics, Inc. (CCX 800 (Ringley, Dep. at 1)).

434. BER Plastics purchased the ECM additive between 2009 and 2014. (CCX 800 (Ringley, Dep. at 12)).

435. In years 2009 through 2014, BER Plastics had approximately 10 million dollars in revenue each year. (CCX 800 (Ringley, Dep. at 12–13)).

436. BER Plastics first heard of ECM through an article in Plastics Technology, a respected trade magazine. (CCX 800 (Ringley, Dep. at 15, 20)).

437. After seeing the article in Plastics Technology, and after a couple of their customers asked them about the Plastic containing the ECM additive, BER Plastics called ECM and "had a long conversation with Mr. Sinclair [who] gave [BER Plastics] the information [they] were looking for." (CCX 800 (Ringley, Dep. at 20)).

438. BER Plastics only purchased the ECM additive after speaking to ECM and getting the answers to the questions with which they were most concerned. (CCX 800 (Ringley, Dep. at 20)).

439. BER Plastic read the testing information that ECM supplied to them about the ECM additive. (CCX 800 (Ringley, Dep. at 23–24)).

440. BER Plastic does not sell to any end user. (CCX 800 (Ringley, Dep. at 11)).

441. All of BER Plastic's film is sold to converters where it is printed and converted into a plastic. (CCX 800 (Ringley, Dep. at 11)).

442. Converters are the people who place orders for BER Plastic's film. (CCX 800, (Ringley, Dep. at 11)).

443. BER plastics sold low density polyethylene film to 10 customers. (CCX 800 (Ringley, Dep. at 10)).

444. The only information BER Plastics received from ECM that BER Plastics passed on to its customers was the certificate of biodegradability given by ECM to BER Plastics. (CCX 800 (Ringley, Dep. at 30–32)).

445. ECM never misled BER Plastics. (CCX 800 (Ringley, Dep. at 35)).

446. BER Plastics never heard any negative comments about the ECM amended film they sold to their customers. (CCX 800 (Ringley, Dep. at 35)).

447. Donald Kizer is a supply chain manager for D & W Fine Pack. (CCX 801 (Kizer, Dep. at 11–13)).

448. D & W Fine Pack is a manufacturer of disposable products for the food service industry. (CCX 801 (Kizer, Dep. at 12)).

449. D & W Fine Pack has been in business since 2009. (CCX 801 (Kizer, Dep. at 2)).

450. Before 2009, D & W Fine Pack was known as Dispoz-o Products. (CCX 801 (Kizer, Dep. at 11–12)).

451. D & W Fine Pack has a 580,000 square foot manufacturing plant. (CCX 801(Kizer, Dep. at 14)).

452. In 2008 Dispoz-o had approximately 83 million dollars in revenue. (CCX 801(Kizer, Dep. at 15)).

453. In 2009 D & W Fine Pack had approximately 120 million dollars in revenue. (CCX 801 (Kizer, Dep. at 16)).

454. In 2013 D & W Fine Pack had approximately 424 million dollars in revenue. (CCX 801 (Kizer, Dep. at 16)).

455. In 2008, Dispoz-o had 740 employees. (CCX 801 (Kizer, Dep. at 16)).

456. In 2009, D & W Fine Pack had 1,540 employees. (CCX 801 (Kizer, Dep. at 17)).

457. D & W Fine Pack hired outside contractors with scientific knowledge. (CCX 801 (Kizer, Dep. at 18)).

458. Dispoz-o waited about three or four months from their initial contact with ECM to actually make their first purchase of the ECM additive. (CCX 801 (Kizer, Dep. at 22–23)).

459. Dispoz-o's CEO and operations manager were the individuals who decided to purchase the ECM additive. (CCX 801 (Kizer, Dep. at 24)).

460. ECM provided answers to Dispoz-o's and D & W Fine Pack's questions concerning the properties of the ECM additive. (CCX 801 (Kizer, Dep. at 25)).

461. Dispoz-o and D & W Fine Pack communicated directly with Bob Sinclair. (CCX 801 (Kizer, Dep. at 26)).

462. D & W Fine Pack at one time purchased an additional additive similar to the ECM additive, but stopped purchasing the other additive because D & W Fine Pack had issues with processing the other additive into their materials. (CCX 801 (Kizer, Dep. at 34)).

463. For D & W Fine Pack and Dispoz-o, adding the ECM additive into the manufacturing process was just like adding a colorant in the manufacturing process. (CCX 801 (Kizer, Dep. at 35–36)).

464. Ashley Leiti has been employed by Dispoz-o and D & W Fine Pack since 2008 in the fields of marketing, product development, and sales. (CCX 802 (Leiti, Dep. at 14)).

465. ECM provided to Dispoz-o and D & W Fine Pack testing results, research about the ECM additive, and information about the additive. (CCX 802 (Leiti, Dep. at 21)).

466. ECM provided their certificate of biodegradability to Dispoz-o in 2008. (CCX 802 (Leiti, Dep. at 22)).

467. Dispoz-o understood that ECM's claims meant that products amended with the ECM additive were degradable as defined by the ASTM standards. (CCX 802 (Leiti, Dep. at 23)).

468. Dispoz-o and D & W Fine Pack renewed their certificate of biodegradability with ECM on annual basis. (CCX 802 (Leiti, Dep. at 24)).

469. Dispoz-o and D & W Fine Pack believed that ECM's former nine months to five years claim was true because of the totality of information ECM provided to Dispoz-o and D & W Fine Pack. (CCX 802 (Leiti, Dep. at 33)).

470. In August, 2009, D & W Fine Pack stopped making the claim "biodegradable" regarding its enviroware line of products containing the ECM additive. (CCX 802 (Leiti, Dep. at 62; 67-68)).

471. Dispoz-o and D & W Fine Pack looked to additional sources besides ECM in determining whether to rely on the claims made by ECM regarding the ECM additive. (CCX 802 (Leiti, Dep. at 66)).

472. Dispoz-o and D & W Fine Pack asked Robert Sinclair directly questions about biodegradability, which Mr. Sinclair answered. (CCX 802 (Leiti, Dep. at 66–67)).

473. In August 2008, Dispoz-o had a meeting with Robert Sinclair. (CCX 802 (Leiti, Dep. at 68)).

474. ECM, through Robert Sinclair, qualified the nine months to five years biodegradation claim to Dispoz-o and D & W Fine Pack. (CCX 802 (Leiti, Dep. at 72–73)).

475. In August, 2009, D & W Fine Pack stopped making the claim "biodegradable" regarding its enviroware line of products containing the ECM additive. (CCX 802 (Leiti, Dep. at 73)).

476. ECM gave Dispoz-o and D & W Fine Pack test reports. (CCX 802 (Leiti, Dep. at 91–92)).

477. Dispoz-o and D & W Fine Pack conducted their own testing on ECM amended plastics to determine the biodegradability of those plastics. (CCX 802 (Leiti, Dep. at 95–96)).

478. Dispoz-o and D & W Fine Pack chose to make their own claims regarding the products they sold amended with the ECM additive, regardless of what claims ECM made about plastic containing the ECM additive. (CCX 802 (Leiti, Dep. at 135–37)).

479. Dispoz-o and D & W Fine Pack did not inform ECM that they had received an inquiry from the NAD. (CCX 802 (Leiti, Dep. at 148)).

480. Dispoz-o and D & W Fine Pack has a product development group. (CCX 802 (Leiti, Dep. at 155)).

481. Dispoz-o and D & W Fine Pack takes multiple steps before actually producing a new product to sell. (CCX 802 (Leiti, Dep. at 155)).

482. Dispoz-o and D & W Fine Pack makes samples of a product before selling that product. (CCX 802 (Leiti, Dep. at 157)).

483. Dispoz-o and D & W Fine Pack have three channels of customers: the distribution channel, the grocery processor, and the national accounts. (CCX 802 (Leiti, Dep. at 160)).

484. All products sold by Dispoz-o and D & W Fine Pack are sold to distributors. (CCX 802 (Leiti, Dep. at 161)).

485. All distributors that Dispoz-o and D & W Fine Pack sell products to then sell to businesses, such as restaurants. (CCX 802 (Leiti, Dep. at 161)).

486. An end use consumer of products initially produced by D & W Fine Pack or Dispoz-does not know that the product came from Dispoz-o or D & W Fine Pack. (CCX 802 (Leiti, Dep. at 161–62)).

487. Frank Santana is the marketing director for Down to Earth Organic and Natural. (CCX 803 (Santana, Dep. at 6, 8)).

488. Down to Earth Organic and Natural has had five stores since at least 2008. (CCX 803 (Santana, Dep. at 10)).

489. Down to Earth Organic and Natural had approximate annual revenue of 30 million dollars between 2008 and 2013. (CCX 803 (Santana, Dep. at 10)).

490. Down to Earth Organic and Natural has employed approximately 200 employees at all times since 2008. (CCX 803 (Santana, Dep. at 12–13)).

491. Down to Earth Organic and Natural first became aware of ECM through word of mouth in 2008. (CCX 803 (Santana, Dep. at 19)).

492. Down to Earth Organic and Natural reviewed material on the ECM website. (CCX 803 (Santana, Dep. at 23)).

493. Down to Earth Organic and Natural was aware that ECM's certificate of biodegradability did not state that ECM amended plastics were biodegradable within nine months to five years. (CCX 803 (Santana, Dep. at 32)).

494. Down to Earth Organic and Natural completed its own evaluation of lab reports to determine whether ECM amended plastic was fully biodegradable. (CCX 803 (Santana, Dep. at 33)).

495. Down to Earth Organic and Natural reviewed laboratory reports regarding ECM amended plastic before purchasing ECM amended plastic. (CCX 803 (Santana, Dep. at 34)).

496. Down to Earth Organic and Natural investigated the ECM technology for the better part of a year before deciding to purchase plastic bags amended with the ECM additive. (CCX 803 (Santana, Dep. at 38)).

497. ECM made recommendations to Down to Earth Organic and Natural about how to market the ECM amended plastic they provided to customers, but Down to Earth Organic and Natural used their judgment and ignored ECM's recommendations. (CCX 803 (Santana, Dep. at 54–55)).

498. As part of their Earth Day 2009 promotions, Down to Earth Organic and Natural offered 30% off on over 50 of their best-selling items. (CCX 803 (Santana, Dep. at 59)).

499. Down to Earth Organic and Natural believed that lab reports assessing the biodegradability of ECM amended plastics were independent lab reports because of the "test in the lab report[s]." (CCX 803 (Santana, Dep. at 66–67)).

500. On Earth Day 2009, Down to Earth Organic and Natural had more sales than a normal day because they had a storewide sale on that day. (CCX 803 (Santana, Dep. at 83, 85)).

501. Down to Earth Organic and Natural purchased ECM amended plastic bags from Triple F, who purchased the ECM amended plastic bags from Island Plastic Bags. (CCX 803 (Santana, Dep. at 46–47)).

502. Down to Earth Organic and Natural received criticism from Dr. Ramani Narayan regarding the ECM additive, and received a response to Dr. Narayan's criticism from ECM, and Down to Earth Organic and Natural was "satisfied that ECM had successfully addressed those criticisms." (CCX 803 (Santana, Dep. at 91–93)).

503. Down to Earth Organic and Natural used its own judgment to determine whether the McLaren report substantiated ECM's advertising claims. (CCX 803 (Santana, Dep. at 96)).

504. Island Plastic Bags purchases the ECM additive because it makes plastic biodegradable. (CCX 811 (Hong, Dep. at 11)).

505. Island Plastic Bags' customers, such as Down to Earth Natural and Organic, simply wanted biodegradable products. (CCX 811 (Hong, Dep. at 42, 66, 70–71, 76, 79–81, 83, 89, 91, 105–08)).

506. Island Plastics Bags was most concerned with whether the ECM additive could be used in their machines, because the additive "doesn't do [Island Plastic Bags] any good if [Island Plastic Bags] can't use it through [their] machines." (CCX 811 (Hong, Dep. at 44)).

507. Island Plastic Bag's customers were interested in biodegradable plastic because they were interested in sustainability. (CCX 811 (Hong, Dep. at 25)).

508. There is no evidence that the rate of biodegradation was material to Island Plastic Bags when purchasing the ECM additive, so long as the final products were biodegradable. (CCX 811 (Hong, Dep. at 1–117)).

509. There is no evidence that the rate of biodegradation was material to Island Plastic Bags' customers when purchasing the ECM amended plastics from Island Plastic Bags, so long as ECM amended plastics would be biodegradable. (CCX 811 (Hong, Dep. at 1–117)).

510. There is no evidence that the rate of biodegradation was relevant to Island Plastic Bags when purchasing the ECM additive, so long as the final products were biodegradable. (CCX 811 (Hong, Dep. at 1–117)).

511. There is no evidence that the rate of biodegradation was relevant to Island Plastic Bags' customers when purchasing the ECM amended plastics from Island Plastic Bags, so long as ECM amended plastics would be biodegradable. (CCX 811 (Hong, Dep. at 1–117)).

512. George Collins is the President of Eagle Film Extruders, Inc. (CCX 804 (Collins, Dep. at 9)).

513. George Collins has been employed at Eagle Film extruders, Inc. since 2001. (CCX 804 (Collins, Dep. at 9)).

514. Eagle Film Extruders, Inc. is a blown film manufacturer of single three layer sheeting. (CCX 804 (Collins, Dep. at 10)).

515. Eagle Film Extruders, Inc. manufacturers only blown film. (CCX 804 (Collins, Dep. at 10)).

516. Eagle Film Extruders, Inc. sells blown film to the markets of food, medical, pharmaceutical, health and beauty, coating films, and signage. (CCX 804 (Collins, Dep. at 10)).

517. Eagle Film Extruders, Inc. purchased the ECM additive beginning in 2008. (CCX 804 (Collins, Dep. at 11, 16)).

518. In 2013, Eagle Film Extruders, Inc. had approximately 18 million dollars in sales. (CCX 804 (Collins, Dep. at 12)).

519. After customers inquired about a product, Eagle Film Extruders contacted Robert Sinclair and then talked with Mr. Sinclair about the ECM additive before deciding to purchase the additive. (CCX 804 (Collins, Dep. at 14–15)).

520. ECM provided information, including test reports, to Eagle Film Extruders, Inc. (CCX 804 (Collins, Dep. at 17)).

521. When discussing biodegradation of plastic containing the ECM additive with Eagle Film Extruders, Inc., Mr. Sinclair did not discuss any specific time frame regarding how long it takes ECM amended plastics to biodegrade. (CCX 804 (Collins, Dep. at 17–18)).

522. Eagle Film Extruders, Inc. understood that plastic containing the ECM additive could take years to biodegrade. (CCX 804 (Collins, Dep. at 18)).

523. If customers had questions about the ECM additive, Eagle Film Extruders, Inc. instructed those customers to talk directly with Bob Sinclair. (CCX 804 (Collins, Dep. at 22)).

524. Eagle Film Extruders, Inc. allows its customers to determine for themselves whether the ECM additive works as claimed. (CCX 804 (Collins, Dep. at 33–34, 53–54)).

525. Eagle Film Extruders, Inc. did not promote blown film containing the ECM additive. (CCX 804 (Collins, Dep. at 35)).

526. Eagle Film Extruders, Inc. represented that ECM amended blown film breaks down in 15 months. (CCX 804 (Collins, Dep. at 47)).

527. David Sandry is the corporate representative for Flexible Plastics. (CCX 809 (Sandry, Dep. at 4)).

528. Flexible Plastics prints and manufactures plastic bags. (CCX 809 (Sandry, Dep. at 8)).

529. Flexible Plastics purchases rolls of plastic from extruders. (CCX 809 (Sandry, Dep. at 9)).

530. Flexible Plastics has used and continues to use the ECM additive in their plastic bags. (CCX 809 (Sandry, Dep. at 10)).

531. Corn based plastics bags were too expensive for Flexible Plastic's customer to purchase. (CCX 809 (Sandry, Dep. at 14–15)).

532. Flexible Plastics understood that by adding the ECM additive to their plastic bags, the additive would simply break down faster than an untreated bag. (CCX 809 (Sandry, Dep. at 17)).

533. Flexible Plastics never distributed ECM marketing materials to their customers. (CCX 809 (Sandry, Dep. at 40)).

534. There is no evidence that any of Flexible Plastic's customers marketed any rate claim associated with their biodegradable plastic bags. (CCX 809 (Sandry, Dep. at 53)).

535. Flexible Plastics sells their product all over the country. (CCX 809 (Sandry, Dep. at 62)).

536. Flexible Plastics uses high temperatures, 700 to 750 degrees, in order to make plastic bags. (CCX 809 (Sandry, Dep. at 63–64)).

537. Flexible Plastics sells its product 1) through distributors, who sell the product to the meat processing industry, 2) to small cities, municipalities, and small trash haulers, and 3) through other distributors. (CCX 809 (Sandry, Dep. at 66)).

538. James Blood is the corporate designee for FP International. (CCX 810 (Blood, Dep. at 12–13).

539. James Blood is the senior vice president and general counsel of FP International. (CCX 810 (Blood, Dep. at 214)).

540. FP International is in the business of manufacturing and selling protective packaging products and packaging systems. (CCX 810 (Blood, Dep. at 13)).

541. FP International's customers are distributors that distribute and sell to entities that ship products in boxes. (CCX 810 (Blood, Dep. at 15)).

542. FP International began purchasing the ECM additive in 2008. (CCX 810 (Blood, Dep. at 13)).

543. FP International provides a "Biodegradable Packaging Materials: Questions and Answers" section on its website. (RX 33).

544. FP International's Questions and Answers section explains that the time it takes for a product to fully biodegrade depends on environmental conditions, that the product will biodegrade in either anaerobic or aerobic conditions, and that the products will perform like conventional plastic products. (RX 33).

545. FP International sold loosefill product and air cushion product amended with the ECM additive. (CCX 810 (Blood, Dep. at 17, 22)).

546. FP International engaged the services of multiple scientists to test the biodegradability of their products. (CCX 810 (Blood, Dep. at 57, 87, 163)).

547. FP International engaged Stevens Ecology to test the biodegradability of their products. (CCX 810 (Blood, Dep. at 57)).

548. FP International engaged the services of Dr. Timothy Barber of Environ to test the biodegradability of their products. CCX 810 (Blood, Dep. at 87)).

549. FP International engaged the services of Eden Laboratories to test the biodegradability of their products. (CCX 810 (Blood, Dep. at 163))

550. FP International believes that Environ's test results demonstrated that plastic amended with the ECM additive will biodegrade. (CCX 810 (Blood, Dep. at 119)).

551. FP International does not state that its products amended with the ECM additive will biodegrade in "some period greater than a year." (CCX 810 (Blood, Dep. at 192)).

552. FP International decided to transition its prior claims to the claim that ECM amended plastic will biodegrade in landfills in one to five years or more independent of any communication with ECM. (CCX 810 (Blood, Dep. at 193–94)).

553. Based on their testing and experience, FP International realized that it was difficult to assess the time periods in which ECM amended plastic would biodegrade in landfills. (CCX 810 (Blood, Dep. at 194–95)).

554. FP International met with Robert Sinclair in person before entering into any contract with ECM. (CCX 810 (Blood, Dep. at 206)).

555. Adrian Hong is the corporate designee for Island Plastic Bags. (CCX 811 (Hong, Dep. at 9)).

556. Adrian Hong is the General Manager for Island Plastic Bags. (CCX 811 (Hong, Dep. at 110)).

557. Island Plastic Bags has been in business since 1992. (CCX 811 (Hong, Dep. at 9)).

558. Island Plastic Bags manufactures and sells high density and low density polyethylene bags in various dimensions and gauges. (CCX 811 (Hong, Dep. at 9–10)).

559. Island Plastic Bags manufactures and sells plastic cutlery. (CCX 811 (Hong, Dep. at 10)).

560. Island Plastic Bags sells its products to either distributors or retailers. (CCX 811 (Hong, Dep. at 11)).

561. Island Plastic Bags became aware of the ECM additive through discussions with different manufacturing partners. (CCX 811 (Hong, Dep. at 11)).

562. Island Plastic Bags reviewed the McLaren/Hart Report and came to their own conclusions about the biodegradability of plastic amended with the ECM additive. (CCX 811 (Hong, Dep. at 32–33, 38–40)).

563. Island Plastic Bags chose to maintain the nine months to five years claim and not transition the claim to greater than a year even after the Green Guides were revised. (CCX 811 (Hong, Dep. at 55–56, 61)).

564. Consumers do not purchase products from Island Plastic Bags. (CCX 811 (Hong, Dep. at 77)).

565. Consumers do not purchase products made by Island Plastic Bags. (CCX 811 (Hong, Dep. at 77)).

566. Island Plastic Bags created their own marketing materials without ECM's assistance. (CCX 811 (Hong, Dep. at 100)).

567. ECM made itself available to answer Island Plastic Bags' customers' questions. (CCX 811 (Hong, Dep. at 100)).

568. Island Plastic Bags had an approximate annual revenue of 6.8 million dollars each year from 2008 through 2013. (CCX 811 (Hong, Dep. at 113–14)).

569. ECM informed Island Plastic Bags that they needed to qualify their claims in light of the Green Guides. (CCX 811 (Hong, Dep. at 114)).

570. Annette Gormly is the vice president of Kappus Plastic Company. (CCX 812 (Gormly, Dep. at 5)).

571. Kappus Plastic Company manufactures calendered vinyl rigid sheeting. (CCX 812 (Gormly, Dep. at 11)).

572. Kappus Plastic Company produces sheet stock or rolls that it sells to companies. (CCX 812 (Gormly, Dep. at 11)).

573. Most of Kappus Plastic Company's customers are credit card companies. (CCX 812 (Gormly, Dep. at 12)).

574. Kappus Plastic Company has been manufacturing since 1970. (CCX 812 (Gormly, Dep. at 12)).

575. Kappus Plastic Company's customer's customers are primarily banks, and some are other companies or department stores. (CCX 812 (Gormly, Dep. at 12)).

576. Kappus Plastic Company purchased the ECM additive from 2009 through 2013. (CCX 812 (Gormly, Dep. at 13)).

577. Kappus Plastic Company has a laboratory. (CCX 812 (Gormly, Dep. at 17–18, 21)).

578. Kappus Plastic Company did not provide its ECM Certificate directly to any of its customers. (CCX 812 (Gormly, Dep. at 29)).

579. Kappus Plastic Company is familiar with the ASTM. (CCX 812 (Gormly, Dep. at 41)).

580. James Bean is the corporate designee for Quest Plastics, Inc. (CCX 817 (Bean, Dep. at 7)).

581. James Bean is the president and owner of Quest Plastics, Inc. (CCX 817 (Bean, Dep. at 11)).

582. Quest Plastics, Inc. is an injection molding company that makes caps for aerosols, fragrances, and cosmetic packaging. (CCX 817 (Bean, Dep. at 9)).

583. In essence, Quest Plastics, Inc. converts thermoplastic raw material into products such as caps, closures, lipstick cases and other custom molding. (CCX 817 (Bean, Dep. at 10)).

584. James Bean worked for three years at Harvard Medical School conducting open heart surgery on dogs and sheep. (CCX 817 (Bean, Dep. at 16–17)).

585. Quest Plastics, Inc. has been in business for 24 years. (CCX 817 (Bean, Dep. at 11)).

586. James Bean worked as a consultant in the plastics industry. (CCX 817 (Bean, Dep. at 17)).

587. Quest Plastics, Inc. sells its products primarily to companies in the eyelet industry. (CCX 817 (Bean, Dep. at 18)).

588. All of Quest Plastics, Inc.'s customers are companies. (CCX 817 (Bean, Dep. at 19)).

589. Quest Plastics, Inc. has facilities that run tests. (CCX 817 (Bean, Dep. at 39)).

590. Quest Plastics, Inc. does not sell any product directly to consumers. (CCX 817 (Bean, Dep. at 41)).

591. Stephen Joseph is 3M Company's corporate representative. (CCX 821 (Joseph, Dep. at 9)).

592. Stephen Joseph is a senior division scientist at 3M Company. (CCX 821 (Joseph, Dep. at 28)).

593. 3M Company first became aware of the ECM additive by reviewing ECM's website. (CCX 821 (Joseph, Dep. at 31–32)).

594. 3M Company is not aware of using carbon 14 type testing to evaluate the biodegradability of a sample. (CCX 821 (Joseph, Dep. at 67)).

595. 3M Company does not rely on third party information with respect to claims regarding biodegradation of a polymer. (CCX 821 (Joseph, Dep. at 113)).

596. Ramy Samuel is the corporate designee for ANS Plastics Corporation. (CCX 822 (Samuels, Dep. at 7)).

597. Ramy Samuels is one of the owners and is the vice president of ANS Plastics Corporation. (CCX 822 (Samuels, Dep. at 9)).

598. ANS Plastics Corporation manufactures plastic shopping bags. (CCX 822 (Samuels, Dep. at 8)).

599. ANS Plastics Corporation sells to wholesalers, distributors, and retailers such as restaurants, bagel shops, auto part stores, supermarkets, pet stores, and pizza stores. (CCX 822 (Samuels, Dep. at 8–9)).

600. ANS Plastics Corporation has been in business since 1993. (CCX 822 (Samuels, Dep. at 9)).

601. Remy Samuels has been around plastics his entire life. (CCX 822 (Samuels, Dep. at 11))

602. ANS Plastic Corporation's customers contacted ECM directly. (CCX 822 (Samuels, Dep. at 23–24)).

603. No consumer ever purchased an ECM amended product from ANS Plastic Corporation. (CCX 822 (Samuels, Dep. at 26)).

604. No consumer ever purchased an ECM amended product that was manufactured by ANS Plastic Corporation. (CCX 822 (Samuels, Dep. at 26)).

C. Deposition Testimony Confirms that the Rate of Biodegradation of Plastic Containing the ECM Additive is not Material to any of ECM's Customers' Purchasing Decisions

605. BER Plastics never really thought about how long it would take an ECM amended plastic to biodegrade. ((CCX 800 (Ringley, Dep. at 32)).

606. BER Plastic's customers are interested in biodegradable products. (CCX 800 (Ringley, Dep. at 17)).

607. BER Plastic's customers wanted a product that they could call biodegradable. (CCX 800 (Ringley, Dep. at 17)).

608. BER Plastic's customers wanted a product that they could market as degradable so they could say they are being environmentally sensitive. (CCX 800 (Ringley, Dep. at 18)).

609. BER Plastic's customers want to be able to mark biodegradable on packaging because they are afraid they might otherwise lose business. (CCX 800 (Ringley, Dep. at 18)).

610. All of the customers that BER Plastic's sold ECM amended low density polyethylene to make low density polyethylene bags. (CCX 800 (Ringley, Dep. at 19)).

611. BER Plastics is one of the biggest pillow film producers in the country. (CCX 800 (Ringley, Dep. at 11)).

612. No customer of BER Plastics ever complained that the ECM amended film was not biodegradable. (CCX 800 (Ringley, Dep. at 35)).

613. There is no evidence that the rate of biodegradation was relevant to BER Plastics when purchasing the ECM additive. (CCX 800 (Ringley, Dep. at 1–36)).

614. There is no evidence that the rate of biodegradation was relevant to BER Plastics' customers when purchasing the ECM amended film from BER Plastics. (CCX 800 (Ringley, Dep. at 1–36)).

615. There is no evidence that the rate of biodegradation was material to BER Plastics when purchasing the ECM additive. (CCX 800 (Ringley, Dep. at 1–36)).

616. There is no evidence that the rate of biodegradation was material to BER Plastics' customers when purchasing the ECM amended film from BER Plastics. (CCX 800 (Ringley, Dep. at 1–36)).

617. Dispoz-o's customers were distributors that distributed products to the food service industry, hotel, hospitality, paper houses, and paper industry. (CCX 801 (Kizer, Dep. at 13–14)).

618. Since becoming D & W Fine Pack, the customer base has stayed the same, and D & W Fine Pack sells to distributors. (CCX 801(Kizer, Dep. at 14)).

619. Dispoz-o and D & W Fine Pack purchased an additive from ECM starting in 2008. (CCX 801 (Kizer, Dep. at 19)).

620. Dispoz-o began purchasing the ECM additive because they wanted a "green product that [they] could bring to the marketplace." (CCX 801 (Kizer, Dep. at 19)).

621. Dispoz-o believed that if they were able to market "a foam tray that had a green story behind it that it would be beneficial." (CCX 801 (Kizer, Dep. at 20)).

622. By being a "green" product, Dispoz-o wanted something that would be biodegradable or compostable. (CCX 801 (Kizer, Dep. at 21)).

623. Dispoz-o understood that by adding the ECM additive to their products that they would see biodegradation. (CCX 801 (Kizer, Dep. at 22)).

624. Dispoz-o understood biodegradation to mean that the product "would degrade over a period of time." (CCX 801 (Kizer, Dep. at 22)).

625. Dispoz-o and D & W Fine Pack purchased the ECM additive so that the company could sell a "green" product. (CCX 801 (Kizer, Dep. at 30)).

626. Dispoz-o and D & W Fine Pack's customers sold the ECM amended plastics through their own chains of distribution with business such as restaurants and hospitality being the at the end of the chains of distribution. (CCX 801 (Kizer, Dep. at 31)).

627. The most prominent marketing claims that Dispoz-o and D & W Fine Pack made regarding their enviroware product line, which was amended with the ECM additive was that it was "100% biodegradable" and that it was "biodegradable." (CCX 802 (Leiti, Dep. at 47, 49–50)).

628. Mr. Kizer does not know how long Dispoz-o thought an ECM amended product would take to biodegrade. (CCX 801 (Kizer, Dep. at 23)).

629. In May, 2009, D & W Fine Pack stopped making the claim "100% biodegradable" regarding its enviroware line of products containing the ECM additive. (CCX 802 (Leiti, Dep. at 47, 54)).

630. In August, 2009, D & W Fine Pack stopped making the claim "biodegradable" regarding its enviroware line of products containing the ECM additive. (CCX 802 (Leiti, Dep. at 47, 55)).

631. By July, 2011, D & W Fine Pack started making the claim "accelerates the degradation process" regarding its enviroware line of products containing the ECM additive. (CCX 802 (Leiti, Dep. at 47, 55)).

632. D & W Fine Pack's customers were concerned with what effects enviroware would have on insects in the ground. (CCX 802 (Leiti, Dep. at 61)).

633. There is no evidence that the rate of biodegradation was relevant to Dispoz-o or D & W Fine Pack when purchasing the ECM additive. (CCX 801 (Kizer, Dep. at 1–41); CCX 802 (Leiti, Dep. at 1–182)).

634. There is no evidence that the rate of biodegradation was material Dispoz-o or D & W Fine Pack when purchasing the ECM additive. (CCX 801 (Kizer, Dep. at 1–41); CCX 802 (Leiti, Dep. at 1–182)).

635. There is no evidence that the rate of biodegradation was relevant to Dispoz-o or D & W Fine Pack customers when purchasing the ECM amended film from Dispoz-o or D & W Fine Pack. (CCX 801 (Kizer, Dep. at 1–41); CCX 802 (Leiti, Dep. at 1–182)).

636. Down to Earth Organic and Natural purchased ECM amended plastic because it biodegrades with or without oxygen and because of the price as compared to compostable products. (CCX 803 (Santana, Dep. at 39)).

637. Down to Earth Organic and Natural informed customers that their plastic bags were biodegradable because they wanted to inform customers that they were doing their part to help the environment. (CCX 803 (Santana, Dep. at 43)).

638. Down to Earth Organic and Natural thought the ECM amended plastics would further their purpose of cherishing the land and living in health and harmony. (CCX 803 (Santana, Dep. at 45–46)).

639. Down to Earth Organic and Natural promotes organic farming, sells organic and natural products, and promotes an organic and natural lifestyle. (CCX 803 (Santana, Dep. at 12)).

640. Environmental activists challenging Down to Earth Organic's biodegradability claims thought that it was unacceptable for bags to take nine months to five years for a plastic bag to break down. (CCX 803 (Santana, Dep. at 99)).

641. No consumer actually purchased an ECM amended plastic bag from Down to Earth Organic and Natural. (CCX 803 (Santana, Dep. at 47–48)).

642. There is no evidence that the rate of biodegradation was relevant to Down to Earth Organic and Natural when purchasing the ECM additive. (CCX 803 (Santana, Dep. at 1–114)).

643. There is no evidence that any customer of Down to Earth Organic and Natural purchased items from Down to Earth Organic and Natural because Down to Earth Organic and Natural provided ECM amended bags. (CCX 803 (Santana, Dep. at 1–114)).

644. There is no evidence that the rate of biodegradation of their plastic bags was relevant to Down to Earth Organic and Natural customers when purchasing items from Down to Earth Organic and Natural. (CCX 803 (Santana, Dep. at 1–114)).

645. There is no evidence that the rate of biodegradation was material to Down to Earth Natural and Organic when purchasing the ECM amended plastic bags. (CCX 803 (Santana, Dep. at 1–114)).

646. There is no evidence that the rate of biodegradation of their plastic bags was material to Down to Earth Organic and Natural customers when purchasing items from Down to Earth Organic and Natural. (CCX 803 (Santana, Dep. at 1–114)).

647. Eagle Film Extruders, Inc.'s customers wanted blown film amended with the ECM additive because they wanted to sell an environmentally-friendly biodegradable product. (CCX 804 (Collins, Dep. at 15)).

648. Eagle Film Extruders, Inc. sells blown film to converters. (CCX 804 (Collins, Dep. at 65)).

649. Eagle Film Extruders, Inc. does not sell to end users. (CCX 804 (Collins, Dep. at 65)).

650. "Industry osmosis" is the process of learning things about an industry from being immersed in that industry. (CCX 804 (Collins, Dep. at 67–68)).

651. Eagle Film Extruders, Inc. became aware of ECM through industry osmosis. (CCX 804 (Collins, Dep. at 30)).

652. Eagle Film Extruders, Inc. uses a complex process to determine which products to sell or not to sell. (CCX 804 (Collins, Dep. at 68–69)).

653. There is no evidence that the rate of biodegradation was relevant to Eagle Film Extruders, Inc. when purchasing the ECM additive. (CCX 804 (Collins, Dep. at 1–71)).

654. There is no evidence that the rate of biodegradation was relevant to Eagle Film Extruders, Inc.'s customer when purchasing the ECM amended film from Eagle Film Extruders, Inc. (CCX 804 (Collins, Dep. at 1–71)).

655. There is no evidence that the rate of biodegradation was material to Eagle Film Extruders, Inc. when purchasing the ECM additive. (CCX 804 (Collins, Dep. at 1–71)).

656. There is no evidence that the rate of biodegradation was material to Eagle Film Extruders Inc.'s customers when purchasing the ECM amended film from Eagle Film Extruders, Inc. (CCX 804 (Collins, Dep. at 1–71)).

657. Flexible Plastics was interested in the Plastic containing the ECM additive because their customers asked for biodegradable or greener bags. (CCX 809 (Sandry, Dep. at 13–14)).

658. Flexible Plastic's customers want to sell a more environmentally friendly plastic bag. (CCX 809 (Sandry, Dep. at 15)).

659. It was important to Flexible Plastics that any additive they added to their bags would not dramatically change their pricing. (CCX 809 (Sandry, Dep. at 18)).

660. When a customer or potential customer asked Flexible Plastics whether they sold biodegradable bags, Flexible Plastics referred the customer or potential customer to ECM's website. (CCX 809 (Sandry, Dep. at 30–31, 33)).

661. Some of Flexible Plastic's customer simply wanted a biodegradable bag. (CCX 809 (Sandry, Dep. at 33–34)).

662. Flexible Plastics' customers simply wanted a product that was more environmentally friendly than traditional plastic bags. (CCX 809 (Sandry, Dep. at 72–73)).

663. Flexible Plastics' customers provided no specific definition of "biodegradable." (CCX 809 (Sandry, Dep. at 73)).

664. No Flexible Plastics' customer every said that they needed their products to biodegrade in any specific time frame. (CCX 809 (Sandry, Dep. at 74)).

665. It was important to Flexible Plastics that the ECM additive would cause their plastic bags to become biodegradable. (CCX 809 (Sandry, Dep. at 75)).

666. Flexible Plastics had no definition or time frame in mind regarding the term "biodegradable." (CCX 809 (Sandry, Dep. at 75)).

667. Medical Arts Press, formerly Flexible Plastics' second largest customer, ceased purchasing from Flexible Plastics in 2013 because of the price of Flexible Plastics' product. (CCX 809 (Sandry, Dep. at 75–77)).

668. Flexible Plastics relied on representations made by ECM to the extent that Flexible Plastics could make a "biodegradable" product. (CCX 809 (Sandry, Dep. at 83)).

669. On some of the bags Flexible Plastics sold which contained the ECM additive, there was no identification at all that those bags contained the ECM additive. (CCX 809 (Sandry, Dep. at 43–44)).

670. Some of Flexible Plastic's customers marketed plastic bags amended with the ECM additive as "biodegradable." (CCX 809 (Sandry, Dep. at 52–53)).

671. Quality and cost are the most important factors for Flexible Plastics when deciding which rolls of plastics to purchase. (CCX 809 (Sandry, Dep. at 69–70)).

672. By quality, Flexible Plastics means that they want to purchase plastic rolls that work best with the products that they are producing with the machines that they are using. (CCX 809 (Sandry, Dep. at 70)).

673. There is no evidence that the rate of biodegradation was relevant to Flexible Plastics when purchasing the ECM additive. (CCX 809 (Sandry, Dep. at 1–86)).

674. There is no evidence that the rate of biodegradation was relevant to Flexible Plastics' customers when purchasing the ECM amended bags from Flexible Plastics (CCX 809 (Sandry, Dep. at 1–86)).

675. There is no evidence that the rate of biodegradation was material to Flexible Plastics when purchasing the ECM additive. (CCX 809 (Sandry, Dep. at 1–86)).

676. There is no evidence that the rate of biodegradation was material to Flexible Plastic's customers when purchasing the ECM amended bags from Flexible Plastics. (CCX 809 (Sandry, Dep. at 1–86)).

677. FP International purchases the ECM additive because it allegedly renders plastic biodegradable and because the ECM additive helps with FP International's general philosophy of lessening their impact on the environment. (CCX 810 (Blood, Dep. at 15)).

678. FP International believed that the biodegradable features of the ECM additive would give them a market advantage over competitors. (CCX 810 (Blood, Dep. at 18)).

679. FP International's customers wanted a product that would help lessen the impact on the environment. (CCX 810 (Blood, Dep. at 19)).

680. FP International's customers believed that by using a biodegradable product that they were lessening their impact on the environment. (CCX 810 (Blood, Dep. at 28)).

681. FP International employed a chief scientist, Rod Alire. (CCX 810 (Blood, Dep. at 34, 57, 104)).

682. FP International has an engineering department. (CCX 810 (Blood, Dep. at 67)).

683. FP International relied on testing information and reports provided by ECM, as well as background research by their Chief Scientist when making claims that their ECM amended products would biodegrade. (CCX 810 (Blood, Dep. at 68–69)).

684. FP International's customers do not care how long it takes ECM amended plastic to biodegrade, so long as it takes less time than non-amended conventional plastics. (CCX 810 (Blood, Dep. at 197)).

685. FP International's customers only care that, by purchasing ECM amended plastic as opposed to non-amended plastic, that they are lessening their impact on the environment. (CCX 810 (Blood, Dep. at 197)).

686. FP International's customers define "reasonably short period of time" in the context of how long it takes a plastic to biodegrade as faster than typical plastic. (CCX 810 (Blood, Dep. at 198–99)).

687. FP International made the claim that its ECM amended products would "decompose completely within 9 to 60 months in the presence of microorganisms" because "[i]t was important to convey a message of biodegradability." (CCX 810 (Blood, Dep. at 25)).

688. FP International provided its customer with the 9 to 60 month time frame for decomposing because they wanted their customers to understand that their products would not biodegrade in the same time frame as a compostable product; FP

International was "trying to portray that [their product] was not something that is going to degrade in a much quicker time frame." (CCX 810 (Blood, Dep. at 28)).

689. There is no evidence that the rate of biodegradation was relevant to FP International when purchasing the ECM additive, so long as ECM amended plastics would biodegrade more quickly than plastic not containing the ECM additive. (CCX 810 (Blood, Dep. at 1–234)).

690. There is no evidence that the rate of biodegradation was relevant to FP International's customers when purchasing the ECM amended bags from FP International so long as ECM amended plastics would biodegrade more quickly than plastic not containing the ECM additive. (CCX 810 (Blood, Dep. at 1–234)).

691. There is no evidence that the rate of biodegradation was material to FP International when purchasing the ECM additive, so long as ECM amended plastics would biodegrade more quickly than plastic not containing the ECM additive. (CCX 810 (Blood, Dep. at 1–234)).

692. There is no evidence that the rate of biodegradation was material to FP International's customers when purchasing the ECM amended plastics from FP International, so long as ECM amended plastics would biodegrade more quickly than plastic not containing the ECM additive. (CCX 810 (Blood, Dep. at 1–234)).

693. Kappus Plastic Company purchased the ECM additive because it makes plastic biodegradable. (CCX 812 (Gormly, Dep. at 14)).

694. Kappus Plastic Company's customers purchased ECM amended plastic in part because it was biodegradable. (CCX 812 (Gormly, Dep. at 15)).

695. Kappus Plastic Company's customers were interested in a biodegradable product because they were looking for environmentally friendly products. (CCX 812 (Gormly, Dep. at 15)).

696. No Kappus Plastic Company products amended with the ECM additive contained any sort of biodegradable logo. (CCX 812 (Gormly, Dep. at 22)).

697. Regarding the biodegradability of their products, Kappus Plastic Company simply informed their customers that they were selling a biodegradable product. (CCX 812 (Gormly, Dep. at 23).

698. Kappus Plastic Company's customer asked Kappus Plastic Company whether Kappus Plastic Company has a biodegradable product. (CCX 812 (Gormly, Dep. at 46)).

699. Kappus Plastic Company believes that nine months to five years was not a rigid standard for the amount of time it takes ECM amended plastics to biodegrade. (CCX 812 (Gormly, Dep. at 48–50)).

700. There is no evidence that the rate of biodegradation was relevant to Kappus Plastic Company when purchasing the ECM additive. (CCX 812 (Gormly, Dep. at 1–53)).

701. There is no evidence that the rate of biodegradation was relevant to Kappus Plastic Company's customers when purchasing the ECM amended product from Kappus Plastic Company. (CCX 812 (Gormly, Dep. at 1–53)).

702. There is no evidence that the rate of biodegradation was material to Kappus Plastic Company when purchasing the ECM additive. (CCX 812 (Gormly, Dep. at 1–53)).

703. There is no evidence that the rate of biodegradation was material to Kappus Plastic Company's customers when purchasing the ECM amended product from Kappus Plastic Company. (CCX 812 (Gormly, Dep. at 1–53)).

704. Quest Plastics, Inc. purchased the ECM additive on behalf of a customer because that customer wanted to produce biodegradable golf tees. (CCX 817 (Bean, Dep. at 19)).

705. Many of Quest Plastics, Inc.'s customers are not interested in biodegradable products because they are concerned with shelf life issues. (CCX 817 (Bean, Dep. at 22–23)).

706. Quest Plastics, Inc. chose to purchase the ECM additive because it is usable in their manufacturing process, was not cost prohibitive, and rendered golf tees biodegradable. (CCX 817 (Bean, Dep. at 25–26)).

707. Quest Plastics, Inc. does not know or care how long it would take the golf tees amended with the ECM additive to biodegrade. (CCX 817 (Bean, Dep. at 27)).

708. 3M Company does not recall whether ECM made any claim regarding the rate at which plastic containing the ECM additive biodegrade. (CCX 821 (Joseph, Dep. at 32)).

709. 3M Company was interested in the ECM additive because they wanted to research whether the additive can help reduce the impact of 3M Company's products on the environment following disposal. (CCX 821 (Joseph, Dep. at 42)).

710. 3M Company's customer never told 3M that they needed a biodegradable product to meet a specific definition. (CCX 821 (Joseph, Dep. at 126)).

711. 3M Company was interested in the ECM additive because of the fact that the ECM additive could potentially lead to biodegradation of the host plastic while at the same time preserving the characteristics of the host plastic. (CCX 821 (Joseph, Dep. at 112)).

712. ANS Plastic Corporation's customers were interested in a biodegradable or "green" product. (CCX 822 (Samuels, Dep. at 12–13)).

713. ANS Plastic Corporation's customers were interested in a biodegradable product because they "want to be green" and wanted to "call themselves green." (CCX 822 (Samuels, Dep. at 13)).

714. ANS Plastic Corporation marketed plastic products amended with the ECM additive simply as biodegradable. (CCX 822 (Samuels, Dep. at 22)).

715. ANS Plastic Corporation's customers just give the ECM amended products to consumers at no cost. (CCX 822 (Samuels, Dep. at 27)).

716. ANS Plastic Corporation simply told its customers that they could purchase a biodegradable bag. (CCX 822 (Samuels, Dep. at 27–28)).

717. ANS Plastic Corporation's customers never asked about the rate of biodegradation for ECM amended products. (CCX 822 (Samuels, Dep. at 28)).

718. ANS Plastic Corporation's customers only wanted to know whether they were buying a biodegradable bag. (CCX 822 (Samuels, Dep. at 28)).

719. ANS Plastic Corporation's customers wanted to purchase a biodegradable bag because they are environmentally conscious and wanted to use bags that would biodegrade. (CCX 822 (Samuels, Dep. at 28)).

720. There is no evidence that the rate of biodegradation was relevant to ANS Plastic Corporation when purchasing the ECM additive. (CCX 822 (Samuels, Dep. at 1–40)).

721. There is no evidence that the rate of biodegradation was relevant to ANS Plastic Corporation's customers when purchasing the ECM amended product from ANS Plastic Corporation. (CCX 822 (Samuels, Dep. at 1–40)).

722. There is no evidence that the rate of biodegradation was material to ANS Plastic Corporation when purchasing the ECM additive. (CCX 822 (Samuels, Dep. at 1–40)).

723. There is no evidence that the rate of biodegradation was material to ANS Plastic Corporation's customers when purchasing the ECM amended product from ANS Plastic Corporation. (CCX 822 (Samuels, Dep. at 1–40)).

724. ECM Customers are far more concerned with shelf-life and product durability than the time it takes for the product to fully biodegrade. (RX 132).

725. In fact, customers only request information on the time it takes ECM plastics to fully biodegrade in the context of regulatory compliance inquiries. (RX 132-135).

D. Deposition Testimony Does Not Help Complaint Counsel Meet Its Burden of Proof

726. No direct customer of ECM testified and no customer of ECM testified at the hearing in this case. (Tr. 1–3006).

727. No consumer of any product manufactured with the ECM additive testified at the hearing in this case. (Tr. 1–3006).

728. No consumer relied on any claim made by ECM when making a purchasing decision. (Tr. 1–3006; CCX 0–CCX 1108).

729. No consumer considers the rate of biodegradation to be material to his or her purchasing decision when choosing to buy a product labeled biodegradable as opposed to a similar product not labeled biodegradable. (Tr. 1–3006; CCX 0–CCX 1108).

730. No consumer relied on any rate claim made by ECM when making a purchasing decision. (Tr. 1–3006; CCX 0–CCX 1108).

731. No consumer suffered a legally cognizable injury as a result of any claim made by ECM. (Tr. 1–3006; CCX 0–CCX 1108).

732. No consumer ever knowingly purchased a Plastic containing the ECM additive. (Tr. 1–3006; CCX 0–CCX 1108).

733. No consumer ever purchased a Plastic containing the ECM additive. (Tr. 1–3006; CCX 0–CCX 1108).

734. No consumer ever spent any money on any Plastic containing the ECM additive. (Tr. 1–3006; CCX 0–CCX 1108).

735. ECM never communicated directly with any consumer regarding the biodegradability features of the ECM additive. (Tr. 1–3006; CCX 0–CCX 1108).

736. It is not relevant to consumers how long a biodegradable product takes to fully biodegrade. (Tr. 1–3006; CCX 0–CCX 1108).

737. None of ECM's customers expect ECM amended plastics to completely decompose into elements found in nature within one year of customary disposal. (Sinclair, Tr. 785).

738. No harm occurs to any consumer even if ECM's claims are false. (Tr. 1–3006; CCX 0–CCX 1108).

739. The vast majority of advertisements and products made by ECM and ECM's customers regarding ECM amended plastics do not mention or focus on rates of biodegradation. (RX 00; RX 02; RX 03; RX 14; RX 15; RX 16; RX 17; RX 22; RX

26; RX 28; RX 29; RX 30; RX 315; CCX-30 ; CCX-31; CCX 32; CCX 36; CCX 39; CCX 43; CCX 46; CCX 47; CCX 49; CCX 50; CCX 52; CCX 59; CCX 60; CCX 63' CCX 64; CCX 65; CCX 66; CCX 79; CCX 97; CCX 98; CCX 99; CCX 100; CCX 101; CCX 103;CCX 104; CCX 107; CCX 109–CCX 133; CCX 135; CCX 136; CCX 138; CCX 139; CCX 140; CCX 142–CCX 151).

V. BACKGROUND ON THE ECM ADDITIVE AND PLASTICS PRODUCED WITH THE ECM ADDITIVE

740. ECM sells a "MasterBatch Pellet" that includes a biodegradable component along with an otherwise non-biodegradable (or conventional) plastic carrier resin. (RX 371; RX 656; RX 681).

741. The ECM additive's formula is a trade secret. (Sinclair, Tr. 777).

742. ECM chose not to patent the additive because scientists had convinced them that it could not be reverse-engineered, and it has yet to be. (Sinclair, Tr. 777–78).

743. Analytical laboratories attempted to determine the specific ingredients, but none has identified the correct formula. (Sinclair, Tr. 777–78; RX 563).

744. ECM offers a "load rate" of 70% in its pellets, meaning that every pellet will contain approximately 70% of the "active" biodegradable formula, along with 30% conventional polymer resin. (CCX 818 (Sinclair, Dep. 118–20)).

745. ECM prescribes that plastics manufacturers blend the pellet into their plastics at a 1% rate, resulting in a uniform distribution of the pellet throughout the plastic and at a level that ensures maximum utility without compromising the plastic's integrity. (Sinclair, Tr. 765, 775–76, 783, 787–88, 790; CCX 20; RX 137).

746. Blending of the ECM additive requires no additional equipment from plastics manufacturers so long as the manufacturer is already equipped to blend color additives. (RX 137).

747. Through testing and history of use, ECM has established that a 1% load rating in finished plastics is required to maintain the additive's efficacy vis-à-vis biodegradation. (Sinclair, Tr. 765, 775–76, 783, 787–88, 790; RX 683; CCX 2).

748. For all plastics properly manufactured with ECM's additive, at least 1% of the final plastic will include the ECM additive based on weight. (Sinclair, Tr. 783; RX 678).

749. Like many other plastic additives (e.g., coloring agents), manufacturers introduce the ECM additive into the plastic during the initial blending process. (Sinclair, Tr. 797; RX 135).

750. Plastics are commonly manufactured using one of several techniques, including extrusion molding, injection molding, or blow molding. (Sahu, Tr. 1816–17; RX 656).

751. Extrusion molding involves a heated plastic compound continuously injected through a long die cast in the desired shape. (Sahu, Tr. 1816; RX 783).

752. There are many different types of plastic polymers, but where ECM additives are used, the additive is intended to be mixed uniformly throughout the plastic polymer through a heated blending process, just like a coloring additive. (Sahu, Tr. 1813–14; RX 520).

753. ECM's customers manufacture many plastic polymers, but the bulk of the plastics incorporating ECM's technology consist of polypropylene (PP), polystyrene (PS), and polyethylenes (PE). (RX 458; RX 522).

754. Over seventy (70) percent of ECM plastics are PE plastics. Companies frequently use ECM's technology in plastics such as films (e.g., grocery "t-shirt" bags, packaging cushions, etc.). (RX 520; RX 471; RX 849).

755. In North America, conventional plastics like PE or PP primarily come from domestic natural gas and are substances that contain varying formations of hydrocarbon bonds or polymers. (RX 458).

756. A polymer is simply a molecular structure consisting of a string of similar units bonded together. (RX 458).

757. Prior to a potential customer running product samples, ECM will often discuss the manufacturing process with the customer ahead of time to determine the most cost effective and productive method. (Sinclair, Tr. 762).

758. Manufacturing some plastics with the ECM additive can require more process modifications than others, so ECM works with potential customers to prevent scorching and other manufacturing problems. (Sinclair, Tr. 762).

759. Although the process is involved, most ECM customers can accomplish it quite readily. (Sinclair, Tr. 762).

VI. WHY BIODEGRADATION OF PLASTIC CONTAINING THE ECM ADDITIVE MAY NOT OCCUR

760. There are four primary manufacturing considerations that affect the biodegradability of an ECM plastic. (Sinclair, Tr. 787–790).

761. First, polymers that are manufactured at very high temperatures can run the risk of scorching the ECM additive. (Sinclair, Tr. 788).

762. Second, the ECM additive must remain dry because it is hydroscopic and will absorb atmospheric moisture. (Sinclair, Tr. 789).

763. To prevent this, ECM ships its additive in bags with a moisture barrier liner, but customers must properly store the additive as well. (Sinclair, Tr. 789).

764. Third, uniform and complete distribution of the additive throughout every layer of the plastic is essential to guarantee biodegradability. (Sinclair, Tr. 788).

765. Fourth, the load rate of the additive must be at least one percent (1%) by weight. (Sinclair, Tr. 787–88).

766. The failure to adhere to all four elements compromises the biodegradability of the plastic. (Sinclair, Tr. 790).

VII. CONTRARY TO COMPLAINT COUNSEL'S EXTREMELY NARROW DEFINITION, THE ONLY SCIENTIFICALLY ACCEPTED DEFINITION OF "BIODEGRADABLE" IS BROAD

767. Complaint Counsel requires that any unqualified biodegradable claim regarding any item be supported by competent and reliable scientific evidence "assur[ing] complete decomposition within **one year** and replicat[ing], i.e., simulat[ing], the physical conditions found in landfills, where most trash is disposed." (Complaint, ¶ 4(A)) (emphasis added and subtracted).

768. Complaint Counsel defines a biodegradable item as an "entire item that [will] break down into elements found in nature within one year after customary disposal." (Complaint, P. 9; McCarthy, Tr. 484–85; CCX 891 (McCarthy Rep.)).

769. The FTC's Green Guides "state that marketers should not make unqualified degradable claims for items destined for landfills, incinerators, or recycling facilities because complete decomposition in those specific environments will not occur within one year." (RX 347 § IV).

770. The FTC's Statement of Basis and Purpose make clear that "[t]he final [Green] guides state that an qualified degradable claim for items entering the solid waste stream should be substantiated with competent and reliable scientific evidence that the entire item will fully decompose within one year after customary disposal." (RX 358 § IV(E)(4)).

771. Complaint Counsel asked Dr. McCarthy to assume, and Dr. McCarthy did assume, that "'biodegradable' means that the entire treated plastic will completely break down and return to nature, decompose into elements found in nature, within one year after customary disposal." (McCarthy, Tr. 681).

772. The FTC's Green Guides and the FTC's Statement of Basis and Purpose cite no support in any peer reviewed literature that "degradable" means that a product fully decomposes within one year after customary disposal. (RX347; RX 348).

773. The FTC's Green Guides and the FTC's Statement of Basis and Purpose cite no support in any peer reviewed literature that the definition of "degradable" includes any time limit or time constraint. (RX 347; RX 348).

774. Scientific literature defines the term "biodegradable" as *an on-going process* without any specific time limit: "the chemical dissolution of materials by bacteria or by other biological means." (G. Gnanavel, V.P. Mohana Jeya Vali, and M. Thirumarimurugan, 1:3 International Journal of Pharmaceutical and Chemical Sciences 670, 671 (July–Sept. 2012)).

775. "Biodegradation takes place by the action of enzymes, chemical degradation with living organisms." (G. Gnanavel, V.P. Mohana Jeya Vali, and M. Thirumarimurugan, 1:3 International Journal of Pharmaceutical and Chemical Sciences 670, 671 (July–Sept. 2012)).

776. Biodegradation has been described as a "two step" process. (G. Gnanavel, V.P. Mohana Jeya Vali, and M. Thirumarimurugan, 1:3 International Journal of Pharmaceutical and Chemical Sciences 670, 671 (July–Sept. 2012)).

777. "The first step is the fragmentation of the polymers into lower molecular mass species by means of abiotic reactions, like oxidation, photodegradation or hydrolysis, or biotic reactions, like degradations by microorganisms." (G. Gnanavel, V.P. Mohana Jeya Vali, and M. Thirumarimurugan, 1:3 International Journal of Pharmaceutical and Chemical Sciences 670, 671 (July–Sept. 2012)).

778. The second step is "the bioassimilation of polymer fragments by the microorganisms and their mineralization." (G. Gnanavel, V.P. Mohana Jeya Vali, and M. Thirumarimurugan, 1:3 International Journal of Pharmaceutical and Chemical Sciences 670, 671 (July–Sept. 2012)).

779. Degradation results "from the action of naturally occurring microorganisms such as bacteria, fungi, and algae." (G. Gnanavel, V.P. Mohana Jeya Vali, and M. Thirumarimurugan, 1:3 International Journal of Pharmaceutical and Chemical Sciences 670, 671 (July–Sept. 2012)).

780. The Merriam-Webster dictionary defines "biodegradable" as something "capable of being **slowly** destroyed and broken down into very small parts by natural processes, bacteria, etc." or "capable of being broken down especially into innocuous products by the action of living things (as microorganisms)." (*See* "Biodegradable." *Merriam-*

Webster.com. Merriam-Webster, n.d. Web. 22 July 2014, *available at* http://www.merriam-webster.com/dictionary/biodegradable) (emphasis added).

781. Other sources have defined "biodegradable" to mean "capable of being decomposed by bacteria or other biological means." (*Collins English Dictionary,* 10th Ed. 2009 (July 22, 2014), *available at* http://dictionary.reference.com/browse/biodegradation).

782. Contrary to Complaint Counsel's and the FTC's one year restricted definition of biodegradation, Dr. Tolaymat testified that "[b]iodegradation is the conversion of organic matter through the action of bacteria and fungi into more elementary components or elements." (Tolaymat, Tr. 130).

783. Dr. Tolaymat's definition of biodegradation includes no time limit or time constraint. (Tolaymat, Tr. 130).

784. Dr. Tolaymat's definition of biodegradation—containing no time limit or time constraint—conflicts with Dr. McCarthy's definition in footnote one of McCarthy's report, which requires "that the entire treated plastic will completely break down and return to nature (*i.e.*, decompose into elements found in nature) within one year after customary disposal (*i.e.*, incinerator, landfill, or recycling). (Tolaymat, Tr. 130; CCX 891 (McCarthy, Rep. at 5 n. 1)).

785. Dr. McCarthy has published that "the definition of biodegradable polymer varies greatly among scientists, manufacturers, and consumers." (McCarthy, Tr. 489–490; RX 924).

786. Similarly, Dr. McCarthy testified that "[m]any different definitions [of biodegradation] have officially been adopted, depending on the background of the defining standard organizations and their particular interests." (McCarthy, Tr. 527–528; RX 925).

787. Dr. McCarthy's own writings, outside of this litigation, that define biodegradation do not include the qualifier that an item must completely breakdown within a period of one year. (Sahu, Tr. 1783, 1785).

788. Contrary to Complaint Counsel's and the FTC's time restricted definition of biodegradation, Dr. Michel testified that "Biodegradation is the mineralization of materials as a result of the action of naturally-occurring microorganisms such as bacteria and fungi." (Michel, Tr. 2907–08; CCX 880).

789. Dr. Michel's definition of biodegradation—containing no time limit or time constraint—conflicts with Dr. McCarthy's definition in footnote one of McCarthy's report, which requires "that the entire treated plastic will completely break down and return to nature (*i.e.*, decompose into elements found in nature) within one year after customary disposal (*i.e.*, incinerator, landfill, or recycling). (Michel, Tr. 2907–08; CCX 880; CCX 891 (McCarthy, Rep. at 5 n. 1)).

790. The common scientific definition of biodegradation is degradation by biological means. (Sahu, Tr. 1782).

791. "[B]iodgradation means different things to different researchers … or in different contexts." (Sahu, Tr. 1760).

792. Biodegradation is a process by which microbial organisms sustain their life by eating and metabolizing a material. (Barber, Tr. 2069).

793. "[F]rom a microbiological standpoint [biodegradation] really is [] the conversion of … one substance to another substance as the result of biological activity." (Burnette, Tr. 2375).

794. "[I]n all contexts [biodegradation] simply means the breakdown of whatever is the object of interest using biological means, using essentially biota such as bacteria or fungi or other type of naturally occurring or evolving biota in the environment." (Sahu, Tr. 1760).

795. The ASTM defines biodegradation, as related to plastic products, as the process by which natural biota decompose a plastic product into different chemical materials. (Sinclair, Tr. 782).

796. The ASTM has never defined biodegradation as the test plastic completely breaking down into elements found in nature within one year of customary disposal. (Sinclair, Tr. 782).

797. The plastics industry has never adopted a definition of biodegradation that requires a plastic product to completely decompose and break down into elements found in nature within one year after customary disposal in a landfill. (Sinclair, Tr. 782–83).

798. The scientific literature defining biodegradation does not contain a time restraint. (Sahu, Tr. 1783).

799. No peer reviewed literature defines "biodegradation" to be limited to a "complete breakdown of plastics into elements found in nature within one year after customary disposal." (Barlaz, Tr. 2281).

800. No scientist has published a peer reviewed article defining biodegradation to be limited to the "complete breakdown of a plastic or material into elements found in nature within one year after customary disposal." (Burnette, Tr. 2376).

801. Dr. Tolaymat understands that anaerobic biodegradation occurs at a slower rate than aerobic biodegradation. (Tolaymat, Tr. 130).

802. According to Dr. Tolaymat, "[a]erobic biodegradation is the process of decomposing organic matter in the presence of oxygen." (Tolaymat, Tr. 127).

803. According to Dr. Tolaymat, "[a]naerobic biodegrading is the process of decomposing organic matter without the presence of oxygen." (Tolaymat, Tr. 130).

804. Even the most easily biodegradable substances, such as food waste, will not biodegrade in a MSW landfill within one year after customary disposal. (RX 853 (Barlaz, Rep. at 11); CCX 893 (Tolaymat, Rep. at 16)).

805. Not even tree trunks, orange peels, or banana peels, all generally accepted to be biodegradable in the environment, can reliably break down into elements found in nature within one year after customary disposal. (McCarthy, Tr. 503, 506, 508–09, RX 841 (McCarthy, Dep. at 187)).

806. Outside of this litigation, Drs. McCarthy, Tolaymat, and Michel have never defined biodegradation to be the complete breakdown of an item into elements found in nature within one year after customary disposal. (Michel, Tr. 2908; McCarthy, Tr. 488; *see generally* Tolaymat, Tr.).

807. There is no evidence that, outside the context of this litigation, any one of Drs. McCarthy, Tolaymat, and Michel have ever defined biodegradable to be limited by any time or rate restriction. (*See generally* McCarthy, Tr; Tolaymat, Tr; Michel, Tr.).

808. Biodegradability is a process. (Barber, Tr. 2069).

809. Whether a material is "biodegradable" means whether biological organisms, microbial organisms, can sustain their life functions and eat and metabolize the material. (Barber, Tr. 2069).

810. Some standards have been put in place by various organizations that attempt to define a time span for this process, but biodegradation is not subject to a time span limitation because it is an ongoing process. (Barber, Tr. 2069).

811. The ASTM definition of "degradable plastics" is a plastic that will break down into different chemical materials. (Sinclair, Tr. 782).

812. The ASTM definition of "biodegradable plastics" is a plastic which breaks down by natural biota. (Sinclair, Tr. 782).

813. The ASTM definition of "biodegradation" contains no requirement that the test plastic completely break down into elements found in nature within one year of customary disposal. (Sinclair, Tr. 782).

814. The biodegradable plastics industry has never adopted a definition of "biodegradation" that the test plastic completely break down into elements found in nature within one year of customary disposal. (Sinclair, Tr. 782–83).

815. In 16 CFR § 260.8(c), codifying FTC guidance language, FTC prevents marketers from marketing their products as degradable "if the items do not completely decompose within one year after customary disposal." (RX 347).

816. In 16 CFR 260.7(b), codifying FTC guidance language, FTC allows marketers to market their products as compostable if the marketer has "competent and reliable scientific evidence that all the materials in the item will break down into, or otherwise become part of usable compost in a safe and timely manner in an appropriate composting facility, or in a home compost pile or device." (RX 347).

817. Thus, the definition of biodegradable includes a year time limit and a complete degradation component, while the definition of compostable includes no time limit. (RX 347).

A. THE GREEN GUIDES' DEFINITION OF BIODEGRADABLE IS INAPPOSITE IN THIS CASE

A. Both Dr. Stewart and Dr. Frederick Agree that the APCO and Synovate Surveys are Flawed and Insufficient to Support the One Year Rule

818. Complaint Counsel and FTC's definition of biodegradation as requiring the complete decomposition of a material into elements found in nature within one year after customary disposal is referenced in an agency guidance in the Green Guides and in the Green Guides' Statement of Basis and Purpose. (RX 347; RX 348).

819. The Green Guides state that "[i]t is deceptive to make an unqualified degradable claim for items entering the solid waste stream if the items do not completely decompose within one year after customary disposal." (RX 347, at § 260.8).

820. The FTC Commission cites two consumer perception surveys to support the one year rule. (RX 347, at § IV(E)(4)(A)).

821. These were the only two consumer perception surveys available to the FTC regarding consumer perception of biodegradability at the time the FTC issued its guidance definition of biodegradable to mean that the product must completely decompose into elements found in nature within one year after customary disposal. (Stewart, Tr. 2511).

822. The first survey cited by the Commission is a survey done by APCO Insight, wherein 60 percent of respondents purportedly expected that an item marked as degradable without qualification will fully decompose in less than one year. (RX 347, at § IV(E)(4)(A)).

823. The second survey cited by the Commission in drafting the one year rule was conducted by Synovate, wherein 25 percent of respondents expected that an item marked as degradable without qualification will fully decompose in less than one year. (RX 347, at § IV(E)(4)(A)).

824. The APCO survey found that:

- "Americans are slightly more likely to say the terms biodegradable and compostable mean something different rather than the same."
- 48% of those surveyed thought that the terms meant something different, while 40% thought they meant the same.
- The leading perceived similarity between both terms was that both decompose and are not harmful to the environment.
- Those surveyed believed that compostable materials will break down in three months to a year, while biodegradable materials are expected to break down in one to two years.
- Most adults believe that compostable materials are natural (leaves, trigs, etc.) while biodegradable materials are manmade (synthetics).
- Most adults believe that biodegradable materials will completely disappear whereas compostable materials turn into soil or fertilizer.
- Both compostable and biodegradable packaging "are seen as likely to reduce landfill burdens, pollution, and even the amount of litter in the environment."
- Americans are uneducated about both compostable material and biodegradable material, and an education component associated with the rollout of the packaging is needed.
- Educated individuals (college graduates) are more understanding of longer natural decomposition times.

(RX 596).

825. The Synovate study found that:

- "Of all the venues in which respondents were asked where products labeled biodegradable would decompose, 'landfills' received the highest score (72%) followed by 'open environment' (51%) and 'commercial composting' (51%)."
- 23% of respondents attributed the difference between biodegradation in landfills and biodegradation in composting environments to "duration of degradation."
- "Of those who mentioned factors related to the duration of degradation, the majority said landfills take longer to biodegrade."

- 72% of respondents believe that traditional plastics will not biodegrade on their own.

- 84% of respondents believe biodegradable plastic products will be beneficial to landfills.

- 25% of respondents believed plastics should biodegrade in less than one year.

- 70% of respondents believed that a biodegradation window of 5 years or less for plastics was appropriate.

- 93% of respondents believe it is ok to label a package "biodegradable" if it decomposes in a landfill.

- 38% of respondents claimed they often or always check for green aspects on a product label.

- 62% of respondents stated they are willing to pay a higher price for products that are less burdensome on the environment.

(RX 673).

826. Both Dr. Stewart and Dr. Frederick believe the APCO and Synovate studies are flawed. (Frederick, Tr. 1045, 1049-51; Stewart, Tr. 2513–17; RX 856 (Stewart Rep. at 5-9)).

827. A close ended question is one in which "there was a list of possible responses that were presented to the respondent, and the respondent needed to choose from one of the responses that was presented in order to give an answer." (Stewart, Tr. 2513).

828. As part of his work in this case, Complaint Counsel's survey expert Dr. Frederick reviewed both the APCO and Synovate surveys. (Frederick, Tr. 1036).

829. APCO stands for American Plastics Council. (Frederick, Tr. 1036).

830. The APCO survey was a telephone survey with 1003 responses. (Frederick, Tr. 1036).

831. According to Dr. Frederick, the validity of a survey refers to how accurately the survey measured what it intended to measure. (Frederick, Tr. 1042; CCX 890 (Frederick, Rep. at 8)).

832. According to Dr. Frederick's testimony, the APCO is not valid; however, in his expert report, Dr. Frederick concludes that the APCO survey is valid. (Frederick, Tr. 1042; CCX 890 (Frederick, Rep. at 8-9)).

833. Question four of the APCO study asked respondents "[i]f a package is labeled 'biodegradable,' what should be the maximum amount of time that it should take for that package to decompose?" (RX 597, P. 2).

834. Question four of the APCO survey was closed-ended. (RX 597, at P. 2).

835. Question four of the APCO survey provided respondents with 6 substantive answer options: "One month or less," "Three months," "six months," "one year," "two to four years," "Five years or more." (RX 597, at P. 2).

836. According to Dr. Frederick, the biggest problem with question four of the APCO survey "is the allocation of response options." (Frederick, Tr. 1045).

837. According to Dr. Frederick, the response options in question four of the APCO survey, with four of the six response options being one year or less, carry the "strong suggestion that the experimenter expects these are the responses that people are going to give ... causing people to give those responses in greater numbers than they would if the question used a different design." (Frederick, Tr. 1045).

838. Another problem with APCO Survey Question four, according to Dr. Frederick, is that it used the word "should" instead of "would." (Frederick, Tr. 1142).

839. According to Dr. Frederick, the Synovate study is reliable but invalid. (Frederick, Tr. 1048–51).

840. Question 19 of the Synovate survey asked respondents, "[w]hat do you believe is a reasonable amount of time for a biodegradable plastic package to decompose in a landfill?" (Frederick, Tr. 1048).

841. According to Dr. Frederick, Synovate survey question 19 uses the word "reasonable," meaning that the interviewer is asking the respondent what he or she "would like to happen, what kind of product should be produced." (Frederick, Tr. 1050).

842. Another flaw, according to Dr. Frederick, in Synovate survey question 19 is that it is a close ended question. (Frederick, Tr. 1049–1051, 1276–77, 1280).

843. According to Dr. Frederick, it happens "a fair bit" that a survey is reliable but not valid. (Frederick, Tr. 1041).

844. According to Dr. Frederick, a close ended question asking respondents to define "love" cannot afford the respondents the full opportunity to explain what they understand love to mean. (Frederick, Tr. 1273).

845. According to Dr. Frederick, it is difficult for a person to offer a response to a question when that person does not understand a verb in the question being asked, for example, when the respondent does not understand "biodegradable," in the question "how much time will it take to biodegrade." (Frederick, Tr., 1276).

846. Dr. Frederick faults both the APCO and Synovate surveys for having closed-ended rather than open-ended questions. (Frederick, Tr. 1280).

847. Dr. Stewart reviewed both the APCO and Synovate surveys. (Stewart, Tr. 2512).

848. The use of close ended questions in the APCO survey was premature given the state of knowledge of consumers' understanding of biodegradability. (Stewart, Tr. 2513-14).

849. To use closed-ended questions in a meaningful way requires a deep understanding of all the potential responses that an individual might give. (Stewart, Tr. 2513).

850. The response options to APCO survey question four were not balanced. (Stewart, Tr. 2513).

851. Two-thirds of the options that were offered to respondents in APCO question four were one year or less, which predisposes people to select a shorter time frame rather than a longer time frame. (Stewart, Tr. 2513).

852. The APCO survey, with respect to the question of how long would it take for something to biodegrade, is not valid. (Stewart, Tr. 2514).

853. The APCO survey is invalid because it does not provide adequate opportunity for consumers to offer their perceptions of how long it would take for something to biodegrade. (Stewart, Tr. 2514).

854. APCO survey question four is inherently biased because it offers many more opportunities to select an answer that reflects one year or less than a longer time period. (Stewart, Tr. 2514–15).

855. Conclusions about people's perceptions of the length of time that biodegradation should require cannot be drawn from the APCO survey. (Stewart, Tr. 2515).

856. The Synovate survey is flawed because it uses closed-ended questions when asking about the length of time that biodegradation should occur. (Stewart, Tr. 2515).

857. Given the current understanding and state of knowledge with respect to consumer perception of biodegradation, open-ended questions are "much more suitable, much more appropriate, much more informative, than closed-ended questions." (Stewart, Tr. 2516).

858. Numerous problems arise when using closed-ended questions to determine the percentage of the population that share the same beliefs. (Stewart, Tr. 2516–17).

859. One problem with using closed-ended questions is that the limited possible answer choices will preclude respondents from giving an accurate answer that reflects their real perceptions. (Stewart, Tr. 2517).

860. One reason surveyors need to do more work involving open-ended questions and interviews early in the exploration of a topic like biodegradation is so that surveyors can be sure that when they do finally do design close-ended questions, that they have given people the full array of response options. (Stewart, Tr. 2517).

861. "'[M]isleading homogeneity' is simply a situation in which one characterizes a sample or a population as being more alike, more similar, more homogenous than is actually the case." (Stewart, Tr. 2518).

862. One good example of misleading homogeneity is that in the 1950s it looked like Americans were very homogenous with respect to their preferences for media; however that false appearance of homogeneity, i.e. misleading homogeneity, occurred only because Americans had only three channels to choose from when watching television. (Stewart, Tr. 2518–19).

863. APCO survey question four created a sense of far greater homogeneity than actually exists. (Stewart, Tr. 2519).

864. Misleading homogeneity also exists in the Synovate survey. (Stewart, Tr. 2520).

865. Both the APCO and Synovate surveys have "serious limitations." (Stewart, Tr. 2593).

866. The Green Guides criticize the APCO and Synovate surveys in a manner similar to Dr. Stewart. (Stewart, Tr. 2593–94).

867. The APCO study uses close-ended questions, which are unhelpful and misleading when there are many possible answers among respondents. (Stewart, Tr. 2512–13; RX 856 (Stewart Rep. at 7); RX-858 (Frederick, Dep. at 35–36, 165)).

868. When beginning consumer perception work in a new area, open-ended questions are essential. (Stewart, Tr. 2509–10, 2516–18; RX 856 (Stewart, Rep. at 7)).

869. Close-ended questions inherently suggest greater homogeneity within a sample of respondents than may actually exist because close-ended questions exist in a universe with only four or five possible responses. (Stewart, Tr. 2516–17; RX 856 (Stewart, Rep. at 7))

870. An example of misleading homogeneity is found in the APCO survey question regarding how long it should take for something to decompose if it is labeled biodegradable. (Stewart, Tr. 2514, 2519; RX 856 (Stewart, Rep. at 7)).

871. In question four of the APCO survey, four of the six response options are a year or less, and Drs. Frederick and Stewart concluded that it is not surprising that 60% of the respondents selected an answer of one year or less. (Frederick, Tr. 1045; RX 856 (Stewart, Rep. at 7–8)).

872. In fact, a random selection of answers by respondents to question four of the APCO survey would yield 66% of responses within the "year or less" category. (RX 856 (Stewart, Rep. at 7–8); RX-597, at 2).

873. Dr. Frederick disagrees with the statement in the FTC's Green Guides Statement of Basis and Purpose that "[t]he Synovate study results suggest that respondents' answers may have been not only biased but also influenced by a tendency to avoid extreme answers." (RX 348 at IV(E)(4)(a); RX-858 (Frederick, Dep. at 155–56)).

874. Dr. Frederick disagrees with the statement in the FTC's Green Guides Statement of Basis and Purpose that "[r]eliable real word conclusions cannot be drawn from the Synovate study." (RX 348 at IV(E)(4)(a); RX-858 (Frederick, Dep. at 157–58)).

875. Dr. Frederick has criticisms for both the APCO and Synovate surveys. (Frederick, Tr. 1270).

876. Dr. Frederick believes that the APCO study has the potential to introduce bias because of the way in which response options were presented and because of the use of the word "should." (Frederick, Tr. 1270).

877. Dr. Stewart and Dr. Frederick both agree that the APCO survey is flawed with respect to the response options provided to respondents. (Stewart, Tr. 2618).

B. Complaint Counsel's Survey is Incompetent and Unreliable, and Should be Disregarded

878. Dr. Frederick is not an expert in the standards that apply to the evaluation of survey evidence in federal administrative proceedings. (Frederick, Tr. 1185).

879. Dr. Frederick is not familiar with the standards used to determine qualifications of survey experts to testify in federal court. (Frederick, Tr. 1185).

880. Dr. Frederick is not familiar with the standards that are used to determine the qualifications of survey evidence in proceedings before the Federal Trade Commission. (Frederick, Tr. 1185)

881. Dr. Frederick is not familiar with the Reference Manual on Scientific Evidence, Third Edition. (Frederick, Tr. 1187).

882. Dr. Frederick is not familiar with the Manual on Complex Litigation, Fourth Edition. (Frederick, Tr. 1187).

883. Dr. Frederick knows of no specific criteria that are required to be present in a survey in order for a survey to be valid. (Frederick, Tr. 1190).

884. Dr. Frederick is not familiar with the concept of "disruptive questioning." (Frederick, Tr. 1190).

885. Complaint Counsel drafted sections of Dr. Frederick's expert report. (Frederick, Tr. 1191–92).

886. Dr. Frederick did not draft the table of contents to his expert report. (Frederick, Tr. 1191).

887. Dr. Frederick did not draft paragraphs 6, 7, 9, 10, 12 and part of paragraph 13 of his expert report. (Frederick, Tr. 1194–95).

888. Dr. Frederick believes that Complaint Counsel drafted the table of contents, and paragraphs 6, 7, 9, 10, and 12 and part of paragraph 13 of his expert report. (Frederick, Tr. 1194–95).

889. Complaint Counsel drafted three of the four references on page seven of Dr. Frederick's expert report, namely the Google Consumer Surveys Product Overview reference, the Google Incorporated, et al. reference, and the Nate Silver reference. (Frederick, Tr. 1195).

890. Dr. Frederick did not draft footnotes two and three on page seven of his expert report. (Frederick, Tr. 1196).

891. Dr. Frederick did not draft footnote 6 on page 11 of his expert report. (Frederick, Tr. 1196).

892. Dr. Frederick did not draft, and Complaint Counsel drafted footnotes 8 and 10 and the parenthetical which reads "besting better-known rivals such as Gallup, CNN, and Rasmussen," on page 12 of Dr. Frederick's expert report. (Frederick, Tr. 1196).

893. Complaint Counsel also drafted the reference to Nate Silver's blog on page 12 of Dr. Frederick's expert report. (Frederick, Tr. 1196).

894. Before seeing the draft of his expert report after Complaint Counsel revised it, Dr. Frederick was not aware of any of the content that Complaint Counsel added to his expert report. (Frederick, Tr. 1195–96).

895. The only surveys Dr. Frederick conducted in this proceeding were Google Consumer Surveys. (Frederick, Tr. 1196).

896. Dr. Frederick knew of but failed to perform an internet panel survey for this proceeding. (Frederick, Tr. 1197).

897. Dr. Frederick knew of but failed to perform an in person interview for this proceeding. (Frederick, Tr. 1197).

898. Dr. Frederick knew of but failed to perform an e-mail survey for this proceeding. (Frederick, Tr. 1197).

899. The FTC paid Dr. Frederick a flat fee of $40,000 to be a witness in this case. (Frederick, Tr. 1201).

900. The less Dr. Frederick had to pay for a survey, on assistants, and on costs, the more money he would net as pay for his work in this case. (Frederick, Tr. 1201).

901. In total, Dr. Frederick's Google Consumer Surveys cost an estimated $2,000.00. (Frederick, Tr. 1203).

902. Of the $40,000.00 the FTC paid to Dr. Frederick, Dr. Frederick profited approximately $32,010.00. (Frederick, Tr. 1203).

903. Two important reasons why Dr. Frederick chose to use Google Consumer Surveys for his work in this case as opposed to other survey methodologies are because of the low costs of conducting a Google Consumer Survey and because of his familiarity with Google Consumer Survey. (Frederick, Tr. 1206).

904. The purpose of Dr. Frederick's Google Consumer Survey was an effort to demonstrate that despite its flaws, the APCO survey produced valid and reliable results. (Stewart, Tr. 2616; RX 856 (Stewart, Rep at 8 n. 4)).

905. The purpose of Dr. Frederick's Google Consumer Survey was not intended to be an objective analysis of what people believe about biodegradability. (Stewart, Tr. 2616; RX 856 (Stewart, Rep at 8 n. 4)).

906. Dr. Frederick conducted survey research for this litigation using Google Consumer Surveys. (Frederick, Tr. 1060).

907. No single person was ever presented with more than one question in Dr. Frederick's Google Consumer Surveys. (Frederick, Tr. 1224).

908. Dr. Frederick's Google Consumer Surveys did not contain any screening questions. (Frederick, Tr. 1224–25).

909. Dr. Frederick could have, but did not ask any questions to help eliminate those respondents who may have been completely ignorant of the subject of plastics biodegradation or entirely uninterested in participating in his Google Consumer Surveys. (Frederick, Tr. 1227–28).

910. Dr. Frederick did not provide to any of the respondents any definitions of terms in his Google Consumer Survey questions. (Frederick, Tr. 1228).

911. The survey research Dr. Frederick performed for this litigation cannot be characterized as a survey. (Stewart, Tr. 2596).

912. Dr. Frederick's Google Consumer Surveys do not meet the typical definitions of a survey as would be used in the marketing and survey profession. (Stewart, Tr. 2596).

913. Dr. Frederick did not follow the principles for survey research explained in the Manual for Complex Litigation, Fourth Edition in conducting his Google Consumer Surveys. (Stewart, Tr. 2596–97).

914. Dr. Frederick did not follow the Standards for Scientific Evidence, Third Edition in conducting his Google Consumer Surveys. (Stewart, Tr. 2597).

915. Dr. Frederick's Google Consumer Survey does not meet generally accepted standards for survey research. (Stewart, Tr. 2598; RX 856 (Stewart, Rep. at 10)).

916. There are seven characteristics of acceptable survey research: 1) the population was properly chosen and defined; 2) the sample chosen was representative of that population 3) the data gathered were accurately reported; 4) the data were analyzed in accordance with accepted statistical principles; 5) the questions asked were clear and not leading; 6) the survey was conducted by qualified persons following proper interview procedures; and 7) the process was conducted so as to ensure objectivity (the study was double blind). (Stewart, Tr. 2599; RX 856 (Stewart, Rep. at 10)).

917. Dr. Frederick's Google Consumer Survey fails to satisfy most of the seven characteristics of acceptable survey research. (Stewart, Tr. 2599-2604).

918. Dr. Frederick's Google Consumer Survey failed to properly choose and define a population because it is not clear what the population was that he was analyzing; while it appears to be some subset of the American population, it's not defined by an age and there is no lower bound. (Stewart, Tr. 2600).

919. Dr. Frederick's Google Consumer Survey is defined in terms of who participated in the survey, which is not an appropriate way to define a population. (Stewart, Tr. 2600).

920. Dr. Frederick collected no demographic information from his respondents. (Stewart, Tr. 2600).

921. Dr. Frederick's Google Consumer Survey failed to implement a sample that was representative of the population. (Stewart, Tr. 2600).

922. There is no way to know whether Dr. Frederick's population was representative or not. (Stewart, Tr. 2600).

923. Dr. Frederick failed to gather and accurately report the data obtained in his Google Consumer Survey. (Stewart, Tr. 2601).

924. Dr. Frederick ignored some data because some respondents did not offer the time frames he was looking for. (Stewart, Tr. 2601).

925. Dr. Frederick's questions provided no opportunity for respondents to qualify their answers. (Stewart, Tr. 2601).

926. Ignoring some data is the same as not reporting it accurately. (Stewart, Tr. 2601).

927. Dr. Frederick failed to analyze the data in accordance with accepted statistical principles. (Stewart, Tr. 2601–02).

928. By ignoring significant portions of the data obtained in his Google Consumer Surveys, Dr. Frederick is misrepresenting the data. (Stewart, Tr. 2602).

929. It is not appropriate for a researcher not to code a response because that response does not fit into a desirable structure. (Stewart, Tr. 2602).

930. Dr. Frederick provided no evidence or testimony that consumer's thought that it was important for a product to be labeled "biodegradable." (Frederick, Tr. 1025–1424; CCX 860 (Frederick, Rep.); CCX 865 (Frederick Rebuttal Rep.)).

931. Dr. Frederick provided no evidence or testimony that the term "biodegradable" was material to any consumer's purchasing decision. (Frederick, Tr. 1025–1424; CCX 860 (Frederick, Rep.); CCX 865 (Frederick Rebuttal Rep.)).

932. Dr. Frederick provided no evidence or testimony that any consumer relied on any representation made by ECM. (Frederick, Tr. 1025–1424; CCX 860 (Frederick, Rep.); CCX 865 (Frederick Rebuttal Rep.)).

933. In order to be valid, a survey must report all of the data and statistics. (Stewart, Tr. 2602).

934. The questions in Dr. Frederick's Google Consumer Surveys were not clear and were misleading. (Stewart, Tr. 2602).

935. For individuals who have no understanding of the general meaning of biodegradability, it is not clear what questions asking about biodegradability would mean to those individuals. (Stewart, Tr. 2602–03).

936. Proper interview procedures as understood in generally accepted standards of survey research were not followed in Dr. Frederick's Google Consumer Surveys. (Stewart, Tr. 2603).

937. Dr. Frederick's Google Consumer Surveys involved Dr. Frederick, a researcher knowledgeable of the desire for a particular outcome, being very active in the data collection and coding of the research. (Stewart, Tr. 2603).

938. Andrew Meyer is Dr. Frederick's graduate student. (Frederick, Tr. 1284, 1316).

939. The process of Dr. Frederick's Google Consumer Survey was not conducted so as to ensure objectivity. (Stewart, Tr. 2603).

940. Dr. Frederick and Mr. Meyer coded nearly all of the responses to the Google Consumer Survey questions. (Stewart, Tr. 2604; Frederick, Tr 1285).

941. Dr. Frederick's coding process was not double-blinded; the people involved in the actual coding were not blind. (Stewart, Tr. 2604).

942. Dr. Frederick and Mr. Meyer were aware of the sponsor of the research, the purpose of the research, and understood what was sought as a result of the research. (Stewart, 2604; Frederick, Tr. 1285)

943. Dr. Frederick's Google Consumer Survey is not reliable and is not valid. (Stewart, Tr. 2604).

944. Dr. Frederick's Google Consumer Survey results cannot be relied upon. (Stewart, Tr. 2604).

945. No conclusions can be drawn from Dr. Frederick's Google Consumer Surveys. (Stewart, Tr. 2604).

946. It is very difficult to draw any inferences about the validity of research based on an answer to a single question, particularly when the researcher does not know anything about that particular respondent. (Stewart, Tr. 2605).

947. When there is only one question asked of a respondent, a researcher cannot know what the response indicates, whether it is a sincere response, whether it is a response that would be subject to qualification if there were a follow-up question. (Stewart, Tr. 2605).

948. When there is only one question asked of a respondent, a researcher cannot know what that response means. (Stewart, Tr. 2605–06).

949. A researcher cannot address the question of what a consumer's perception of "biodegradable" is with a single question. (Stewart, Tr. 2606).

950. In order to obtain nuances, dependencies, and contextual effects of a consumer's belief of what "biodegradable" means, a researcher must ask follow up questions. (Stewart, Tr. 2606).

951. Dr. Frederick's used a strictly numerical approach in his Google Consumer Surveys. (Stewart, Tr. 2606).

952. A strictly numerical approach is objectionable, particularly in the absence of other information, because it narrowly limits the ability of respondents to express their full opinions. (Stewart, Tr. 2606–07).

953. By restricting responses to a particular type of response, a researcher by definition creates greater homogeneity than would be the case if the researcher allowed

respondents more latitude in terms of how they answer the question. (Stewart, Tr. 2607).

954. Dr. Frederick's sampling methods were haphazard and inconsistent. (Stewart, Tr. 2607–08; RX 856 (Stewart, Rep. at 11).

955. As a result of Dr. Frederick's population being poorly defined and the inability to know the characteristics of people who may show up at the particular website where Dr. Frederick's survey questions were posted, there is no way to develop an assessment of whether or not the respondents to Dr. Frederick's Google Consumer Survey were appropriate, interested, or even willing to give sincere responses. (Stewart, Tr. 2608).

956. Many of the responses given to Dr. Frederick's Google Consumer Survey were nonsensical and inappropriate to the question asked. (Stewart, Tr. 2608).

957. The GreenBook Blog is a publication that is well-known in the practicing market research community and well-read researchers. (Stewart, Tr. 2611).

958. Disinterest bias refers to the fact that if people are uninterested in a survey, if they are disengaged, or, even worse, if the survey serves as an interruption for an activity that they are more interested in than the survey, that those people will be likely to give insincere, random, and often nonsensical response to simply get past what is essentially an interruption in what they were doing before being confronted by the survey. (Stewart, Tr. 2609, 2612).

959. "Editing," in the survey research context, refers to a process whereby one or more neutral individuals will go through data and identify nonsensical, nonresponsive types and eliminate those. (Stewart, Tr. 2613).

960. The editing process is very important and needs to be carried out by someone who is not knowledgeable of the purpose of the research. (Stewart, Tr. 2613).

961. Dr. Frederick failed to appropriately use the editing process in his Google Consumer Surveys. (Stewart, Tr. 2616).

962. Dr. Frederick inappropriately used the editing process to edit out responses which did not fit his prior notion of the structure that acceptable answers should fit. (Stewart, Tr. 2616).

963. Dr. Frederick inappropriately used the editing process to push the responses in a direction consistent with what he was looking for as opposed to an honest reporting of the responses of the participants in the survey. (Stewart, Tr. 2616).

964. The design of Dr. Frederick's Google Consumer Surveys prevents anyone from making any conclusions about the source of the respondents' false beliefs. (Stewart, Tr. 2616–17).

965. There is no evidence in or from Dr. Frederick's Google Consumer Surveys that ECM caused any false belief in any respondent. (Stewart, Tr. 2617).

966. Dr. Stewart's survey produced very different results than Dr. Frederick's Google Consumer Survey. (Stewart, Tr. 2617).

967. Two surveys that are both flawed that produce similar results are still flawed. (Stewart, Tr. 2620).

968. The fact that two flawed surveys might reflect something similar may simply reflect the fact that they share the same flaw. (Stewart, Tr. 2620).

969. Regardless of how many flawed surveys produce similar results, the surveys remain flawed. (Stewart, Tr. 2620).

970. When numerous flawed surveys produce similar outcomes, the similarity of outcomes may simply be a reflection of the fact that the flawed surveys share the same flaw. (Stewart, Tr. 2620).

971. Dr. Frederick adopted a rule in coding his responses that held that any response with a number and a unit was counted, whether valid or not. (Stewart, Tr. 2613).

972. Dr. Frederick did not code response to his Google Consumer Survey questions that suggest that the respondent did not know the answer. (Stewart, Tr. 2613; RX 856 (Stewart, Rep. at 12)).

973. The implications of Dr. Fredrick failing to code response wherein respondents are suggesting that they do not know the answer are 1) that no one can know how many people who gave a response that Dr. Frederick coded might have actually not known an answer, but gave a response he or she thought valid to get through the survey wall; and 2) that to the extent that "don't know" is a perfectly reasonable response, the researcher needs to include those individuals who do not know into the total sample—the "don't know" responses cannot be ignored simply because they did not give the type of answer the researcher wanted. (Stewart, Tr. 2614).

974. The coding in Dr. Frederick's Google Consumer Surveys was not double blind. (Stewart, Tr. 2615).

975. In Dr. Frederick's Google Consumer Surveys, the people doing the vast majority of the coding were fully aware of what was being sought from the survey. (Stewart, Tr. 2615; Frederick, Tr. 1285).

976. Dr. Frederick's coding of his Google Consumer Surveys lacked objectivity because the coding ignored certain responses that did not fit into the form of answer that Dr. Frederick desired. (Stewart, Tr. 2615; Frederick, Tr. 1128).

977. The results of Dr. Frederick's coding demonstrate that there was a clear desire to push the responses in a particular direction. (Stewart, Tr. 2615).

978. The coding in Dr. Frederick's Google Consumer Surveys lacked objectivity. (Stewart, Tr. 2615).

979. Using Google Consumer Surveys, Dr. Frederick asked a single question to nearly 29,000 individual respondents. (Frederick, Tr. 1060, 1207, 1223).

980. When Judge Chappell asked Dr. Frederick "did I understand you to say that anyone who responds to the Google survey, each person only gets one question?" Dr. Frederick replied "in my survey, any single respondent only received one question." (Frederick, Tr. 1217)

981. When Judge Chappell then clarified, "so one person may say how long does it take for a product to biodegrade, and that same person is not asked how long does it take for a product to biodegrade." Dr. Frederick answered "that's absolutely correct." (Frederick, Tr. 1217).

982. Dr. Frederick is not familiar with anonymous browsing features. (Frederick, Tr. 1088).

983. Dr. Frederick does not know what Google does with a respondent to a Google Consumer Survey question that, for example, goes to a proxy server or uses any of the new anonymous surfing features on most late editions of web browsers. (Frederick, Tr. 1088–89).

984. Dr. Frederick does not know what Google does if a respondent uses some type of cloaking or anonymous technology before responding to a Google Consumer Survey question. (Frederick, Tr. 1088).

985. Dr. Frederick does not know what proxy servers are. (Frederick, Tr. 1088).

986. Google, and not Dr. Frederick, chooses the websites on which to present the surveys.

987. The Federal Trade Commission has never relied upon a Google Consumer Survey as the basis for its decision in administrative case. (Frederick, Tr. 1191).

988. A person engaged in an online search for specific content can suddenly be presented with an unanticipated popup or a survey wall that contains a single survey question, or multiple survey questions from Google Consumer Surveys. (Frederick, Tr. 1207).

989. Dr. Frederick does not know which websites featured his survey questions. (Frederick, Tr. 1208).

990. Dr. Frederick does not know the specific sites on which any particular respondent encountered his Google Consumer Survey questions. (Frederick, Tr. 1209).

991. When a person using the internet encounters a Google Consumer Survey question after clicking a link, that person gets some of the content from that link, but the rest of

the content is redacted unless and until that person either completes the Google Consumer Survey question or pays money for the content. (Frederick, Tr. 1212).

992. Dr. Frederick did not choose the number of websites on which his questions were posted. (Frederick, Tr. 1213).

993. Google limits the number of characters in a survey question to a set figure. (Frederick, Tr. 1214–15).

994. In three separate instances Dr. Frederick had to revise questions he wanted to ask survey respondents because his proposed questions contained too many characters according to Google. (Frederick, Tr. 1215).

995. Dr. Frederick used four types of questions in his surveys: open-ended questions, binary questions, multichotomous questions, and hybrid questions. (Frederick, Tr. 1215–16).

996. In an open-ended question a respondent can type in whatever he or she wants. (Frederick, Tr. 1215–16).

997. In a binary question, the respondent can click either the button yes or the button no. (Frederick, Tr. 1516).

998. In a multichotomous question, the respondent can choose one of five answers.

999. In a hybrid question, respondents were restricted to providing a numeric answer. (Frederick, Tr. 1216).

1000. For the binary and multichotomous questions, Dr. Frederick does not know whether any answers given by respondents were valid. (Frederick, Tr. 1220).

1001. In the binary and multichotomous questions, Dr. Frederick believes that some respondents were actually just clicking buttons at random in order to get through the survey. (Frederick, Tr. 1220).

1002. Dr. Frederick did not ask any questions of respondents in his Google Consumer Surveys to determine if the respondents understood the meaning of any of the terms in the questions. (Frederick, Tr. 1228).

1003. Dr. Frederick did not ask any questions in his Google Consumer Surveys to prevent those who lack knowledge of, or an interest in, the subject matter of plastic biodegradation from participating in his surveys. (Frederick, Tr. 1228).

1004. Google provides only indirect circumstantial evidence or information on Google Consumer Survey's respondents' demographics. (Frederick, Tr. 1229).

1005. Google uses a respondent's cookies or web site visitation information to infer a respondent's gender and age, and these inferences can be wrong. (Frederick, Tr. 1229).

1006. According to Dr. Frederick, "there are several reasons why it would be difficult for Google to make, you know, a really accurate imputation of various demographic characteristics. (Frederick, Tr. 1230).

1007. Dr. Frederick, could have, but chose not to, ask any two part questions in his surveys where the first question obtains direct information on the respondent's demographics. (Frederick, Tr. 1231).

1008. Dr. Frederick is confused as to who the relevant population was for his survey, whether it is "any adult that would buy a plastic product" or "any person who would buy a plastic product." (Frederick, Tr. 1232).

1009. Dr. Frederick has no way of knowing whether someone who would not buy a plastic product participated in his Google Consumer Surveys. (Frederick, Tr. 1235–36).

1010. Regardless of how Dr. Frederick wanted to define his survey population, Google defined it for him as the "general population in the United States on Google Consumer Surveys Publisher Network." (Frederick, Tr. 1238–39).

1011. People who are not adults may have responded to Dr. Frederick's survey. (Frederick, Tr. 1239).

1012. An IP address of a survey respondent can only tell Google the location, but not the age, nationality, or gender of the person who is actually answered the survey question. (Frederick, Tr. 1239).

1013. Google, and by extension Dr. Frederick, cannot know who is answering any given Google Consumer Survey question. (Frederick, Tr. 1239).

1014. Google Consumer Surveys provides no means for the surveyor to follow up with a respondent in order to gain a better understanding of what the respondent intended to convey in his or her response to an open-ended question. (Frederick, Tr. 1247–48).

1015. Dr. Frederick does not contend that all responses to his Google Consumer Surveys were given sincerely. (Frederick, Tr. 1248–49).

1016. Dr. Frederick does not contend that all respondents who answered his Google Consumer Survey questions actually read the questions. (Frederick, Tr. 1253).

1017. Dr. Frederick's only basis for determining whether any given response to any question in his Google Consumer Surveys is sincere is "entirely inferential." (Frederick, Tr. 1254).

1018. Dr. Frederick does not contend that all respondents to his Google Consumer Surveys comprehended every term in his questions. (Frederick, Tr. 1254).

1019. Seventy-five percent of potential respondents who saw Dr. Frederick's Google Consumer Survey questions opted not to answer the question. (Frederick, Tr. 1254-55).

1020. Dr. Frederick is one of the authors of an article entitled "The Limits of Attraction." (CCX 977).

1021. This article notes that some respondents who answer questions from Google Consumer Surveys "answer randomly to regain access to the web page as quickly as possible[.]" (CCX 977 at P. 5 n. 5).

1022. Dr. Frederick thinks "it's a certainty" that some respondents to Google Consumer Survey questions will answer questions randomly. (Frederick, Tr. 1257).

1023. The images Dr. Frederick used in his Google Consumer Survey questions are not actual images of products in the marketplace. (Frederick, Tr. 1265).

1024. The images Dr. Frederick used in his Google Consumer Survey questions are invented photo-shopped images created electronically by Andrew Meyer's wife, who superimposed the ECM logo onto certain electronic images. (Frederick, Tr. 1265, 1316).

1025. Dr. Frederick has never seen any actual product containing an ECM logo or the words "biodegradable from ECM." (Frederick, Tr. 1266).

1026. Dr. Frederick did not specify in his Google Consumer Survey questions the type of plastic to which he was referring to in any given question. (Frederick, Tr. 1266).

1027. One such image created by Dr. Frederick and his employees was what appeared to be a Tupperware container with the ECM logo; this Tupperware container appears to be thicker than other plastic images Dr. Frederick used in his Google Consumer Surveys. (Frederick, Tr. 1266–67; CCX 860 (Frederick, Rep. at 31–32)).

1028. None of the questions in Dr. Frederick's Google Consumer Surveys were identical to any of the questions in the APCO or Synovate surveys. (Frederick, Tr. 1277–78).

1029. Dr. Frederick's Google Consumer Survey did not use the same survey method as either the APCO or Synovate surveys. (Frederick, Tr. 1278).

1030. Dr. Frederick defines coding as extracting from a raw response to a survey question an amount of time. (Frederick, Tr. 1282).

1031. Dr. Frederick, Andrew Meyer, Mohammad Saeed, Lacie D'Amato, and Jane Coates were the coders for Dr. Frederick's Google Consumer Surveys. (Frederick, Tr. 1282).

1032. Andrew Meyer is Dr. Frederick's graduate student. (Frederick, Tr. 1284).

1033. Mohammad Saeed is an undergraduate student. (Frederick, Tr. 1285).

1034. According to Dr. Frederick, some degree of judgment is required in order to code response. (Frederick, Tr. 1283).

1035. Mr. Meyer was aware that FTC was the sponsor of the Google Consumer Surveys. (Frederick, Tr. 1285).

1036. Dr. Frederick was the primary coder of the Google Consumer Surveys. (Frederick, Tr. 1285).

1037. Collectively, Dr. Frederick and Mr. Meyer coded almost all of the responses to Dr. Frederick's Google Consumer Surveys. (Frederick, Tr. 1285).

1038. Both Dr. Frederick and Mr. Meyer knew that ECM is the respondent in this case. (Frederick, Tr. 1286).

1039. The first e-mail Dr. Frederick received regarding this proceeding was from Bob Klein, president of Applied Marketing Sciences, Inc., on February 3, 2014. (Frederick, Tr. 1287–88; RX 814).

1040. The first e-mail Dr. Frederick received regarding this proceeding stated in its entirety:

> Hi Shane –
>
> An interesting opportunity has come up that you may be interested in. The FTC is going after a maker of an additive to plastic that claims to make the resulting film "biodegradable." Science says it doesn't work. One of their advertising claims is "biodegrades in some period greater than one year" (which is ridiculous when you think it because everything will biodegrade eventually.) But the issue is anchoring which is why I am calling you. Will this claim result in consumers thinking that it is closer to a year than 100 years? Is it okay for me to pass your name along to the FTC attorney who can explain more about what he wants. My sense is that it will be a short report that spells out your credentials and states your opinion. There will be a trial in June. He would like to speak with you this week if you are interested. Let me know if is okay to pass your name along to him.

(RX 814).

1041. As a coder and as the principal investigator, Dr. Frederick purportedly exercised his judgment to set a bright-line rule no non-numerical response of time periods to his Google Consumer Survey question would be coded. (Frederick, Tr. 1306).

1042. When coding responses to his Google Consumer Survey questions, Dr. Frederick chose to exclude from his data answers like "I don't know," "it varies," and "it depends," "depends on what it is made of," "depends on what it is made of, who knows," who knows," "unknown," "depends on what it is," "not sure," varies," "I think it varies," "it depends on what type of material," "no idea," "I have no clue," "depends on the type of material," "depends on environment," "depends on product," "not enough information," "it varies based on many different conditions," "depends on the material," "ambiguous," "it would be ambig," and "ambig." (Frederick, Tr. 1299; 1306–09).

1043. Dr. Frederick chose to code the raw responses of "one nanosecond," "forever," "24 hours," "immediately," "17 days," "one hour," "one second," "a human lifetime," "10,100 years," "ten minutes," "122 minutes," "one minute," "one hour," "ten seconds," "276.5 days," one second," "ten minutes," "minutes," "22 days," "72 hours," "30 minutes," "45 seconds," a week," "90 minutes," 60 seconds," "a few days," and "one hour." (Frederick, Tr. 1302–05; RX 951).

1044. Dr. Frederick chose to code the raw response "never." (Frederick, Tr. 1302; RX 951).

1045. According to Dr. Frederick, a respondent who is otherwise predisposed to take a survey question seriously might think that a question about how much time a plastic takes to biodegrade is ridiculous because it lacks essential facts. (Frederick, Tr. 1313).

1046. According to Dr. Frederick, a person who does not take a survey question seriously is more likely to answer that question insincerely, whimsically, or with just a guess. (Frederick, Tr. 1313–14).

1047. According to Dr. Frederick, most people do not have the experience of watching a plastic biodegrade. (Frederick, Tr. 1315).

1048. Not a single one of the images Dr. Frederick used in his Google Consumer Surveys was an actual plastic product in the market with an ECM logo or with a biodegradable claim upon it. (Frederick, Tr. 1317).

1049. Andrew Meyer's wife, who photo-shopped the images used in Dr. Frederick's survey, was probably aware that ECM was the respondent in this case and that this was being brought by the FTC against ECM. (Frederick, Tr. 1317–18).

1050. Dr. Frederick has never seen any product that contained both the ECM logo and term "biodegradable" on it. (Frederick, Tr. 1318).

1051. Dr. Frederick had no formatting discretion when presenting images in his Google survey because Google provides only fifteen image formats from which to choose. (Frederick, Tr. 1319).

1052. Dr. Frederick had no ability to control how much contrast Google used when presenting the images in his Google Consumer Surveys. (Frederick, Tr. 1319).

1053. Dr. Frederick had no ability to control the actual screen size that is presented to a respondent answering his Google Consumer Surveys. (Frederick, Tr. 1319).

1054. Dr. Frederick had no ability to control the number of pixels associated with the images he used in his Google Consumer Surveys. (Frederick, Tr. 1319).

1055. At the time Dr. Frederick conducted his Google Consumer Surveys, he had never actually seen a Google Consumer Survey question live on a website. (Frederick, Tr. 1320).

1056. According to Dr. Frederick, Google Consumer Survey respondents sometimes give random answers to questions. (Frederick, Tr. 1320).

1057. According to Dr. Frederick, a stratified sample is when you try to have a full range of demographic characteristics in a study. (Frederick, Tr. 1322).

1058. According to Dr. Frederick, Google Consumer Survey attempts to have a stratified sample by merely inferring demographic characteristics. (Frederick, Tr. 1322).

1059. Dr. Frederick does not know how many people with cell phones live in households with landlines. (Frederick, Tr. 1324).

1060. Dr. Frederick does not know how many adult children live with their parents or grandparents in the United States. (Frederick, Tr. 1325).

1061. Complaint Counsel provided Dr. Frederick with CCX 862, which is information on the demographics of the United States' population from the Census Bureau. (Frederick, Tr. 1327; CCX 862).

1062. According to Dr. Frederick, about 40% of Americans over age 14 are also over age 50. (Frederick, Tr. 1327; CCX 862).

1063. According to Dr. Frederick about half of Americans over age 19 are also over age 50. (Frederick, Tr. 1327; CCX 862).

1064. Dr. Frederick does not know what percentage of people in the United States under age 50 access the internet exclusively through mobile devices.

1065. Dr. Frederick does not know whether people can access a Google Consumer Survey on a mobile device. (Frederick, Tr. 1329).

1066. Dr. Frederick does not know what percentage of global mobile internet users use a mobile device as their primary or exclusive means of using the internet. (Frederick, Tr. 1331).

1067. Dr. Frederick believes that younger people use more mobile devices and that older people tend to you fixed PC to access the internet. (Frederick, Tr. 1332).

1068. Dr. Frederick does not know the difference between a static IP address and a dynamic IP address. (Frederick, Tr. 1332).

1069. Dr. Frederick is not familiar with dynamic host configuration protocol. (Frederick, Tr. 1333).

1070. Dr. Frederick does not know how dynamic host configuration protocol assigns IP addresses. (Frederick, Tr. 1333).

1071. Dr. Frederick does not know what percentage of internet users block cookies. (Frederick, Tr. 1335).

1072. Dr. Frederick does not know what percentage of internet users mask their identities online. (Frederick, Tr. 1335)

1073. Dr. Frederick does not know what percentage of internet users rely on Google Chrome's feature that allows you to browse privately. (Frederick, Tr. 1334–35).

1074. Dr. Frederick does not know whether Google accepts a response from a user browsing anonymously. (Frederick, Tr. 1337).

1075. If a family of four shares one computer, and one of those users answers a Google Consumer Survey question, neither Google nor the surveyor can know which of those four users answered the survey question. (Frederick, Tr. 1337-38).

1076. Dr. Frederick cannot know what caused his survey respondents to wait 20 seconds before keying in a response to his survey questions. (Frederick, Tr. 1342).

1077. Survey respondents were able to read part of the article before deciding whether to answer the Google Consumer Survey question in Dr. Frederick's surveys. (Frederick, Tr. 1343).

1078. Dr. Frederick cannot account for the exact reason why any particular person took 22 seconds to respond to his survey questions. (Frederick, Tr. 1344).

1079. The only qualified claims Dr. Frederick tested in his Google Consumer surveys were ECM's former nine month to five year qualification and ECM's some period greater than a year claims. (Frederick, Tr. 1345–46).

1080. Before writing his expert report, Dr. Frederick had never read the FTC's Green Guides. (Frederick, Tr. 1346).

1081. In support of the One Year Rule, FTC relies on a survey conducted by APCO Insight, and dismisses a survey conducted by Synovate. (RX 347, at § IV(E)(4)(A)).

1082. According to FTC, the APCO survey concluded that 60% of respondents expect that an item marketed as degradable will fully decompose in one year or less. (RX 347, at § IV(E)(4)(A)).

1083. However, four of the six potential answer choices fell within the range of "one year or less." (RX 856 (Stewart Rep. at 7)).

1084. A random selection of these potential answer choices would yield 66% falling within the range of "one year or less," and when people are asked questions about that which they know little, a near perfect distribution of answer choices should be expected. (RX 856 (Stewart Rep. at 8)).

1085. Dr. Frederick is unfamiliar with the Reference Manual on Scientific Evidence, and has no "specific criterion in mind" as to what makes a survey valid. (Frederick, Tr. 1185–1191; RX 858 (Frederick, Dep. at 186)).

1086. Dr. Frederick does not "know what other people have written" regarding what constitutes acceptable survey principles that define a valid survey. (RX 858 (Frederick, Dep. at 186–187)).

1087. Dr. Frederick chose the Google Survey interface despite the fact that no Google Consumer Survey has ever been relied upon as evidence in an FTC proceeding, and that its use has never been approved of or validated in any peer reviewed literature. (Frederick, Tr. 1191; RX 858 (Frederick, Dep. at 189)).

1088. Dr. Frederick also chose to use a Google Consumer Survey to save money. (Frederick, Tr. 1206; RX 858 (Frederick, Dep. at 123)).

1089. Dr. Frederick was paid a flat fee of $40,000 by the FTC, of which Dr. Frederick was entitled to keep whatever amount he did not spend. (Frederick, Tr. 1201; RX 858 (Frederick, Dep. at 8)).

1090. There is no way to ascertain the degree to which the sample of respondents used in Google Consumer Surveys is representative of any identifiable population; the sample itself is unknown and unknowable, because there is no verification of respondents with Google Survey; rather, information on respondents is merely inferred by Google from information associated with or that resides on a computer. (Frederick, Tr. 1228; RX 856 (Stewart, Rep. at 10–11)).

1091. Dr. Frederick declined to pay the additional fee to include two-part questions that would have provided direct information about the respondent population. (Frederick, Tr. 1230–1231).

1092. Dr. Frederick rejected the option of including screener questions in his Google surveys. (Frederick, Tr. 1224).

1093. Google survey uses no screener questions to assure that the respondent is of relevant age or even understands the English language. (RX 856 (Stewart, Rep. at 11)).

1094. Dr. Frederick admits that his Google survey population is not representative of the target population; stating that there are "two populations here…the population about

which we're trying to draw inferences... [and] the people who answered the surveys that I posted on Google Consumer Surveys." (Frederick, Tr. 1234).

1095. Google survey generally works by giving internet users access to "premium content" in exchange for answering a question, as opposed to paying for a subscription; therefore, the questions are at best a distraction and barrier to respondents whose objective is to access information, not complete a survey. (Frederick, Tr. 1206–1207; RX 856 (Stewart, Rep. at 11)).

1096. The disinterest bias explains why so many respondents answered Dr. Frederick's survey with nonsensical answers. (RX 856 (Stewart, Rep. at 11)).

1097. While Dr. Stewart's survey utilized well-trained and blind coders, Dr. Frederick merely vetted coders for the ability to read and follow directions and did not ensure blinding. (RX 856 (Stewart, Rep. at 26); RX 858 (Frederick, Dep. at 168–169)).

1098. Dr. Frederick's coders did not consistently apply the coding rules. (RX 856 (Stewart, Rep. at 13)).

1099. Dr. Frederick's survey failed to code accurate and relevant responses such as "don't know." (Frederick, Tr. 1306–1308; RX 856 (Stewart, Rep. at 12)).

1100. Dr. Frederick's survey did not code answers indicating critical thought by the respondent, such as, "it depends on where it ends up" or "it depends on what it is." (Frederick, Tr. 1306–1308).

1101. Dr. Frederick's supervising coder, Andrew Meyer, was aware that Dr. Frederick's research was going to be used by Complaint Counsel against ECM. (Frederick, Tr. 1285–1287; RX 858 (Frederick, Dep. at 176)).

1102. This failure to use "blind coders" deviates from customary practice and may infect the survey with coder bias. (RX 856 (Stewart Rep. at 13)).

1103. Unlike in Dr. Stewart's survey, there is no evidence that Dr. Frederick used multiple coders in the coding process to implement a reliability check. (RX 856 (Stewart, Rep. at 13)).

1104. Significant flaws aside, Dr. Frederick's survey indicates considerable diversity among respondents in terms of their claimed knowledge about biodegradable products and their views about the time it takes various materials to biodegrade. (RX 856 (Stewart Rep. at 13-14)).

VIII. COMPLAINT COUNSEL HAS NOT DEMONSTRATED THAT THE RATE OF BIODEGRADATION IN LANDFILLS IS MATERIAL TO CONSUMER PURCHASING DECISIONS

1105. In support of his expert opinion in this case, Dr. Stewart performed a survey in the spring of 2014. (Stewart, Tr. 2494).

1106. When exploring a new field of consumer survey research that has not previously been researched extensively it is best to conduct open-ended survey research with a personal interviewer, either face to face or by telephone. (Stewart, Tr. 2510).

1107. Using a personal interviewer in a survey affords the surveyor to explore in depth what people's perceptions are. (Stewart, Tr. 2510).

1108. The subject of public perception of biodegradation and biodegradation of plastics as a field of consumer survey research has not been researched extensively. (Stewart, Tr. 2510–11).

1109. Outside of the surveys conducted for the present litigation, only two surveys exist that explore the issue of public perception of biodegradation and biodegradation of plastics. (Stewart, Tr. 2511).

1110. Given the limited amount of research work done in the field of public perception of biodegradation and biodegradation of plastics, the survey methodologies that should be used to explore that field can only be done with a personal interview and the use of open-ended questions. (Stewart, Tr. 2511).

1111. Dr. Stewart reviewed the APCO study and the Synovate study. (Stewart, Tr. 2512).

1112. One purported purpose of the APCO survey was to discern public perception of the rate of biodegradation. (Stewart, Tr. 2514).

1113. The APCO study used mostly closed-ended questions. (Stewart, Tr. 2513).

1114. The Synovate survey included questions relative to the rate of biodegradation. (Stewart, Tr. 2515).

1115. Closed-ended questions are questions where a list of possible responses to a question are provided to the respondent, and where the respondent must choose from one of the responses that were provided in order to give an answer to the question. (Stewart, Tr. 2513).

1116. The form of the questions used in the APCO survey was premature given the state of knowledge of the topics covered by the APCO survey. (Stewart, Tr. 2513).

1117. Closed-ended questions are appropriate only where the surveyor already has a deep understanding of all potential responses that an individual might give to a question. (Stewart, Tr. 2513).

1118. The response options given in the APCO survey were incomplete. (Stewart, Tr. 2513).

1119. The response options in the APCO survey to questions about how long it should take for something to biodegrade were not balanced. (Stewart, Tr. 2514).

1120. Two-thirds of the response options in the APCO survey to the question of how long it should take for something to biodegrade were one year or less, which predisposes people to select a short time frame than a longer time frame. (Stewart, Tr. 2514).

1121. With respect to the question of how long it would take something to biodegrade, the APCO survey is invalid. (Stewart, Tr. 2514).

1122. The APCO survey is invalid because it does not provide adequate opportunity for respondents to offer their perceptions. (Stewart, Tr. 2514).

1123. The APCO survey's question of how long it would take something to biodegrade is biased because it offers many more opportunities to select an answer that reflects one year or less than a longer time period. (Stewart, Tr. 2514–15).

1124. The Synovate survey inappropriately uses closed-ended questions when asking about the length of time that biodegradation should occur. (Stewart, Tr. 2515).

1125. The response options in the Synovate survey for the question of how long should something take to biodegrade are biased. (Stewart, Tr. 2515).

1126. Given the current understanding and state of knowledge with respect to consumer perception of biodegradation, open-ended questions are much more suitable, appropriate, and informative than closed-ended questions. (Stewart, Tr. 2516).

1127. One problem with closed-ended questions is that the limited response options may preclude respondents from giving an accurate answer that reflects their real perceptions by forcing the respondent to choose a response that may most closely reflect his or her view but may not be close at all. (Stewart, Tr. 2517).

1128. On reason why surveyors need more work involving open-ended questions and interviews early in the exploration of a topic like biodegradation is so that surveyors can be sure that when they do finally design closed-ended questions, that they give people the full array of response options. (Stewart, Tr. 2517).

1129. "Misleading homogeneity" is a situation in which one characterizes a sample or a population as being more alike, more similar, or more homogeneous than is actually the case. (Stewart, Tr. 2518).

1130. Misleading homogeneity in a survey occurs when respondents have a limited number of potential responses they can offer. (Stewart, Tr. 2518).

1131. The APCO survey afforded respondents no opportunity for any dependencies or contexts. (Stewart, Tr. 2519).

1132. The Synovate survey results in misleading homogeneity because of the relatively small number of time frames in the response options. (Stewart, Tr. 2520).

1133. Consumers have nuanced perceptions of biodegradability. (Stewart, Tr. 2630).

1134. There is evidence that consumers who purchase biodegradable products seek out and obtain truthful scientific information about what "biodegradable" means. (Stewart, Tr. 2658–59).

1135. If there are no shared beliefs among consumers, there is no evidence that deception occurred. (Stewart, Tr. 2660).

1136. According to Dr. Frederick, a protest or bypass response is a response given by a respondent for the sole purpose of getting past a survey wall. (Frederick, Tr. 1123).

1137. In a telephone survey, a protest response is in the form of the respondent hanging up the telephone. (Stewart, Tr. 2665),

1138. In an internet survey, where the respondent must enter some information in order to obtain desired content, a protest response can take any number of forms, including what could be interpreted answers. (Stewart, Tr. 2666; Frederick, Tr. 1123).

1139. In terms of the validity of a survey, it is far better for a protest response to be a hang up of the telephone—thus providing the researcher absolutely no data—than entering a protest response into a survey which actually becomes incorporated into the larger data set and is ultimately used in an analysis. (Stewart, Tr. 2666).

1140. The composition of Dr. Frederick's Google Consumer Survey sample cannot be known. (Stewart, Tr. 2672–73).

1141. Dr. Stewart obtained demographic information from his respondents directly. (Stewart, Tr. 2672–75).

1142. Dr. Frederick received demographic information from Google that Google merely inferred. (Stewart, Tr. 2674–75, 2743).

1143. Google Consumer Surveys is an untested product. (Stewart, Tr. 2683).

1144. Google Consumer Surveys is not a transparent product. (Stewart, Tr. 2683).

1145. Google Consumer Surveys will not provide market researchers sufficient information to adequately evaluate the product. (Stewart, Tr. 2683).

1146. Many professional marketing associations require transparency when evaluating whether a survey product is legitimate. (Stewart, Tr. 2683).

1147. Most marketing research professionals agree that Google Consumer Surveys is not in the legitimate market research business. (Stewart, Tr. 2683).

1148. There is no such thing as misleading heterogeneity. (Stewart, Tr. 2770).

1149. To the extent that misleading heterogeneity exists, it is not analogous to misleading homogeneity. (Stewart, Tr. 2770).

1150. Scholars have written two responses criticizing Dr. Frederick's article entitled "The Limits of Attraction." (Stewart, Tr. 2807).

1151. The article entitled "The Limits of Attraction" does not rely on Google Consumer Surveys at all. (Stewart, Tr. 2808).

1152. The only reference to Google Consumer Surveys in the article entitled "The Limits of Attraction" was in a footnote. (Stewart, Tr. 2808; CCX 977).

1153. The footnote in the article entitled "The Limits of Attraction" referring to Google Consumer Surveys was neither supportive nor non-supportive of what was actually contained in "The Limits of Attraction" article. (Stewart, Tr. 2808).

1154. Dr. Stewart coded every response to his survey. (Stewart, Tr. 2810).

1155. Dr. Frederick coded only those responses which happened to give a numerical score a time interval. (Stewart, Tr. 2810).

1156. Dr. Stewart's codes classified the actual responses of the survey participants. (Stewart, Tr. 2811).

1157. The totality of the questions asked in Dr. Stewart's survey provided a much brighter and richer picture of people's perceptions of biodegradability than if Dr. Stewart asked only one question of each respondent. (Stewart, Tr. 2812).

1158. In interpreting the meaning of any specific time offered by a survey respondent, it is important to know how they responded to other questions in the survey. (Stewart, Tr. 2813).

1159. Virtually everyone understands that the time a product takes to biodegrade is dependent upon a variety of factors. (Stewart, Tr. 2813).

1160. The totality of the evidence obtained from Dr. Stewart's survey indicates that consumers have a very rich and nuanced understanding of biodegradability. (Stewart, Tr. 2814).

1161. Consumers understand that the process of biodegradation is highly dependent upon the type of material, the environment, the size of material, and the biodegrading context. (Stewart, Tr. 2814).

1162. There is a huge variety of opinions among consumers about how long biodegradation actually takes and what the process actually entails. (Stewart, Tr. 2814).

1163. There is an empirical basis for concluding that the ages of the respondents in Dr. Stewart's survey were representative of the relevant population. (Stewart, Tr. 2808).

1164. Dr. Stewart's survey was designed and conducted under a variety of general principles of survey research that are reflected in various textbooks and in other treatments of survey research. (Stewart, Tr. 2521).

1165. The Manual for Complex Litigation lists specific characteristics that a reliable and valid survey should possess, and those principles reflect the general understanding in the professional literature. (Stewart, Tr. 2521).

1166. In designing and implementing his survey, Dr. Stewart relied upon the principle that the relevant population should be clearly identified. (Stewart, Tr. 2522–23).

1167. When designing a survey, the individuals or other entities to which one wants to extrapolate the results of a survey need to be very clearly identified, appropriate, and relevant to whatever the issue may be. (Stewart, Tr. 2523).

1168. In designing and implementing his survey, Dr. Stewart relied upon the principle that there needs to be a well-articulated sampling plan that results in sample from the population—a smaller subset of individuals from the relevant population so that the results of the survey can be extrapolated to the relevant population. (Stewart, Tr. 2523).

1169. In designing and implementing his survey, Dr. Stewart relied upon the principle that the questions asked must be clear and not misleading (Stewart, Tr. 2523).

1170. In designing and implementing his survey, Dr. Stewart relied upon the principle that the survey needs to be designed and implemented by people who are well-qualified and who follow well-accepted procedures. (Stewart, Tr. 2523).

1171. In designing and implementing his survey, Dr. Stewart relied upon the principle that the data analysis needs to follow well-accepted standards of data analysis. (Stewart, Tr. 2523).

1172. All four of the general standards Dr. Stewart relied upon when implementing and designing his survey in this case, "really need[] to be used as the metric against which one evaluates the reliability and validity of a survey." (Stewart, Tr. 2524).

1173. The Federal Trade Commission accepts and applies the standards that are articulated in most professional organizations as well as in the Manual for Complex Litigation. (Stewart, Tr. 2525).

1174. Dr. Stewart's survey used interviewers who could ask follow-up questions and use probes to obtain more complete answers from respondents. (Stewart, Tr. 2526).

1175. Dr. Stewart's survey also utilized some open-ended questions in order to fully explore people's complete perceptions rather than simply asking people to select from a set of predetermined alternatives. (Stewart, Tr. 2526).

1176. Dr. Stewart ultimately decided to conduct a telephone survey because it is more efficient than a mall intercept or a central location study while maintaining the benefit of an interviewer and open-ended questions. (Stewart, Tr. 2526–27).

1177. By using a telephone survey, Dr. Stewart was able to obtain a more representative sample than using a mall intercept survey. (Stewart, Tr. 2527).

1178. The interviewers in Dr. Stewart's survey were live callers who were well –trained professional interviewers who were assisted in their work by computer-assisted telephone interviewing technology which provides a means by which their work could be monitored and a means for capturing responses of the survey respondents. (Stewart, Tr. 2527).

1179. Dr. Stewart authored the questions used in his survey. (Stewart, Tr. 2527).

1180. Dr. Stewart identified the universe studied in his survey. (Stewart, Tr. 2527).

1181. Dr. Stewart identified the sampling source used for making phone calls in his survey. (Stewart, Tr. 2527–28).

1182. California Survey Research Services programmed Dr. Stewart's questionnaire into the computer-assisted telephone interviewing under Dr. Stewart's direction. (Stewart, Tr. 2528).

1183. Dr. Stewart has relied upon California Survey Research Services in a variety of contexts for more than twenty years. (Stewart, Tr. 2528).

1184. Other than ECM's attorneys providing Dr. Stewart with the initial issue, "what does 'biodegradable' mean to consumers," it was entirely Dr. Stewart's responsibility to design, implement, and interpret the survey. (Stewart, Tr. 2529).

1185. Dr. Stewart was wholly responsible for writing the questions asked in his survey. (Stewart, Tr. 2529).

1186. Dr. Stewart's survey was a telephone interview assisted by a technology known as computer-assisted telephone interviewing. (Stewart, Tr. 2529).

1187. Dr. Stewart's survey intended to use a large majority of open ended questions. (Stewart, Tr. 2529-30).

1188. Dr. Stewart's survey was intended to obtain a random sample of households with landlines. (Stewart, Tr. 2529–30).

1189. The acronym for computer-assisted telephone interviewing is "CATI." (Stewart, Tr. 2530).

1190. CATI is essentially hardware and software that is designed to create a structure to assist interviewers in the design and implementation of a telephone survey. (Stewart, Tr. 2530).

1191. CATI essentially automates the dialing of telephone numbers so that it takes the control of what number is dialed away from the interviewer. (Stewart, Tr. 2530).

1192. Once CATI reaches a connection with a potential respondent, CATI causes the interviewer's monitor to bring up one question at a time so that there is no opportunity for the interviewer to deviate from the order of questions. (Stewart, Tr. 2530–31).

1193. After recording a response from a respondent, the interviewer clicks a "continue" button that brings up the next question in the survey. (Stewart, Tr. 2531).

1194. Dr. Stewart's survey had the simple objective of trying to understand the perceptions of consumers with respect biodegradability, what the meaning of the term was, complete with any contingencies, dependencies, or context effects that they might bring to bear. (Stewart, Tr. 2531).

1195. "Relevant population" means the group of people to whom the researcher wants to extrapolate the results of the survey. (Stewart, Tr. 2532).

1196. Dr. Stewart defined the relevant population for his survey as adults in the United States age 18 and older who indicated that they had some general understanding of what the term "biodegradable" means. (Stewart, Tr. 2532).

1197. Dr. Stewart's survey's population also excluded anyone who he thought was atypically knowledgeable on the subject of biodegradation. (Stewart, Tr. 2532–33).

1198. Dr. Stewart chose to exclude from his survey people who indicated that they did not have a general understanding of the term "biodegradable" because it makes no sense to ask people the meaning of a term when they have already self-identified that they do not know what that term means. (Stewart, Tr. 2533).

1199. If people who had no general understanding of the term "biodegradable" nevertheless participated in Dr. Stewart's survey, they would simply be guessing, offering random responses, and not be giving meaningful responses to the survey questions. (Stewart, Tr. 2533).

1200. As a precursor to asking questions that explore more deeply the meaning of a term, the first thing a researcher needs to understand is whether people have the basic knowledge base necessary to respond to that question. (Stewart, Tr. 2533).

1201. If a potential respondent indicates that he or she has no idea what biodegradation means, there is no point in asking them a series of questions about something that they have already said they do not know anything about. (Stewart, Tr. 2533).

1202. Screening questions are a set of preliminary questions that are asked at the very beginning of a survey to determine whether or not a respondent should receive the substantive questionnaire or whether they should be excluded. (Stewart, Tr. 2534).

1203. Screening questions can be used to assure that a certain variability among respondents exists. (Stewart, Tr. 2534).

1204. An example of a screening question is asking whether a respondent is male or female, so that the researcher can assure that the respondents as a whole will be roughly 50% male and 50% female. (Stewart, Tr. 2534).

1205. Screening questions are used for qualifying people and for assuring a more representative sample. (Stewart, Tr. 2541).

1206. Dr. Stewart's survey included screening questions asking about respondents' age, gender, general employment status, and whether the respondent was knowledgeable or not about the term "biodegradable." (Stewart, Tr. 2535).

1207. The gender and age screening questions in Dr. Stewart's survey were designed assure that his survey had an adequate number of people of each gender and within each age category. (Stewart, Tr. 2535).

1208. The general employment screening question in Dr. Stewart's survey was designed to eliminate certain kinds of people from participating in the survey, such as people who might be atypical in terms of their response, which is very commonly done in survey research. (Stewart, Tr. 2535–36).

1209. Dr. Stewart included the screening question about whether respondents had a general knowledge of the term "biodegradable" because it makes no sense to ask people about a topic that they self-identify they know little or nothing about, because those people would only answer, at best, with guesses and random responses. (Stewart, Tr. 2536).

1210. It is a big mistake to have no screening questions in a survey on biodegradation. (Stewart, Tr. 2536).

1211. Without screening questions, the surveyor cannot exclude people that are quite atypical and likely to introduce error into the results. (Stewart, Tr. 2537).

1212. To have no screenings in a survey on biodegradation creates a number of problems and calls into question the validity of that survey. (Stewart, Tr. 2537).

1213. A survey on biodegradation that does not contain screening questions has the potential for introducing a lot of error into the survey. (Stewart, Tr. 2537).

1214. A survey without screening questions is not capable of being analyzed for the general representativeness of the sample. (Stewart, Tr. 2537).

1215. In the field of survey research, "sampling" means the process by which researchers select a subset of individuals from a larger population. (Stewart, Tr. 2538).

1216. In general, appropriate sampling procedures are designed to assure that the subset that researchers select are generally and broadly representative of the larger population. (Stewart, Tr. 2538).

1217. The primary principle to guide the selection of a sample is to create and implement a sampling plan that will provide the researcher a representative sample in the sense that the sample is like the larger population to whom the researcher wishes to extrapolate. (Stewart, Tr. 2538).

1218. There are important elements of the sampling plan that are important in order to have a valid survey. (Stewart, Tr. 2538).

1219. One important element of a sampling plan is to first clearly define what the relevant population is, because without knowing the larger group to which the researcher is extrapolating, it is hard to know whether the sample would be representative of the relevant population. (Stewart, Tr. 2539).

1220. Another important element of a sampling plan is the ability to verify how representative the same is on at least some key demographic information. (Stewart, Tr. 2539).

1221. Another important element of sampling plans is to assure that the respondents are actually capable of answering questions. (Stewart, Tr. 2539).

1222. Two broad categories of sampling plans exist: probability sampling and nonprobability sampling. (Stewart, Tr. 2539–40).

1223. Probability sampling is sampling where the researcher knows, in advance of actually doing the sampling, what the probability of selection of any individual might be. (Stewart, Tr. 2539–40).

1224. Non-probability sampling is where the researcher does not know in advance what the probability of selecting any one individual is because a respondent can simply refuse to participate in the survey. (Stewart, Tr. 2540).

1225. Most of the work done by marketing researches involves non-probability samples because people can decline to participate in the surveys. (Stewart, Tr. 2540).

1226. Dr. Stewart's sample in his survey was a non-probability sample because respondents could refuse to participate. (Stewart, Tr. 2541).

1227. Dr. Stewart's survey used a random digit dialing approach so that the telephone numbers were randomly selected. (Stewart, Tr. 2541).

1228. The use of random-digit dialing sampling is one of the things researchers can do to assure a more representative sample. (Stewart, Tr. 2541).

1229. Most business decisions that employ surveys are based on non-probability samples. (Stewart, Tr. 2542).

1230. The sample in Dr. Stewart's survey was representative. (Stewart, Tr. 2543).

1231. Dr. Stewart used a sample size of 400 in his survey. (Stewart, Tr. 2544).

1232. Dt Stewart chose to use 400 as a sample size because it's near that number that is where the researchers reach the point of diminishing returns in terms of sample. (Stewart, Tr. 2544).

1233. With 400 respondents for a simple yes/no question, in the case of the greatest variability, the research will be within plus or minus 5 percent of any percent the researcher may estimate. (Stewart, Tr. 2545).

1234. In order to get to plus or minus 3 percent, the researcher needs to triple the size of the sample to about 1200 respondents. (Stewart, Tr. 2545).

1235. Dr. Stewart used two sources to obtain telephone numbers of individuals surveyed in his survey. (Stewart, Tr. 2545).

1236. One source Dr. Stewart used to obtain telephone numbers was Scientific Telephone Sampling which is a firm that is in the business of generating samples for survey research. (Stewart, Tr. 2545).

1237. Scientific Telephone Sampling generated a random-digit dialing sample by taking listed phone numbers that are publicly available and randomly changing the last two digits in order to create a true random sample of telephone numbers in the sense that the resulting sample includes unlisted numbers. (Stewart, Tr. 2545–46).

1238. The APCO survey also used a random-digit dialing sample. (Stewart, Tr. 2546).

1239. Dr. Stewart also employed an age-enhanced sample that he obtained from Survey Sampling, Incorporated which is a company that does preparation, analysis, and provision of names and telephone numbers for survey research. (Stewart, Tr. 2546).

1240. Survey Sampling, Incorporated provided Dr. Stewart with a supplement that included a larger percentage of households known to contain younger consumers. (Stewart, Tr. 2546).

1241. Dr. Stewart combined the random-digit dialing sample obtained from Scientific Telephone Sampling and the age-enhanced sample from Survey Sampling

Incorporated to create the final source of numbers that were used for the dialing his survey. (Stewart, Tr. 2546).

1242. Both Scientific Telephone Sampling and Survey Sampling, Incorporated are well-known and highly respected providers of sample lists in survey research. (Stewart, Tr. 2549).

1243. Dr. Stewart included screening questions in his survey in order to ensure that the respondents surveyed were representative of the relevant population. (Stewart, Tr. 2551).

1244. Dr. Stewart established soft quotas for the demographics in his survey to ensure that men and women, as well as various age categories, were well represented in the survey sample. (Stewart, Tr. 2551).

1245. In Dr. Stewart's survey, live interviewers read questions to respondents over the telephone. (Stewart, Tr. 2552).

1246. California Survey Research Services is a well-known firm specializing in telephone, mail, and internet surveys that has been in the business of surveys for 30 years. (Stewart, Tr. 2552).

1247. California Survey Research Services does research for a wide range of business, not-for-profit, university, and government organizations. (Stewart, Tr. 2552).

1248. Dr. Stewart designed the survey, the sampling plan, and the set of questions in his survey. (Stewart, Tr. 2552).

1249. After California Survey Research Services programmed Dr. Stewart's survey into CATI system, Dr. Stewart viewed the questionnaire through a link and, after reviewing it, Dr. Stewart approved the survey.

1250. California Survey Research Services employs multiple layers of supervision when implementing a survey. (Stewart, Tr. 2553).

1251. Dr. Stewart assured that the design of his survey was double blind. (Stewart, Tr. 2553).

1252. "Double blind" means that the interviewers and any of other personnel directly involved with collecting or coding the data were not aware of the sponsor or purpose of the research, nor were the respondents aware of either the purpose or the sponsor of the research. (Stewart, Tr. 2553–54).

1253. Where a survey is double-blind, it is unlikely that a respondent or interviewer will seek to be helpful by offering a response that they think is consistent with what the researcher is looking for. (Stewart, Tr. 2554).

1254. A survey that is not double-blind calls into question the validity of that survey. (Stewart, Tr. 2554).

1255. California Survey Research Services coded the responses to Dr. Stewart's survey. (Stewart, Tr. 2554).

1256. It would have been problematic for Dr. Stewart to code the answers to his survey because the mere fact that he knew the purpose of the research could influence how he coded the data. (Stewart, Tr. 2555).

1257. In Dr. Stewart's survey, disagreements between coders were resolved by the coders getting together, comparing notes, and attempting to resolve their differences. (Stewart, Tr. 2556).

1258. Blinding of coders is very important when coding open-ended questions because the coders are, in effect, transforming the data into categories of responses. (Stewart, Tr. 2557).

1259. To the degree that the coders have a prior understanding of what the researcher is looking for, that prior understanding can influence what codes the coders arrive at and how they code the data. (Stewart, Tr. 2557).

1260. All of the interviewers who implemented Dr. Stewart's were trained in general interviewing technique and also were specifically trained to the protocol that was used in Dr. Stewart's survey. (Stewart, Tr. 2558).

1261. Supervisory personnel trained the interviewers, answered the interviewers' questions, were on-site at the time the interviewing took place, and could therefore address any problems that arose during the survey. (Stewart, Tr. 2558–59).

1262. Supervisory personnel also had the ability to randomly monitor the interviewing as it was taking place in real time, so that they could determine whether the interview was actually taking place and whether the protocol was actually being followed. (Stewart, Tr. 2559).

1263. The mere fact that supervisory personnel were able to listen to interviews in real time at will assures a higher degree of integrity and attention to instructions among the interviewers. (Stewart, Tr. 2559).

1264. The interviewers had an opportunity for debriefing to discuss any questions, problems, or issues that arose after they completed a practice interview. (Stewart, Tr. 2560).

1265. Interviewers' ability to participate in briefing ensures a higher quality and efficiency of the interviewing process and acts as a way to standardize the interviewers. (Stewart, Tr. 2560).

1266. Dr. Stewart's main questionnaire used primarily open-ended questions. (Stewart, Tr. 2561).

1267. By allowing respondents to answer the survey questions in their own words, Dr. Stewart was able to identify any qualifications, dependencies, and contexts that might be present in a respondent's answer. (Stewart, Tr. 2562).

1268. It would have been a mistake for Dr. Stewart not to use a screen questionnaire in his survey for two reasons. (Stewart, Tr. 2562).

1269. First, without a screener questionnaire it is not possible for a researcher to obtain accurate demographic information and therefore the researcher has no way to verify the degree to which the sample was generally representative of the larger population. (Stewart, Tr. 2562).

1270. Second, the absence of a screener prevents a researcher from eliminating people who were atypical. (Stewart, Tr. 2562).

1271. The coders in Dr. Stewart's survey reviewed the responses to the open-ended questions to determine the broad categories that would seem to capture the responses. (Stewart, Tr. 2565).

1272. The categories that best captured respondents' responses to open-ended questions in Dr. Stewart's survey became the code book. (Stewart, Tr. 2564–65).

1273. Dr. Stewart approved the code book. (Stewart, Tr. 2565).

1274. Dr. Stewart survey contained a main questionnaire which is the same as the substantive questionnaire. (Stewart, Tr. 2566).

1275. The main questionnaire in Dr. Stewart's survey answered the question of what the relevant population understands the meaning of the term "biodegradable" to mean. (Stewart, Tr. 2566).

1276. Dr. Stewart's main questionnaire used the funnel approach, which starts with general open-ended questions and progresses to more specific open-ended questions, and finally some closed-ended questions. (Stewart, Tr. 2566).

1277. Leading questions, questions which both suggest an answer and ask a question, are not appropriate. (Stewart, Tr. 2567).

1278. None of the questions in Dr. Stewart's survey were leading. (Stewart, Tr. 2568).

1279. Dr. Stewart's screener questionnaire contained six questions, and his main questionnaire contained about 15 questions. (Stewart, Tr. 2569).

1280. Not every respondent was asked every question in Dr. Stewart's main questionnaire. (Stewart, Tr. 2569).

1281. If a respondent disconnected the phone call during the survey, that respondent's answers were not counted and that respondent was recorded as a "terminate." (Stewart, Tr. 2569–70).

1282. Asking a respondent only one question in a survey on the meaning of "biodegradable" does not allow a researcher to get a rich understanding of how a respondent actually understands "biodegradable." (Stewart, Tr. 2570).

1283. In Dr. Stewart's survey, 19% of respondents were aged 18–34, 23% of respondents were aged 35–49, 29% percent of respondents were aged 50–65, and 29% of respondent were aged 66 and older. (Stewart, Tr. 2572; RX 605).

1284. In Dr. Stewart's survey, 201 respondents were female and 199 respondents were male. (Stewart, Tr. 2572; RX 605).

1285. Dr. Stewart's respondents are broadly representative. (Stewart, Tr. 2572).

1286. Dr. David Stewart, a survey expert whose work has repeatedly been credited by ALJs of the FTC and the Commission itself, designed a telephone survey in order to determine how consumers who actually purchase products made from or packaged in plastic perceive the meaning of the term "biodegradability." (Stewart, Tr. 2493–94, 2505–09; RX 856 (Stewart, Rep. at 15)).

1287. Dr. Stewart's survey also assessed the message that consumers take away from claims made by ECM. (RX-856 (Stewart, D., Expert Report at 15)).

1288. Dr. Stewart's survey used well-designed, non-leading, and clear open-ended questions that allowed real consumers to answer in their own words and to provide qualifications, contextual information, or other information that established a richer meaning of consumer responses than is typically obtained when only closed-ended questions appear (or single questions are posed without human interface) in a survey. (Stewart, Tr. 2526–27; RX 856 (Stewart, Rep. at 15)).

1289. Dr. Stewart designed and conducted his survey in accordance with well-established principles of survey research offered in litigation, as articulated in the Manual for Complex Litigation. (Stewart, Tr. 2522; RX 856 (Stewart, Rep. at 16)).

1290. The interviewers and their supervisors for Dr. Stewart's survey were blind in the sense that they did not know for whom the survey was being conducted. (Stewart, Tr. 2553–54; RX 843 (Stewart Dep. at 276)).

1291. Once the respondents were appropriately selected from a list of telephone numbers based on an algorithm employed by the CATI system, interviewers clarified to potential respondents that the call was for research purposes and not telemarketing. (RX 856 (Stewart, Rep. at 19)).

1292. The screener questions in Dr. Stewart's survey ensured that the respondent was over 18, asked their age and gender to ensure that appropriate diversity was represented

within the sample, ensured that they or anyone in their household did not work for a manufacturer of plastic products or a waste disposal organization, ensured that they had purchased a product in a plastic container or containing plastic within the past month, and ensured they had a general understanding of the term biodegradable. (Stewart, Tr. 2532–33, 2535–36; RX 856 (Stewart, Rep. at 19–20)).

1293. All but two of the questions in Dr. Stewart's main questionnaire were open-ended questions, which have the advantage of allowing respondents to offer answers that are qualified, provide context, or are otherwise nuanced, and which are useful for clarifying terminology by gauging the meanings of words and for informing variability among respondents. (RX 856 (Stewart, Rep. at 20)).

1294. The first few questions in Dr. Stewart's survey asked respondents about their perceptions of biodegradability generally. (RX 856 (Stewart, Rep. at 21)).

1295. For example, Q4 in Dr. Stewart's survey asked, "If something is biodegradable, how long do you think it would take for it to decompose or decay?" (RX 856 (Stewart, Rep. at 21)).

1296. The next set of questions in Dr. Stewart's survey asked the respondents to indicate in their own words what claims adapted from claims used by ECM mean to them. (RX 856 (Stewart, Rep. at 21)).

1297. The field work for Dr. Stewart's survey cost $37,500. (Stewart, Tr. 2648; RX-856 (Stewart, Rep. at 23)).

1298. Dr. Stewart's survey was pre-tested by conducting a small pilot project, which confirmed that no changes to the survey design were necessary. (RX 856 (Stewart, Rep. at 23)).

1299. All verbatim responses to Dr. Stewart's survey were coded independently by two coders and any disagreements were resolved in discussion. (Stewart, Tr. 2556–57; RX 856 (Stewart Rep. at 23)).

1300. Ninety-eight percent of the respondents to Dr. Stewart's survey believe that different types of products biodegrade, decompose, or decay at different rates. (Stewart, Tr. 2577).

1301. Ninety-eight percent of the respondents to Dr. Stewart's indicated that they would have to qualify any answer about the amount of time it would take for something to biodegrade based on the material. (Stewart, Tr. 2577).

1302. Ninety-eight percent of the respondents to Dr. Stewart's do not believe that there is a uniform rate for materials biodegrading and that the rate really depends on the material. (Stewart, Tr. 2577).

1303. Consumers have a very nuanced understanding of biodegradability. (Stewart, Tr. 2579).

1304. Consumers understand that the process of biodegradation is one that can vary quite substantially depending on the material, the context, where the item is disposed of, and the size of the product. (Stewart, Tr. 2579).

1305. Consumers believe that the word "biodegradable" means to decay or destruct, and believe in general terms that the process of biodegradation is one whereby the product breaks down in some way. (Stewart, Tr. 2579).

1306. The most common response, by far, to the question "[i]f something is degradable, how long do you think it would take for it to decompose or decay?" in Dr. Stewart's survey was that "it depends on the material or type of product. " (Stewart, Tr. 2580).

1307. The most common response that provided a clear time period to the question "[i]f something is degradable, how long do you think it would take for it to decompose or decay?" was one to five years, given by 6% of respondents. (Stewart, Tr. 2580).

1308. Any answer to the question "[i]f something is degradable, how long do you think it would take for it to decompose or decay?" in Dr. Stewart's survey must be put into the context of the other questions in his survey because we know that 98% of respondents believe that the type of material makes a difference in the rate of biodegradation. (Stewart, Tr. 2581; RX 856 (Stewart, Rep. at 26)).

1309. If the interviewers in Dr. Stewart's survey probed the respondents who gave a clear time frame in response to the question "[i]f something is degradable, how long do you think it would take for it to decompose or decay?", the data would likely have detected dependencies, contextual effects, and differences among materials. (Stewart, Tr. 2581).

1310. There is a wide array of differences amongst respondents about how long a degradable object takes to decompose or decay.

1311. There is great agreement, 98%, that the amount of time something takes to degrade depends upon factors such as the material, the context, and the environment. (Stewart, Tr. 2581; RX 856 (Stewart, Rep. at 26)).

1312. Not one respondent to Dr. Stewart's survey understood biodegradation to mean the complete breakdown of the substance into elements in nature within one year after customary disposal. (Stewart, Tr. 2583).

1313. The fact that consumers may hold a mistaken belief about how long something takes to biodegrade does not mean that that mistaken belief was attributable the action of any marketer, including ECM. (Stewart, Tr. 2584–85).

1314. Dr. Stewart's survey presented three claims three of ECM's stylized claims to respondents. (Stewart, Tr. 2585).

1315. Americans have a shared understanding of the word "biodegradable" to the extent that it means to break down. (Stewart, Tr. 2586).

1316. Americans have a shared understanding that the amount of time required for biodegradation depends on characteristics like type of material and environment. (Stewart, Tr. 2586).

1317. Americans do not hold a shared belief as to the amount of time a biodegradable substance takes to biodegrade. (Stewart, Tr. 2586).

1318. No significant minority of Americans define "biodegradation" to mean that a product will completely biodegrade into elements in nature within one year after customary disposal. (Stewart, Tr. 2586).

1319. Dr. Stewart's survey is highly reliable. (Stewart, Tr. 2587).

1320. Dr. Stewart's survey was designed in a fashion that is very consistent with accepted standards and best practices in the design of survey research. (Stewart, Tr. 2587).

1321. Dr. Stewart's survey has a representative sample on key demographic characteristics. (Stewart, Tr. 1587),

1322. Because 98% of the respondents to Dr. Stewart's survey believe that the amount of time something takes do decompose varies, even if the survey's demographics are wrong by some percent, the vast majority of Americans still share the belief that the amount of time it takes for something to biodegrade varies based on the material, size, and context in which biodegradation occurs. (Stewart, Tr. 2587).

1323. Dr. Stewart conducted a pilot survey of manufacturers of plastic. (Stewart, Tr. 2587).

1324. For the manufacturers' survey, ECM provided a customer list to Dr. Stewart that included names and telephone numbers of individuals that were identified as most knowledgeable about the manufacture of plastics and the components that would be acquired for that process. (Stewart, Tr. 2588).

1325. California Survey Research Services implemented the pilot survey of manufacturers of plastic by using a telephone survey with professional interviews using a CATI system. (Stewart, Tr. 2588–89).

1326. The pilot survey had a limit of 20 hours of calling. (Stewart, Tr. 2588).

1327. In those 20 hours, California Survey Research Services was able to complete surveys with 10 companies. (Stewart, Tr. 2588).

1328. The pilot survey indicated that there is variability in perceptions of biodegradation even amongst the sophisticated ECM purchasers. (Stewart, Tr. 2588).

1329. The pilot survey was conducted in accordance with the principles necessary for a sound survey. (Stewart, Tr. 2589–90).

1330. The pilot survey indicated that the respondents appear to be more knowledgeable of particular standards or of the Green Guides than the typical consumer. (Stewart, Tr. 2590).

1331. Dr. Stewart's survey first concluded that while consumers do have a conceptual understanding of what biodegradability is, that understanding is not material to any sizable minority of consumers. (RX 856 (Stewart, Rep. at 24)).

1332. Dr. Stewart's survey also concluded that 68% of the respondents recognize differences in the rate of decomposition depending on the type of material or the context. (RX 856 (Stewart, Rep. at 25)).

1333. The results also made very clear that the vast majority of consumers have an understanding that the process of biodegradability is highly varied and that it is not often a rapid process. (Stewart, Tr. 2814; RX 856 (Stewart, Rep. at 25–26)).

1334. Ninety-eight percent of respondents to Dr. Stewart's survey believe that different types of products take different amounts of time to biodegrade, decompose, or decay. (Stewart, Tr. 2577; RX 856 (Stewart, Rep. at 26)).

1335. Such differences, according to the respondents, include the type or size of the material, the context, or the environment. (Stewart, Tr. 2577–78; RX-856 (Stewart, Rep. at 26)).

1336. Consumers recognize significant time variances in decomposition, and that there is little evidence that their understanding of the term biodegradability is restricted to decomposition processes that occur within one year or less. (RX 856 (Stewart, Rep. at 26)).

1337. As for the questions in Dr. Stewart's survey which incorporated ECM's claims made to industrial purchasers, Dr. Stewart found that a common response included a lack of understanding, expressions of confusion, expressions of skepticism or disbelief, or a simple restatement of the claim. (RX 856 (Stewart, Rep. at 26)).

1338. Dr. Stewart concluded that "this lack of understanding, confusion, and skepticism make it highly unlikely that [ECM's] claims would be material" to an end use consumer, even if these claims were directed right at the end use consumer. (RX 856 (Stewart, Rep. at 26)).

1339. Dr. Stewart's further concluded that two of three criteria required for a finding of deception, a false belief attributable to actions of the marketer and that the claim be material to consumers, are not present in ECM's alleged advertising. (RX 856 (Stewart, Rep. at 27)).

1340. Dr. Stewart also conducted a limited Manufacturers Pilot Survey in an attempt to ascertain whether more knowledgeable purchasers have a more common understanding of biodegradability. (Stewart, Tr. 2578; RX 56 (Stewart, Rep. at 27–28)).

1341. ECM provided Dr. Stewart a list of representatives from customer organizations who were involved in the purchase of materials for the manufacturer of plastics. (RX 856 (Stewart, Rep. at 27)).

1342. Representatives from 10 of ECM's customers participated in the pilot survey of manufacturers of plastic, which was also implemented by CSRS. (RX 856 (Stewart, Rep. at 26–27)).

1343. The pilot survey of manufacturers of plastics concluded that even among these more knowledgeable and sophisticated customers there is substantial variation in opinions about how quickly a biodegradable product should take to decompose. (Stewart, Tr. 2590; RX 856 (Stewart, Rep. at 27)).

1344. The reason the pilot survey of manufacturers of plastics was not developed into a full-blown study is because the respondents were people who were difficult to contact, and in 20 hours of interviewing time, CSRS was only able to conduct interviews of 10 respondents. (Stewart, Tr. 2806).

IX. ECM ACCURATELY DEFINED "BIODEGRADABILITY" IN ITS MATERIALS GIVEN TO CONSUMERS

1345. ECM issues a certificate of biodegradability to its customers once they have completed product trials and signed a letter of assurance. (Sinclair, Tr. 783).

1346. The letter of assurance states that they understand the manufacturing process of their plastics with the additive, they understand the additive must be loaded at a minimum of one percent (1%) by weight, and that failing to meet the load rate requirement may endanger the biodegradability of their plastic. (Sinclair, Tr. 783).

1347. Every ECM certificate of biodegradability includes the ASTM definition of "biodegradability." (Sinclair, Tr. 783–84; CCX 14).

1348. The ASTM D883-12 definition of biodegradability is:

> "A degradable plastic is defined as a plastic that is designed to undergo a significant change in its chemical structure under specific environmental conditions resulting in a loss of some properties that may vary as measured by standard test methods appropriate to the plastic and the application in a period of time that determines its classification. A Biodegradable Plastic is defined as a degradable plastic in which the degradation results from the action of naturally occurring microorganisms such as bacteria, fungi and algae."

(Sinclair, Tr. 785; CCX 14).

1349. ECM provides a "certificate of biodegradability" to each of its customers. (Sinclair, Tr. 783).

1350. ECM's certificate of biodegradability defines biodegradability. (Sinclair, Tr. 784; CCX 14).

1351. ECM's certificate of biodegradability defines a degradable plastic in the same way as biodegradability is defined in ASTM D883-12. (Sinclair, Tr. 785; CCX 14).

1352. ECM's certificate of biodegradability defines a degradable plastic "as a plastic that is designed to undergo a significant change in its chemical structure under specific environmental conditions resulting in a loss of some properties that may vary as measured by standard test methods appropriate to the plastic and the application in a period of time that determines its classification. A Biodegradable plastic is defined as a degradable plastic in which the degradation results from the action of naturally occurring microorganisms such as bacteria, fungi, and algae." (Sinclair, Tr. 785; CCX 14).

X. DR. MCCARTHY IS BIASED, INCONSISTENT, AND NOT CREDIBLE

1353. Dr. McCarthy's Ph.D. is in macromolecular science, and not polymer engineering. (McCarthy, Tr. 480–81).

1354. Dr. McCarthy does not have a graduate level degree in organic polymer chemistry. (McCarthy, Tr. 481).

1355. Dr. McCarthy is not a biochemist. (McCarthy, Tr. 481).

1356. Dr. McCarthy does not know about all biochemical interactions. (McCarthy, Tr. 482).

1357. Dr. McCarthy is not a microbiologist. (McCarthy, Tr. 482).

1358. Dr. McCarthy is not expert in the kinds of microorganisms that dwell in a landfill. (McCarthy, Tr. 482).

1359. Dr. McCarthy is not an expert in the colonization of microorganisms that form in landfills. (McCarthy, Tr. 482).

1360. Dr. McCarthy's expert report was the result of a collaborative effort between Dr. McCarthy and Complaint Counsel. (McCarthy, Tr. 482–83).

1361. When Dr. McCarthy was asked "can you identify for me the content in footnote 1 that you yourself drafted?" He stated "probably the scientific definition part of it." (McCarthy, Tr. 487).

1362. When asked if he drafted "any other part of [footnote 1]?" Dr. McCarthy said "no." (McCarthy, Tr. 487).

1363. In his expert report, Dr. McCarthy defines "biodegradable" as "mean[ing] that the entire treated plastic will completely break down and return to nature (i.e., decompose into elements found in nature) within one year after customary disposal (i.e., incinerator, landfill or recycling." (McCarthy, Tr. 484–86; CCX 891 (McCarthy, Rep. at 5 n. 1)).

1364. When asked if "Complaint Counsel asked [him] to use this definition?" Dr. McCarthy replied "Yeah. With regard to the marketing claim." (McCarthy, Tr. 485).

1365. When asked "is it true that you take the position that this is a scientific definition, that is, the definition in footnote 1?" Dr. McCarthy replied "they're equivalent." (McCarthy, Tr. 486).

1366. When asked if the "definition in footnote 1 is interchangeable with the scientific definition of 'biodegradable,'" Dr. McCarthy responded "yeah." (McCarthy, Tr. 487; CCX 891 (McCarthy, Rep. at 5 n. 1)).

1367. When asked if "under [his] expert report footnote 1 definition of the term 'biodegradable,' if 365 days after customary disposal, 99 percent of a treated plastic has completely broken down and returned to nature… but 1 percent remains, the treated plastic is not biodegradable, is it?" Dr. McCarthy replied "for that unqualified marketing claim." (McCarthy, Tr. 495-96).

1368. When further asked "but you said it's interchangeable with the scientific definition, right?" Dr. McCarthy stated **"actually, I believe I would like to change that."** (McCarthy, Tr. 496) (emphasis added).

1369. Dr. McCarthy explained this desire to change his footnote 1 definition: "Yeah. Because it would – it was – 'interchangeable' I think is a bit strong." (McCarthy, Tr. 496).

1370. Dr. McCarthy then stated that the footnote 1 definition was "just for one of the claims. That was just the first one of the claims." (McCarthy, Tr. 497).

1371. When asked "but isn't it the case that in footnote 1 you indicate that that's the definition that you're going to abide by in your expert report?" Dr. McCarthy admits "that's what it says, yeah." (McCarthy, Tr. 497).

1372. Dr. McCarthy has defined the term "biodegradable" or "biodegradation" in articles he has authored. (McCarthy, Tr. 487–88).

1373. When Dr. McCarthy has defined the "biodegradable" or "biodegradation" in articles he has authored, that definition has always been different than the definition he used in his expert report. (McCarthy, Tr. 488).

1374. Dr. McCarthy authored a chapter entitled "Biodegradable Polymers" in the text entitled "Plastics and the Environment." (McCarthy, Tr. 489; RX 924).

1375. In his chapter entitled "Biodegradable Polymers," Dr. McCarthy stated that "[t]he definition of biodegradable polymer varies greatly among scientists, manufacturers, and consumers." (McCarthy, Tr. 489–90; RX 924).

1376. No definition Dr. McCarthy has ever used in published scientific literature included a requirement that plastic completely break down and return to nature within one year of customary disposal in a landfill. (McCarthy, Tr. 494).

1377. The ASTM does not define biodegradable to mean that there will be a complete breakdown and return to nature of the treated plastic within one year after customary disposal. (McCarthy, Tr. 494).

1378. As of 2003, the ASTM defined "biodegradable plastic" as a "plastic designed to undergo a significant change in its chemical structure under specific environmental conditions resulting in a loss of some properties … in which the degradation results from the action of naturally-occurring micro-organisms such as bacteria, fungi, and algae." (McCarthy, Tr. 494–95; RX 924).

1379. In scientific articles, Dr. McCarthy has described plastic as "biodegradable" when it biodegraded, in Dr. McCarthy's own tests, to far less than one hundred percent. (McCarthy, Tr. 499).

1380. According to Dr. McCarthy, a banana is biodegradable. (McCarthy, Tr. 506).

1381. According to Dr. McCarthy, a tree trunk is biodegradable. (McCarthy, Tr. 508–09).

1382. Dr. McCarthy is the editor of the Journal of Polymers and the Environment, formerly the Journal of Polymer Degradation. (McCarthy, Tr. 509).

1383. Dr. McCarthy evaluates the scientific merits of articles published in the Journal of Polymers and the Environment. (McCarthy, Tr. 510).

1384. Dr. McCarthy decides which articles are published in the Journal of Polymers and the Environment. (McCarthy, Tr. 511).

1385. No article would appear in the Journal of Polymers and the Environment without Dr. McCarthy's approval. (McCarthy, Tr. 513).

1386. Dr. McCarthy edits and determines which articles are published in the Journal of Polymers and the Environment. (McCarthy, Tr. 527).

1387. Dr. McCarthy reviewed an article entitled "Biodegradable Polymers-A Review on Recent Trends and Emerging Perspectives" that was published in the Journal of Polymers and the Environment in June of 2011. (McCarthy, Tr. 511–12; RX 925).

1388. In "Biodegradable Polymers-A Review on Recent Trends and Emerging Perspectives," published in the Journal of Polymers and the Environment, the authors state that "[t]he various definitions of biodegradation depend on the field of application of the polymers (biomedical area or natural environment). Many different definitions have officially been adopted, depending on the background of the defining standard organizations and their particular interests." (McCarthy, Tr. 527–28; RX 925).

1389. In "Biodegradable Polymers-A Review on Recent Trends and Emerging Perspectives" the authors list a serious of sources for the definition of "biodegradable" and "biodegradation" that are within the universe of biomedical and the natural environment literature. (McCarthy, Tr. 528; RX 925).

1390. Dr. McCarthy, even though he evaluated the scientific merits of "Biodegradable Polymers-A Review on Recent Trends and Emerging Perspectives" before allowing it in the Journal of Polymers and the Environment, did not ask the authors of that article to include with the definition of biodegradation the requirement that the plastic completely break down and return to nature within one year of customary disposal. (McCarthy, Tr. 529).

1391. No reviewer who reviewed "Biodegradable Polymers-A Review on Recent Trends and Emerging Perspectives" prior to publication changed the content of the article to require it to include that plastic will completely break down and return to nature within one year of customary disposal. (McCarthy, Tr. 529).

1392. During his deposition, Dr. McCarthy testified that a product that biodegraded 95 percent in 364 days would not satisfy the definition of biodegradable Dr. McCarthy uses in his expert report. (McCarthy, Tr. 525–26; RX 841 (McCarthy, Dep. at 28)).

1393. According to Dr. McCarthy, a product that biodegraded by 95 percent in 365 days, and 100 percent in 366 days is not biodegradable under the definition he uses in his expert report. (McCarthy, Tr. 526).

1394. At hearing, when asked "who makes the determination of whether [an article] is accepted for publication?" Dr. McCarthy testified: "the referees." (McCarthy, Tr. 526).

1395. However, at deposition, when asked the same question, Dr. McCarthy testified to the contrary, stating: "it would be my decision, but it would be based on reviews." (McCarthy, Tr. 526–27; RX 841 (McCarthy, Dep. at 38)).

1396. Dr. McCarthy has accepted, on behalf of UMass, millions of dollars in funding from ECM competitors that offer bioplastics and compostable products. (CCX 891 (McCarthy, Rep. at 42–44)).

1397. Some polymer blends which Dr. McCarthy invented are the subject of a United States patent, patent number 5,883,199. (McCarthy, Tr. 534–35; RX 928).

1398. Dr. McCarthy has directly profited from research he performed for ECM competitors, receiving $4,000-$5,000 per year in royalties from a patent he invented that is licensed to Metabolix, an ECM competitor. (McCarthy, Tr. 523–24; RX 841 (McCarthy, Dep. at 60)).

1399. UMass is patent number 5,883,199's assignee. (RX 761; RX 757).

1400. Dr. McCarthy directly profits from compostable plastic resin patent royalties paid to UMass. (McCarthy, Tr. 524).

1401. Metabolix Corporation is the exclusive licensee of a patented biodegradable polymer that Dr. McCarthy invented. (McCarthy, Tr. 523;RX 209; RX 928).

1402. Metabolix's potential royalties from licensing UMass patents surpass $100,000 per year. (RX 209).

1403. Dr. McCarthy receives royalties from the patent he invented for which Metabolix Corporation is the exclusive licensee. (McCarthy, Tr. 524).

1404. As of the date of the hearing, Dr. McCarthy had received about $28,000.00 in royalties as a result of the patent he invented for which Metabolix Corporation is the exclusive licensee. (McCarthy, Tr. 524, 612).

1405. To the extent Metabolix's sales increase based on incursions into ECM's market, royalties from the patent will increase and Dr. McCarthy's income from those royalties will increase as well. (McCarthy, Tr. 524; RX 841 (McCarthy, Dep. at 51–52, 55–61)).

1406. Dr. McCarthy has appeared as an expert for Metabolix Corporation twice. (McCarthy, Tr. 523-24).

1407. UMass-Lowell has boasted of Dr. McCarthy's income earning potential, noting in 2012 that Dr. McCarthy "has obtained nearly $9 million in externally sponsored research grant and contracts, plus nearly $33 million in intellectual property donations to UMass Lowell." (Aguirre, "Plastics Engineering Educator Praised for Research, Service" (Sep. 21, 2012), *available at* http://www.uml.edu/News/stories/2011-12/University-Professor-reception.aspx). (McCarthy, Tr. 530-532).

1408. Under an agreement with the University and in accordance with UMass policy, Dr. McCarthy assigned his patent rights in a compostable plastic resin he invented to UMass. (McCarthy, Tr. 523–24; RX 841 (McCarthy, Dep. at 57)).

1409. In exchange, Dr. McCarthy receives a 10% profit share of the royalty stream. (McCarthy, Tr. 523–24, 535; RX 841 (McCarthy, Dep. at 59)).

1410. The intention of patent number 5,883,199 is to produce compostable products. (McCarthy, Tr. 536).

1411. The companies which Metabolix Corporation sublicense patent number 5,883,199 to, such as BASF and NatureWorks, produce resin that is used in compostable products. (McCarthy, Tr. 536).

1412. Dr. McCarthy acknowledged that Metabolix's products compete directly with ECM's technology for market share. (McCarthy, Tr. 538–408; RX 841 (McCarthy, Dep. 64–66)).

1413. For years ECM's competitors, such as Metabolix, have directly lobbied FTC attorneys to pursue enforcement action against additive companies, including ECM. (RX 211).

1414. Since 2008, Metabolix has also been lobbying the FTC to act against ECM. (RX 211).

1415. Metabolix is also a member of the Biodegradable Products Institute ("BPI"), a primary ECM competitor, and sells approximately a dozen products that are "BPI certified" in direct competition with ECM. (McCarthy, Tr. 564; RX 171; RX 172).

1416. Groups like the BPI, and scientists affiliated with same, zealously lobbied the ASTM to incorporate limited language in biodegradability test standards that would (unscientifically) limit *claim language* based on test results. (RX 741).

1417. Representatives from BPI had open channels to FTC attorneys and frequently reported marketing claims by additive companies, such as ECM and ECM's customers. (RX 718–RX 733).

1418. BPI not only lobbied in favor of regulations that would hurt the biodegradable plastic additive industry, but it also told customers that ECM plastics are not truly biodegradable according to their standards of testing. (RX 124).

1419. BPI harshly and publicly criticized biodegradable additive manufacturers, naming ECM specifically. (RX 125).

1420. Many companies that have funded Dr. McCarthy's UMass Lowell Bioplastics and Medical Plastics Research Center, such as Cargill and Eastman Chemical, are members of the BPI. (McCarthy, Tr. 531; RX 169).

1421. The BPI has hired Dr. McCarthy to be a compostable product certifier. (McCarthy, Tr. 564).

1422. From 2001 through 2011, Dr. McCarthy was paid by the BPI one thousand dollars for each of about thirty certification examinations he completed. (McCarthy, Tr. 564).

1423. At the hearing and at his deposition, Dr. McCarthy testified that his determination would result in either a certification or not certified determination. (McCarthy, Tr. at 564–65; RX 841 (McCarthy, Dep. at 93)).

1424. If Dr. McCarthy certified a company as compostable, that company was then allowed to place a logo or other form of certification on its products. (McCarthy, Tr. 565–66).

1425. At the hearing, when asked what that certification or logo provides, Dr. McCarthy testified: "I don't know." (McCarthy, Tr. 566).

1426. However, at deposition, when asked the same question, Dr. McCarthy testified differently: "[i]t provides a certification that it meets the standards of the D6400" and that it is "compostable." (McCarthy, Tr. 566; RX 841 (McCarthy, Dep. at 94)).

1427. Metabolix supplied grants to UMass of approximately $2.5 million, sponsored more than 50 students for their master's and doctorate degrees, and has made substantial equipment donations (over $500,000) to UMass Lowell. (RX 210).

1428. Dr. McCarthy is the director of the UMass Lowell Bioplastics and Medical Plastics Research Center. (McCarthy, Tr. 529–30).

1429. Companies that have sponsored research at the UMass Lowell Bioplastics and Medical Plastics Research Center include ICI, Monsanto, National Starch, Eastman, Warner-Lambert, Bristol-Myers Squibb, Johnson & Johnson, Metabolix, BASF, and Cargill, the U.S. Army, EcoVerde, 3M Company, and Densified Solutions. (McCarthy, Tr. 531).

1430. Metabolix Corporation essentially leased storage space from UMass Lowell. (McCarthy, Tr. 599–601; RX 962).

1431. Metabolix Corporation donated an air compressor to UMass Lowell in order to offset costs incurred by the university. (McCarthy, Tr. 602–03; RX 963).

1432. If Metabolix goes out of business, Dr. McCarthy hopes that the university would license patent number 5,883,199 to another institution. (McCarthy, Tr. at 606).

1433. Metabolix has paid up to $200,000 per year to UMass-Lowell for fee-for-service projects. (McCarthy, Tr. 612–13).

1434. Metabolix has paid the most money to the UMass Lowell Bioplastics and Medical Plastics Research Center. (McCarthy, Tr. 531).

1435. Metabolix has paid approximately one and a half million dollars in grants to Dr. McCarthy's university. (McCarthy, Tr. 531–32).

1436. Metabolix has also reimbursed UMass Lowell for equipment purchased by UMass Lowell which Metabolix wanted to use. (McCarthy, Tr. 532).

1437. Metabolix employees have worked alongside Dr. McCarthy and his students at the UMass Lowell Bioplastics and Medical Plastics Research Center. (McCarthy, Tr. 532, 608–09).

1438. Dr. McCarthy's students are available to Metabolix to work for Metabolix as requested by Metabolix to Dr. McCarthy's secretary. (McCarthy, Tr. 532, 608–09).

1439. When Dr. McCarthy's students are working for Metabolix, Metabolix has an employee that oversees Dr. McCarthy's students to ensure that the conditions of the work being performed by Dr. McCarthy's students are the conditions that Metabolix wants. (McCarthy, Tr. 533).

1440. The Metabolix employees take notes and give advice to Dr. McCarthy's students while Dr. McCarthy's students perform the work required by Metabolix. (McCarthy, Tr. 533).

1441. When Dr. McCarthy's students are performing the work requested by Metabolix, Dr. McCarthy's students are being paid indirectly by Metabolix. (McCarthy, Tr. 533–34).

1442. Students at UMass Lowell use UMass Lowell equipment for services for Metabolix. (McCarthy, Tr. 604).

1443. At the hearing, when asked whether "the products made under the '199 patent that are on the market are plastic compost bags, right?" Dr. McCarthy testified: "I'm not sure." (McCarthy, Tr. 536).

1444. At deposition, when asked the same question, Dr. McCarthy testified to the contrary, stating: "mainly compostable–compost bags." (McCarthy, Tr. 537; RX 841 (McCarthy, Dep. at 63–64)).

1445. According to Dr. McCarthy, compostable bags are in competition with compostable biodegradable bags. (McCarthy, Tr. 538).

1446. According to Dr. McCarthy, NatureWorks' product, produced under patent number 5,883,199, is in competition with other compostable and biodegradable products in the market. (McCarthy, Tr. 538–39; RX 841 (McCarthy Dep. at 65–66)).

1447. According to Dr. McCarthy, NatureWorks' product exists in a competitive marketplace. (McCarthy, Tr. 539–40; RX 841 (McCarthy Dep. at 65–66).

1448. Dr. McCarthy admitted that the patent he invented is used by Metabolix which competes with ECM for business in the biodegradable plastic bag market. (McCarthy, Tr. 537-540).

1449. In patent number 5,883,199, the test Dr. McCarthy used to demonstrate biodegradation of the polymer blends he invented was not an ASTM standard. (McCarthy, Tr. 540–41; RX 928).

1450. In Dr. McCarthy's expert report, he states that biodegradation may only be shown based on satisfaction of either an ASTM standard specification test or a positive ^{14}C radiolabeling test. (CCX 891 (McCarthy, Rep. at 23-4)).

1451. In patent number 5,883,199, the test Dr. McCarthy used to demonstrate biodegradation of the polymer blends he invented was a method used at UMass Lowell which is not an ASTM method. (McCarthy, Tr. 541; RX 928).

1452. In Dr. McCarthy's expert report, he states that the only definitive test of biodegradation, other than an ASTM standard specification test, is a ^{14}C radiolabeling test. (CCX 891 (McCarthy, Rep. at 24)).

1453. In patent number 5,883,199, the test Dr. McCarthy used to demonstrate biodegradation of the polymer blends he invented did not use any ^{14}C radiolabeling. (McCarthy, Tr. 541–43; RX 928; RX 841 (McCarthy, Dep. at 75).

1454. Patent number 5,883,199 does not contain a requirement that polymer blends biodegrade 100%. (McCarthy, Tr. 543; RX 928).

1455. In Dr. McCarthy's expert report, he states that a claim of biodegradation for a plastic may only be made if the plastic biodegrades 100% within one year: "the entire treated plastic will completely break down and return to nature (i.e., decompose into elements found in nature) within one year after customary disposal (i.e., incinerator, landfill, or recycling)." (CCX 891 (McCarthy, Rep. at 5)).

1456. However, at hearing, when asked "nowhere in the patent do you establish that any of the five plastic resins you invented completely break down and return to nature, that is, decompose into elements found in nature within one year after customary disposal?" Dr. McCarthy states "yeah, that's correct." (McCarthy, Tr. 544; RX 928).

1457. In Dr. McCarthy's expert report, he defines biodegradation in footnote 1 of the report as "the entire treated plastic will completely break down and return to nature (i.e., decompose into elements found in nature) within one year after customary disposal (i.e., incinerator, landfill, or recycling)." (CCX 891 (McCarthy, Rep. at 5)).

1458. Dr. McCarthy did not test the polymer blends in patent number 5,883,199 to establish that they would biodegrade completely within one year after customary disposal. (McCarthy, Tr. 545–46; RX 841 (McCarthy, Dep. at 76–77)).

1459. Patent number 5,883,199 is not limited to the five polymer blends tested in patent number 5,883,199. (McCarthy, Tr. 547; RX 928).

1460. In Dr. McCarthy's expert report, he states that it is scientifically invalid to extrapolate from plastics that are the subject of ASTM tests to those that were not subject to the tests: "Such extrapolation is scientifically invalid because biodegradation is not linear and typically slows down due to recalcitrance." (CCX 891 (McCarthy, Rep. at 27)).

1461. However, Dr. McCarthy extrapolated from the five blends tested in patent number 5,883,199 to classify additional blends not tested as biodegradable. (McCarthy, Tr. 549–50; RX 928).

1462. In Dr. McCarthy's expert report, he states that a plastic may not be deemed "biodegradable" unless it biodegrades by 100%. (CCX 891 (McCarthy, Rep. at 5)).

1463. However, at trial, when asked whether the "'polylactic acid degraded by only 14 percent by loss in weight;' right?" Dr. McCarthy replied "that would be after 45 days in soil. Yeah." (McCarthy, Tr. 547–48; RX 928).

1464. Although patent number 5,883,199 tested only five blends, the patent applies to many more blends. (McCarthy, Tr. 548; RX 928).

1465. Dr. McCarthy reviewed each specification in patent number 5,883,199 and signed a declaration affirming the validity of each specification before submitting patent number 5,883,199 to the United States Patent and Trademark Office. (McCarthy, Tr. 548).

1466. Dr. McCarthy extrapolated from the five blends tested in patent number 5,883,199 to classify additional blends not tested as biodegradable. (McCarthy, Tr. 549–50; RX 928).

1467. In patent number 5,883,199 Dr. McCarthy ran test method UML-7645 for 45 days to determine the biodegradability of polymer blends. (McCarthy, Tr. 554; RX 928).

1468. In patent number 5,883,199 Dr. McCarthy claims that PET mixed with PLA is biodegradable. (McCarthy, Tr. 555; RX 928).

1469. According to Dr. McCarthy, PET is not biodegradable. (McCarthy, Tr. 557).

1470. In his expert report, Dr. McCarthy wrote that a study to determine whether something is biodegradable "must last long enough for the sample to reach at least 60 percent biodegradation." (McCarthy, Tr. 558; CCX 891 (McCarthy, Rep. at 15)).

1471. However, the studies Dr. McCarthy conducted in patent number 5,883,199 did not last long enough for blends to reach at least 60 percent biodegradation, even though Dr. McCarthy identified those blends as biodegradable. (RX 928).

1472. In his expert report, Dr. McCarthy wrote that a study to determine whether something is biodegradable must have a negative control. (McCarthy, Tr. 559; CCX 891 (McCarthy, Rep. at 16)).

1473. At hearing, Dr. McCarthy testified, in response to the question of whether he specifies a negative control anywhere in patent number 5,888,139, that "[a]gain that wasn't to prove that it's biodegradable." (McCarthy, Tr. 559).

1474. However, at deposition, in response to the same question, Dr. McCarthy testified to the contrary, stating: "I don't believe there's a negative control mentioned in the patent." (McCarthy, Tr. 560; RX 928; RX 841 (McCarthy, Dep. at 85)).

1475. In his expert report, Dr. McCarthy argues that extrapolation from a short test to the conclusion that a polymer is biodegradable in the environment is improper. (McCarthy, Tr. 560–61; CCX 891 (McCarthy, Rep. at 22)).

1476. However, the only test Dr. McCarthy reported in patent number 5,883,199 is a 45 day test used to determine that certain polymer blends are biodegradable. (McCarthy, Tr. 561; RX 928).

1477. Dr. McCarthy's position, at least as outlined in his expert report, is that "absent an approved ASTM specification, it is [his] opinion that to scientifically prove a claim that the plastic—not merely the additive and inoculum—is biodegrading, the claimant must support its claim with at least one test with positive results from 14C labeling of the conventional plastic." (McCarthy, Tr. 562; CCX 891 (McCarthy, Rep. at 24)).

1478. However, Dr. McCarthy does not reference any 14C radio labeling testing in patent number 5,888,139. (McCarthy, Tr. 562–63; RX 928).

1479. Dr. McCarthy has never performed any 14C radio labeling testing in any biodegradation experiments he has performed at UMass Lowell. (McCarthy, Tr. 563).

1480. Dr. McCarthy has not informed the United State Patent and Trademark Office of the definition of "biodegradation" or "biodegradable" that is in footnote 1 of his expert report that he identifies as interchangeable with the scientific definition. (McCarthy, Tr. 563–64).

1481. Dr. McCarthy criticizes ECM testing materials for allegedly conflating the concepts of disintegration or degradation with biodegradation. (McCarthy, Tr. 566–68).

1482. However, when asked "is it possible for the two processes, that is, degradation and biodegradation, to be inextricably intertwined?" Dr. McCarthy said, "I mean, they're separate processes. You mean if they occur at similar times or…" (McCarthy, Tr. 567).

1483. McCarthy then admitted that he "know[s] of some instances like the biodegradation of polylactic acid" where the processes of degradation and biodegradation are inextricably intertwined. (McCarthy, Tr. 568).

1484. Dr. McCarthy states that it is possible that a first stage process of biodegradation would be depolymerization of the macromolecules into shorter chains that are then made biodegradable. (McCarthy, Tr. 568).

1485. Furthermore, according to Dr. McCarthy extracellular enzymes and/or coenzymes and abiotic reactions are responsible for polymeric chain cleavage. (McCarthy, Tr. 569).

1486. Dr. McCarthy did not provide any specific citations in support of his opinions in paragraphs 25 and 27 of his expert report. (McCarthy, Tr. 569–70; RX 841 (McCarthy, Dep. at 106); CCX 891 (McCarthy, Rep. at 9)).

1487. Dr. McCarthy cites to no source at all for the proposition stated in his expert report that there is "overwhelming scientific consensus that conventional plastics are not biodegradable after customary disposal." (CCX 891 (McCarthy, Rep. at 13)).

1488. At deposition, Dr. McCarthy referred to RX 924 as peer reviewed support for the proposition that there is "overwhelming scientific consensus that conventional plastics are not biodegradable after customary disposal." (McCarthy, Tr. 570; RX 841 (McCarthy, Dep. at 112–13)).

1489. At hearing, however, when asked whether RX 924 was peer reviewed, Dr. McCarthy testified to the contrary, stating: "Right. It wasn't officially peer-reviewed." (McCarthy, Tr. 571–73).

1490. At hearing, when asked "you are familiar with peer-reviewed scientific publications that conclude that indeed conventional plastics are biodegradable, right?" Dr. McCarthy testified: "I'm not sure." (McCarthy, Tr. 573–74).

1491. However, at deposition, when asked the same question, Dr. McCarthy testified to the contrary, stating: "[t]here are publications concerning polyethylene … [and] there are some on polypropylene … [and] one on PET." (McCarthy, Tr. 574–75; RX 841 (McCarthy, Dep. at 115)).

1492. Despite being aware of peer-reviewed publications that conclude that conventional plastics can biodegrade, Dr. McCarthy failed to provide any qualification in his expert report regarding his statement that there is "overwhelming scientific consensus that conventional plastics are not biodegradable after customary disposal." (McCarthy, Tr. 575–76; CCX 891 (McCarthy, Rep. at 13)).

1493. Dr. McCarthy admits that that there is a particular strain of fungi that biodegrades petroleum-based plastic. (McCarthy, Tr. 577; CCX 891 (McCarthy, Rep. at 29 n. 20)).

1494. In footnote 20 to his expert report, Dr. McCarthy stated without citation to a source that there was no evidence that a fungi that biodegrades petroleum-based plastic existed in the United States. (CCX 891 (McCarthy, Rep. at 29)).

1495. At hearing, however, Dr. McCarthy admitted that he knows of no peer-reviewed article concluding that the strain of fungi that biodegrades petroleum-based plastic does not exist in the United States. (McCarthy, Tr. 577).

1496. Dr. McCarthy authored an article entitled “Advances in Properties and Biodegradability of Co-Continuous, Immiscible, Biodegradable, Polymer Blends.” (McCarthy, Tr. 577–78; RX 940).

1497. In “Advances in Properties and Biodegradability of Co-Continuous, Immiscible, Biodegradable, Polymer Blends, Dr. McCarthy measured the biodegradability with the Proteinase K,” Dr. McCarthy explains testing on the soil and the composting for the blends which are the basis for patent number 5,883,199. (McCarthy, Tr. 578; RX 940).

1498. In measuring biodegradability of polymer blends in “Advances in Properties and Biodegradability of Co-Continuous, Immiscible, Biodegradable, Polymer Blends,” Dr. McCarthy did not use 14C radiolabeling testing. (McCarthy, Tr. 578–79; RX 940).

1499. In measuring biodegradability of polymer blends in “Advances in Properties and Biodegradability of Co-Continuous, Immiscible, Biodegradable, Polymer Blends,” Dr. McCarthy did not rely on an ASTM standard testing method. (McCarthy, Tr. 579; RX 940).

1500. In measuring biodegradability of polymer blends in “Advances in Properties and Biodegradability of Co-Continuous, Immiscible, Biodegradable, Polymer Blends,” Dr. McCarthy used his university’s own testing method. (McCarthy, Tr. 579; RX 940).

1501. In “Advances in Properties and Biodegradability of Co-Continuous, Immiscible, Biodegradable, Polymer Blends,” Dr. McCarthy concluded that certain test samples were biodegradable without proving that the samples completely biodegraded within one year after customary disposal. (McCarthy, Tr. 582; RX 940).

1502. Dr. McCarthy authored an article entitled “Biodegradable Polymer Blends of Poly(lactic acid) and Poly(ethylene glycol).” (McCarthy, Tr. 583; RX 941).

1503. In “Biodegradable Polymer Blends of Poly(lactic acid) and Poly(ethylene glycol),” Dr. McCarthy measured enzymatic degradation based solely on a weight loss calculation. (McCarthy, Tr. 583–84).

1504. In “Biodegradable Polymer Blends of Poly(lactic acid) and Poly(ethylene glycol),” Dr. McCarthy measured enzymatic biodegradation without using an ASTM standard. (McCarthy, Tr. 584).

1505. In “Biodegradable Polymer Blends of Poly(lactic acid) and Poly(ethylene glycol),” Dr. McCarthy measured enzymatic biodegradation without using any 14C radiolabeling testing. (McCarthy, Tr. 584).

1506. Dr. McCarthy co-authored an article entitled “Degradation Ranking of Plastics in a Landfill Environment.” (McCarthy, Tr. 585; RX 942).

1507. In “Degradation Ranking of Plastics in a Landfill Environment,” Dr. McCarthy did not use 14C radiolabeling testing. (McCarthy, Tr. 858; RX 942).

1508. In “Degradation Ranking of Plastics in a Landfill Environment,” Dr. McCarthy used weight loss to measure degradability. (McCarthy, Tr. 858; RX 942).

1509. In “Degradation Ranking of Plastics in a Landfill Environment,” Dr. McCarthy did not use any ASTM method to determine degradability. (McCarthy, Tr. 858; RX 942).

1510. In “Degradation Ranking of Plastics in a Landfill Environment,” Dr. McCarthy evaluated the appearance of samples to determine if they looked weathered. (McCarthy, Tr. 858; RX 942).

1511. Dr. McCarthy authored an article entitled “Biodegradable Blends of Bacterial Polyesters with Polyethylene and Polystyrene.” (McCarthy, Tr. 586; RX 945).

1512. No author of “Biodegradable Blends of Bacterial Polyesters with Polyethylene and Polystyrene” established that the polyethylene and polystyrene blends tested completely break down and return to nature within one year after customary disposal. (McCarthy, Tr. 586; RX 945).

1513. Dr. McCarthy co-authored an article entitled “The Effect of Hyperbranched Polymers on Processing and Thermal Stability of Biodegradable Polyesters.” (McCarthy, Tr. 587; RX 946).

1514. In “The Effect of Hyperbranched Polymers on Processing and Thermal Stability of Biodegradable Polyesters,” Dr. McCarthy characterized polyhydroxybutyrate as wholly biodegradable. (McCarthy, Tr. 587; RX 946).

1515. At hearing, when asked if the authors of “The Effect of Hyperbranched Polymers on Processing and Thermal Stability of Biodegradable Polyesters” established that polyhydroxybutyrate completely decomposed into elements found in nature within one year after customary disposal, Dr. McCarthy testified: “I believe that was demonstrated.” (McCarthy, Tr. 587).

1516. However, at deposition, when asked the same question, Dr. McCarthy testified to the contrary, stating: “No.” (McCarthy, Tr. 589; RX 841 (McCarthy, Dep. at 180)).

1517. Dr. McCarthy co-authored an article entitled “Microwave-Assisted Solvent-Free or Aqueous-Based Synthesis of Biodegradable Polymers.” (McCarthy, Tr. 591–92; RX 948).

1518. At hearing, when asked “does the article [“Microwave-Assisted Solvent-Free or Aqueous-Based Synthesis of Biodegradable Polymers”] establish that the polymers would biodegrade such that they would break down and return to nature, decomposing into elements found in nature within one year after customary disposal?” Dr. McCarthy testified: “Yes.” (McCarthy, Tr. 590).

1519. However, at deposition, when asked the same question, Dr. McCarthy testified to the contrary, stating: "No." (McCarthy Tr. 592; RX 841 (McCarthy, Dep. at 185)).

1520. At hearing, when asked "does all paper completely break down and return to nature, that is, decompose into elements found in nature within one year of customary disposal?" Dr. McCarthy testified: "Yeah. I think so." (McCarthy, Tr. 592–93).

1521. However, at deposition, when asked the same question, Dr. McCarthy testified to the contrary, stating: "No." (McCarthy, Tr. 593; RX 841 (McCarthy, Dep. at 185)).

1522. According to Dr. McCarthy, a tree trunk is biodegradable if it does not completely return to elements found in nature within one year after customary disposal. (McCarthy, Tr. 594).

1523. According to Dr. McCarthy, an orange peel is biodegradable if it does not return to elements in nature within one year after customary disposal. (McCarthy, Tr. 594).

1524. Dr. McCarthy cannot name each species of microbial life that dwell in a landfill. (McCarthy, Tr. 594).

1525. Dr. McCarthy cannot explain the life cycle of all species of microbial life that dwell in a landfill. (McCarthy, Tr. 594).

1526. Dr. McCarthy cannot identify all the stimuli that cause microbial life forms to produce enzymes. (McCarthy, Tr. 594).

1527. There is a Fee-for-Service Agreement between UMass Lowell and Metabolix. (McCarthy, Tr. 595; RX 961).

1528. The Fee-for-Service Agreement between UMass Lowell and Metabolix lists Dr. McCarthy as the principal investigator. (McCarthy Tr. 595–96; RX 961).

1529. According to Dr. McCarthy, it is not necessary from a scientific perspective that "biodegradation" means only that substances break down into single elements. (McCarthy, Tr. 597).

1530. According to Dr. McCarthy, PET is a homopolymer. (McCarthy, Tr. 597–98).

1531. Patent number 5,883,199 allows a blend of a homopolymer to be biodegradable. (McCarthy, Tr. 598; RX 928).

1532. Dr. McCarthy tailored his opinion in this matter to meet Complaint Counsel's needs, even accepting the fundamental definition of what "biodegradation" means from Complaint Counsel, despite contrary representations in his own scientific articles and in his own patent. (McCarthy, Tr. 485–87, 488, 494).

1533. Dr. McCarthy testified that he prepared his expert report as a "collaborative effort between [himself] and complaint counsel." (McCarthy, Tr. 487; RX 841 (McCarthy, Dep. at 20)).

1534. Email correspondence from Complaint Counsel to ECM in July 2013 mirrored the content in Dr. McCarthy's expert report. (RX 593; CCX 891 (McCarthy, Expert Report)).

1535. Dr. McCarthy's expert report stated that radiological marker ^{14}C testing is the only test that can dispositively prove that ECM's additive causes biodegradation of plastics, but he himself has relied on extrapolation and other tests (that neither adhere to an ASTM standard nor involve radiological markers), such as one he used at UMass., UML-7645, and measures of weight loss, to prove biodegradability of polymer products. (McCarthy, Tr. 540–42; RX 841 (McCarthy, Dep. 74–75, 148–149, 165–172)).

1536. In other materials, Dr. McCarthy was silent on the need for a product to biodegrade within a year to be biodegradable, and yet, for ECM's additive, Dr. McCarthy is adhering to the one year rule contained in FTC's Revised Green Guides in collaboration with Complaint Counsel. (McCarthy, Tr. 544–45; RX 841 (McCarthy, Dep. at 19–42)).

1537. Dr. McCarthy did not adhere to the "One-Year Rule" in his '199 patent when defining biodegradable. (McCarthy, Tr. 544–45; RX 841 (McCarthy, Dep. at 69–76); RX 928).

1538. Dr. McCarthy selectively applies the "One-Year Rule," opining that a banana peel, tree trunk, and orange peel are biodegradable despite the fact that they may not fully biodegrade within a year. (McCarthy, Tr. 503–04, 506, 508; RX 841 (McCarthy, Dep. at 185–87)).

1539. Dr. McCarthy's report states that "evidence that a substance is biodegradable is not 'competent and reliable' unless the tested sample reaches 'at least 60% biodegradation,' and there is both a 'negative control' and a 'positive control.'" (McCarthy, Tr. 558–59; RX 891 (McCarthy, Rep. at 15)).

1540. Dr. McCarthy asserts that extrapolation is prohibited under the current ASTM standards, thus 100% biodegradation in the laboratory would be required. (McCarthy, Tr. 477–78).

1541. Dr. McCarthy further asserts that he is unaware of any circumstances where extrapolation would be appropriate when assessing the biodegradability of a product. (McCarthy, Tr. 478).

1542. However, McCarthy's '199 patent made biodegradable claims even though the rate of biodegradation was lower than 60%, reaching only 14% in 45 days, and where he did not use a negative control. (McCarthy, Tr. 558–560; RX 928).

1543. Dr. McCarthy's prior research on biodegradable plastics did not meet the same 60% threshold that he now requires of ECM's additive. (RX 928). There is no consensus in the peer-reviewed literature, or any requirement whatsoever, that a gas evolution should produce 60 percent biodegradation before a test article can be deemed biodegradable. (Sahu, Tr. 1793).

1544. Complaint Counsel's experts have provided no literature or documentary evidence showing that scientists in the field require 60 percent or greater biodegradation before a product can be deemed biodegradable. (McCarthy, Tr. 359-680).

1545. Complaint Counsel's rebuttal expert, Dr. Michel, unambiguously testified that a "material that only biodegrades 44 percent to elements found in nature is biodegradable." (Michel, Tr. 2961).

1546. The fact that a plateau formed in testing conditions before the biodegradation reached sixty percent did not prevent Dr. Michel from declaring the product still biodegradable. (Michel, Tr. 2961).Although Dr. McCarthy's test data showed much less than 60% biodegradation, he extrapolated his gas evolution test data, and used it to say that the test material was fully biodegradable. (Sahu, Tr. 1894; RX 756 at 8-12).

1547. Dr. McCarthy has labeled a substrate "biodegradable" after observing just fourteen (14%) percent biodegradation in 45 days. (Sahu, Tr. 1894; RX 756 at 11).

1548. Dr. McCarthy has said that polylactic acid (PLA) is "biodegradable." According to Dr. McCarthy, "polylactic acid is a biodegradable polymer…" (RX 756 at 2; McCarthy, Tr. 376).

1549. Although Dr. McCarthy has repeatedly acknowledged that PLA is biodegradable (RX 756 at 2; McCarthy, Tr. 376), his testing revealed that PLA biodegraded only 14% after 45 days of biodegradation testing. (RX 756 at 11 (example 3)).

1550. In another of Dr. McCarthy's own composting tests, PLA degraded only 3% in 20 days. (RX 756 at 11 (example 4)).

1551. Dr. McCarthy takes the position that for any given polymer that the amorphous regions will biodegrade faster than the crystalline regions. (McCarthy, Tr. 613).

1552. Dr. McCarthy does not know whether it is possible for an amorphous polymer with extremely high molecular weight and relatively low surface area to biodegrade slower than a crystalline polymer of relatively low molecular weight and with a relatively high surface area. (McCarthy, Tr. 616–17).

1553. Dr. McCarthy's expert report makes no explicit reference to amorphous and crystalline regions of a polymer. (McCarthy, Tr. 625–26).

1554. Dr. McCarthy makes no statement whatsoever as to what percentage of a polymer is comprised of amorphous regions and what percentage of a polymer is comprised of crystalline regions. (McCarthy, Tr. 358–689; CCX 891 (McCarthy, Rep.); CCX 892 (McCarthy, Rebuttal Rep.)).

1555. Polyethylene, polypropylene, polyvinyl chloride, and polystyrene are all thermoplastics (RX 855 at 31), which have an "overall structure that is generally amorphous" (RX 855, at 15 (quoting Lampman, S., Characterization and Failure Analysis of Plastics, ASM International, 2003, p.7)).

1556. Dr. McCarthy believes that "one of the most serious flaws in the conclusion of [ECM's] experts is that once biodegradation is established, it will continue to completion." (McCarthy, Tr. 629; CCX 892 (McCarthy, Rebuttal Rep. at 9)).

1557. However, in patent number 5,883,199, Dr. McCarthy concluded that a substance that biodegraded by 25% in 45 days was biodegradable. (McCarthy, Tr. 630–34; RX 928).

1558. Dr. McCarthy co-authored an article entitled "The Influence of Injection Molding Conditions on Biodegradable Polymers." (McCarthy, Tr. 634; RX 969).

1559. In "The Influence of Injection Molding Conditions on Biodegradable Polymers," Dr. McCarthy analyzed certain polymers for their rates of biodegradation. (McCarthy, Tr. 635–36; RX 969).

1560. Dr. McCarthy believes that a biodegradation study must last long enough for the same to reach at least 60 percent biodegradation. (McCarthy, Tr. 637; RX 891 (McCarthy, Rep. at 15)).

1561. Dr. McCarthy agrees that ordinarily 60 percent biodegradation of a sample is not something that can occur in just a few minutes. (McCarthy, Tr. 637–38).

1562. In "The Influence of Injection Molding Conditions on Biodegradable Polymers," Dr. McCarthy measured rates of degradation by conducting a test that lasted five minutes. (McCarthy, Tr. 638; RX 969).

1563. Dr. McCarthy relied on the tests he reported in "The Influence of Injection Molding Conditions on Biodegradable Polymers" to draw conclusions about the biodegradability of polymers. (McCarthy, Tr. 638–39; RX 969).

1564. The testing reported in "The Influence of Injection Molding Conditions on Biodegradable Polymers" fails to demonstrate 60 percent biodegradation. (McCarthy, Tr. 639; RX 969).

1565. Dr. McCarthy believes the photodegradation is not a form of biodegradation because photodegradation is abiotic. (McCarthy, Tr. 646–47).

1566. However, in "A Review on Recent Trends and Emerging Perspectives," published in the Journal of Polymers and the Environment that Dr. McCarthy edits, the authors include abiotic degradation within a diagrammatic representation of the chemistry of biodegradation. (McCarthy, Tr. 647; RX 925).

1567. Dr. McCarthy failed, in patent number 5,883,199, to provide any data demonstrating that the addition of an aliphatic chain segment to PET would make the PET biodegradable. (McCarthy, Tr. 653–54; RX 928).

1568. Dr. McCarthy did not run any statistics for any D5511 studies on ECM plastic. (McCarthy, Tr. at 654).

1569. At hearing, Dr. McCarthy testified that if a polymer loses a chlorine ion, the polymer's overall molecular weight "will decrease… by like 1 percent." (McCarthy, Tr. 661).

1570. Then, when asked at hearing "so the molecular weight of a repeat unit of PVC is 62?" Dr. McCarthy testified: "Yeah.". (McCarthy, Tr. 663).

1571. When asked "and what is the molecular weight of a repeat unit of PVC after a loss of chlorine, Dr. McCarthy testified: "27." (McCarthy, Tr. 663).

1572. The difference between 62 and 27 is not one percent. (McCarthy, Tr. 664).

1573. Since 2003, Dr. McCarthy has not conducted any surveys of scientists, manufacturers, or consumers concerning their understanding of the meaning of "biodegradation." (McCarthy, Tr. 666).

1574. Dr. McCarthy testified that the only way to make PE biodegradable is by adding a pro-oxidant to the PE or by having the PE achieve a molecular weight of 500. (McCarthy, Tr. 666).

1575. However, in "A Review on Recent Trends and Emerging Perspectives," published in the Journal of Polymers and the Environment that Dr. McCarthy edits, the authors state that the insertion of weak links into polymers can cause biodegradation. (McCarthy, Tr. 670–71; RX 925).

1576. Furthermore, in "A Review on Recent Trends and Emerging Perspectives," published in the Journal of Polymers and the Environment that Dr. McCarthy edits, the authors state that compounding polymers with photosensitizers can cause biodegradation. (McCarthy, Tr. 672; RX 925).

1577. In "A Review on Recent Trends and Emerging Perspectives," published in the Journal of Polymers and the Environment that Dr. McCarthy edits, the authors state "the most frequently adopted approach to degradability design of [Low Density Polyethylene] LDPE has been to introduce pro-degradant additives such as starch and cellulose into synthetic polymers." (McCarthy, Tr. 673–74; RX 925).

1578. Dr. McCarthy failed to inform the authors of "A Review on Recent Trends and Emerging Perspectives" that they had no basis for the claim that one can blend a biodegradable additive into an otherwise nonbiodegradable polymer and cause the nonbiodegradable polymer to become biodegradable. (McCarthy, Tr. 674),

1579. Dr. McCarthy has never performed any tests on ECM amended plastic. (McCarthy, Tr. 678).

1580. Dr. McCarthy did not provide any specific scientific citation to support his statement that all of the ECM additive buried in crystalline phases would become instantly inaccessible for biodegradation. (McCarthy, Tr. 678).

XI. COMPLAINT COUNSEL HAS NOT SHOWN THAT ECM'S BIODEGRADABILITY CLAIM IS FALSE

A. Complaint Counsel Provided No Evidence Concerning What Competent and Reliable Scientific Evidence Can Show the Rate that a Product will Biodegrade in a Landfill

1581. Complaint Counsel provided no testimony or evidence concerning what competent and reliable scientific evidence would be required to prove the rate that a product will biodegrade in an MSW landfill. (Tolaymat, Tr. 218-220; McCarthy, Tr. 359-480).

1582. There is no record evidence showing which tests, if any, are competent and reliable to establish the rate of biodegradation in the highly variable landfill environment. (Tolaymat, Tr. 112-212, 213-358; McCarthy, Tr. 359-480, 523-680).

1583. When questioned repeatedly concerning which tests, if any, can be used by a company to prove the rate of biodegradation in an MSW landfill, Dr. Tolaymat had not test to recommend. (Tolaymat, Tr. 219-21; 222-24).

1584. Dr. Tolaymat has never seen any company use an in-situ study to determine biodegradability. (Tolaymat, Tr. 224).

1585. Dr. Tolaymat never encountered any in-situ landfill experiment that tested a specific product for biodegradability, as opposed to waste generally. (Tolaymat, Tr. 224).

1586. Dr. Tolaymat testified that no one test could support a rate of biodegradation in landfills, and that the rate of biodegradation is a matter of scientific judgment. (Tolaymat, Tr. 261-62).

1587. Dr. McCarthy testified at length concerning types of scientific studies that might be used to assess biodegradability of polymers generally. (McCarthy, Tr. 359-480).

1588. Dr. McCarthy did not, however, provide any testimony concerning the specific type of testing required to demonstrate the rate of biodegradation in an MSW landfill. (McCarthy, Tr. 359-480).

1589. Dr. Barlaz testified that there is no uniformly used method to extrapolate rate data from laboratory scale testing to field-scale landfills. (Barlaz, Tr. 2282).

1590. Dr. Barlaz explained that "it's very, very difficult to measure rates at either – at field scale either for individual components or for bulk waste, so all we have is the lab." (Barlaz, Tr. 2282).

1591. Dr. Barlaz explained that he would never use a BMP test to establish rate data. (Barlaz, Tr. 2231).

1592. Dr. Barlaz has published a proposed theory that suggests an extrapolation method from the lab to the landfill, but that method has not been generally accepted and is not generally used. (Barlaz, Tr. 2281-82).

1593. With respect to the rate of biodegradation, Dr. Barlaz wrote in his report that because the residence of waste in a landfill is essentially infinite, if a material is biodegradable, then it is not clear that it matters whether it biodegrades with a decay rate of 0.02 or 0.2. (RX 853 at 12).

1594. Dr. Barlaz testified that if a material is disposed in a landfill, then for the purpose of whether it biodegrades, it does not matter whether it degrades in two, ten, or twenty years. (Barlaz, Tr. 2283-84).

1595. Dr. Barlaz testified that a material which degrades slowly in a landfill is more environmentally beneficial than a product that biodegrades rapidly. (Barlaz, Tr. 2284-85).

1596. Methane is a greenhouse gas that contributes to climate change. (Barlaz, Tr. 2285).

1597. As methane gas increases in the atmosphere, it contributes to warming of the atmosphere, which the preponderance of scientists would suggest is damaging to the planet. (Barlaz, Tr. 2286).

1598. EPA regulations do not require landfill owners to install gas collection systems until five years after waste burial. (Barlaz, Tr. 2285).

1599. In a typical case, a landfill owner begins collecting gas in about two years after waste burial. (Barlaz, Tr. 2285).

1600. If a product biodegrades rapidly within two years (or five years), it will not take up space in a landfill, but the methane produced will not be captured and that will have less desirous environmental consequences than the simple storage of a product in a landfill for a longer period of time. (Barlaz, Tr. 2285-86).

1601. Dr. Barlaz has mapped (RX 853 at 26 (figure 8)) the global warming potential, which measures a system's contribution to greenhouse gases. (Barlaz, Tr. 2286-87).

1602. Dr. Barlaz testified, and wrote in peer reviewed publications, that based on decay rate the slower a product biodegrades in a landfill environment, the better that product is for the environment after disposal. (Barlaz, Tr. 2287-88).

1603. Stated differently, Dr. Barlaz explained that:

> The reason we make products is for people to use them, not to throw them in a landfill… What we're trying to do here is ask, given the fact that waste exists and waste is generated, what's the best thing to do with it and what's the best way to design a product, without impending its functionality, to minimize environmental impact."

(Barlaz, Tr. 2288).

1604. A plastic product that completely biodegrades in a landfill within one year after customary disposal would be a net contributor to global methane emissions at a typical landfill. (Barlaz, Tr. 2289-90).

1605. For the typical landfill that does not collect gas for years after disposal, a product that biodegraded completely within one year after disposal would be a net emitter of methane to the environment and therefore have negative environmental impact over a more slowly degrading substance. (Barlaz, Tr. 2289-90).

B. Experts Agree that Gas Evolution Tests Are Competent and Reliable Evidence to Prove that a Product is "Biodegradable"

1606. Numerous gas evolution tests have shown that plastics manufactured with ECM's additive, which otherwise do not biodegrade, have biodegraded to a degree that is substantially more than biodegradation that could have been sourced solely by the ECM additive. (Barlaz, Tr. 2175; Sahu, Tr. 1934-37; RX 248; RX 254; RX 263; RX 265; RX 266; RX 268; RX 273; RX 276; RX 392; RX 393; RX 394; RX 395; RX 396; RX 398; RX 399; RX 401; RX 403; RX 402; RX 405; RX 465; RX 467; RX 468; RX 836; RX 838; RX 839; CCX 534; CCX 546; CCX 547; CCX 548; CCX 952).

1607. Other studies, including qualitative tests and data, support the conclusions drawn from gas evolution testing, to wit, that plastics manufactured with the ECM additive render the otherwise non-biodegradable plastic biodegradable. (RX 254; RX 269; RX 271; RX 274; RX 275; RX 278; RX 277; RX 388-91).

1608. Industry has relied on several test models to prove biodegradability, but all experts in this case agree that "gas evolution" data is competent and reliable evidence to prove biodegradability, and it is the most practical and widely used measure of biodegradation (both aerobic and anaerobic) in the scientific field. (RX 853 at 7-8).

1609. Dr. Tolaymat testified that gas evolution tests are reliable evidence to show biodegradation in landfills. (Tolaymat, Tr. 171).

1610. Dr. McCarthy testified that gas evolution or "respirometric" testing is used by scientists to assess biodegradability. (McCarthy, Tr. 413-14).

1611. In fact, Dr. McCarthy himself relied on gas evolution data when assessing whether plastic polymers that he designed were biodegradable under anaerobic conditions. (McCarthy, Tr. 547-48; RX 756 at column 11).

1612. Dr. McCarthy has never himself conducted carbon-14 radiolabeled testing on plastic polymers to demonstrate biodegradability. (McCarthy, Tr. 359-680).

1613. Dr. Sahu testified that gas evolution testing was generally relied upon by scientists to show the biodegradability of materials. (Sahu, Tr. 1792).

1614. Dr. Barlaz testified that data from gas evolution testing was competent and reliable evidence of biodegradability, and that scientists in the field generally rely on same. (Barlaz, Tr. 2245-46).

1615. Dr. Burnette testified that gas evolution tests, like the D5511 test, are useful for predicting some baseline performance in landfill settings, albeit not optimal. (Burnette, Tr. 2435-39).

1616. When assessing whether plastic materials were anaerobically biodegradable, Dr. Michel relied on ASTM D5511 gas evolution testing. (Michel, Tr. 2904-05).

1617. Dr. Michel has never performed a radiolabeled test to measure biodegradation of plastic polymers or products. (Michel, Tr. 2906).

1618. There are no practical tests that precisely simulate or replicate all landfill conditions, and Complaint Counsel has offered no such method through its experts, but tests showing that one or more common bacteria in a closed test environment do biodegrade plastic are generally accepted as predictive of biodegradation in landfills where many multiple kinds of biodegrading bacteria and fungi are present. (RX-756 at 6–12; RX-853 at 7–9; RX-865 at 41–47).

1619. Dr. Tolaymat was unable to give an example of a practical laboratory test that would simulate landfill conditions, but also be accelerated so that testing would not be required to continue for decades. (Tolaymat, Tr. 247-50).

1620. Dr. Sahu testified that accelerated testing was reasonably required to produce results within a reasonable time frame, and that accelerated testing is commonly done in many scientific fields. (Sahu, Tr. 1924).

1621. Dr. Sahu explained that accelerated biodegradation testing, which may not mimic every aspect of the landfill, remains competent and reliable to demonstrate intrinsic biodegradability. (Sahu, Tr. 1924-26).

1622. Dr. Barlaz explained that attempting to truly "simulate" a landfill environment might require testing that spans 100 years. (Barlaz, Tr. 2212).

1623. Dr. Barlaz explained that "it's not practical to try to simulate that kind of ecosystem at the time scale in the laboratory." (Barlaz, Tr. 2212).

1624. Dr. Barlaz explained that the biodegradability (or anaerobic biodegradability) nature of a product is a characteristic of the material generally. (Barlaz, Tr. 2217-18).

1625. The biodegradability of a product describes a property of the material, much like its color or weight or density. (Barlaz, Tr. 2218).

1626. That property will not change regardless of where the material is placed. (Barlaz, Tr. 2218).

1627. Tests like the ASTM D5511, and well-designed gas evolution tests, are competent and reliable to assess the intrinsic biodegradability of a test material. (Barlaz, Tr. 2219).

1628. A product that is "biodegradable" will biodegrade at various rates and to various extents based on the external environmental conditions, but will remain "biodegradable" regardless. (Barlaz, Tr. 2218-19).

XII. DR. RANAJIT SAHU'S TESTIMONY

A. Dr. Sahu Testified that Plastic Containing the ECM Additive is Biodegradable

1629. Plastics manufactured using the ECM additive technology are shown to be biodegradable under conditions of customary disposal, including landfills. (Sahu, Tr. 1752).

1630. Plastics containing the ECM additive are expected to biodegrade at a rate faster than corresponding plastics without such additives. (Sahu, Tr. 1753-54).

1631. Dr. Sahu testified that a plastic containing the ECM additive would fully biodegrade under customary disposal conditions over time. (Sahu, Tr. 1754).

1632. Dr. Sahu based his opinion on a thorough literature review of peer-reviewed literature published since the 1950s, as well as between 30-40 different tests collected during this case. (Sahu, Tr. 1754-56).

1633. He reviewed several hundred peer-reviewed articles. (Sahu, Tr. 1791).

1634. Dr. Sahu's report includes many of the citations to, and discussions of, the literature that he relied on. (Sahu, Tr. 1791; RX 855).

1635. Conventional plastics are those made from petroleum feedstocks or natural gas, as opposed to those manufactured from biological materials like starches. (Sahu, Tr. 1758).

1636. It is commonly accepted that conventional plastics last very long in the environment, perhaps tens of thousands of years. (Sahu, Tr. 1758-59; CCX 891 at ¶ 17).

1637. Polyethylene can be considered a conventional plastic in the sense that it is ordinarily derived from feedstocks like petroleum or natural gas. (Sahu, Tr. 1784).

1638. Conventional plastics have only existed in modern manufacturing for about ninety to one hundred years. (Sahu, Tr. 1879).

1639. Biodegrading a substance into elements found in nature means to reduce the item from complex molecules into smaller molecules that may be broken down. (Sahu, Tr. 1763-64).

1640. Biodegradation processes are highly variable in the heterogeneous landfill environment, where you have different microenvironments throughout the landfill. (Sahu, Tr. 1768-69).

1641. A landfill, by its nature, is different from a controlled laboratory reactor; in the latter scientists attempt to control the environment to eliminate variables. (Sahu, Tr. 1769).

1642. A landfill cannot be standardized or homogenized. (Sahu, Tr. 1769-70).

1643. That means the level of biodegradation and activity will be variable in the landfill environment. (Sahu, Tr. 1769-70).

1644. The differing pockets of activity and varying conditions in a landfill will have an effect on the rate of biodegradation. (Sahu, Tr. 1770-71).

1645. There are methods to degrade plastics that involve chemical agents, or even incineration. (Sahu, Tr. 1771-72).

1646. Biodegradation of materials is a different concept than chemical degradation. (Sahu, Tr. 1771-72).

1647. There are many different grades of plastics in the commercial stream. (Sahu, Tr. 1785).

1648. For instance, polyethylene has at least ten different commercial grades. (Sahu, Tr. 1788).

1649. In general, because the end application of ECM plastics is not demanding (e.g., plastics made for carrying groceries vs. medical devices), the grade of polymer used in manufacturing ECM plastics is not high. (Sahu, Tr. 1877-78).

1650. Plastics that are intended for garbage bags or packaging materials can be made of lesser grade than plastics intended for more specific uses. (Sahu, Tr. 1878).

1651. Lesser grade plastics are more likely to contain impurities and inconsistencies that promote biodegradation. (Sahu, Tr. 1878-79).

1652. Polyethylene is comprised of the monomer ethylene, which is a repeating unit in the polyethylene polymer. (Sahu, Tr. 1788).

1653. Although scientists in the field ordinarily rely on gas evolution data to measure biodegradation in laboratory environments, they also rely on a range of test batteries for supporting data. (Sahu, Tr. 1792-93).

1654. Tests of all durations can be useful in assessing biodegradability, including shorter term testing. (Sahu, Tr. 1795).

1655. Dr. Sahu evaluated different polymers, including polyethylene, polypropylene, and polystyrene. (Sahu, Tr. 1800-01).

1656. He focused on certain polymers because the vast majority of ECM plastics manufactured by customers (about three quarters) are polyethylene-based products. (Sahu, Tr. 1801; RX 471).

1657. Conventional plastics like polyethylene have been proven to be biodegradable in the peer reviewed literature. (Sahu, Tr. 1848-53).

1658. Inclusion of the ECM additive, a biodegradable substance and attractant for microbiological growth, contributes to an acceleration of biodegradation. (Sahu, Tr. 1853-55).

1659. Dr. Sahu's opinion is consistent with the peer reviewed literature. (RX 855).

1660. Tokiwa, Y., et al. explained in the International Journal of Molecular Sciences (2009) that "the adherence of microorganisms on the surface of plastics followed by the colonization of the exposed surface is the major mechanisms involved in the microbial degradation of plastics." (RX 582; RX 855 at 28).

1661. Tokiwa, et al., further explained that many factors, including the polymer morphology, chemical and physical properties of the plastics, the surface conditions (e.g., surface area, hydrophilic and hydrophobic properties), the molecular weight and molecular weight distribution, glass transition temperature, melting temperature, and crystallinity are just some of the many factors that can affect the rate of biodegradability of plastics. (RX 855 at 28; RX 582).

1662. Molecular weight is a basic concept in chemistry, and molecular weights are generally consistent. (Sahu, Tr. 1804-05).

1663. For instance, the molecular weight of carbon dioxide is 44, no matter where it exists because it contains one carbon and two oxygen atoms. (Sahu, Tr. 1804-05).

1664. However, polymers are different because they are not specifically defined molecules. (Sahu, Tr. 1805).

1665. A polyethylene product does not have the same number of repeating monomer units in each strain. (Sahu, Tr. 1805).

1666. Because polymer chains have varying lengths within a product, the strains have different molecular weights, and that creates a molecular weight distribution. (Sahu, Tr. 1805).

1667. There is no way to manufacture a polymer and ensure that all the lengths of the individual chains in the same polyethylene product melt have the same molecular weight. (Sahu, Tr. 1807-08).

1668. Molecular weight distribution will affect product characteristics such as tensile strength. (Sahu, Tr. 1808-09).

1669. The ECM additive affects molecular weight as a system-wide "MasterBatch" additive that enters the structure of the plastic. (Sahu, Tr. 1809-10).

1670. The ECM additive thus alters the plastic matrix, the polymer chains, and adds an attractant that permits microorganisms to take root at the surface and within the plastic. (Sahu, Tr. 1810-11).

B. Dr. Sahu Testified to the Manufacturing Process of Plastic Containing the ECM Additive

1671. The ECM additive is introduced to the plastic as a pellet, which is melted together with the plastic resin to form a film or packaging material. (Sahu, Tr. 1813).

1672. The melted compound is usually extruded or blown and then cooled. (Sahu, Tr. 1813).

1673. ECM plastics are also manufactured using injection molding. (Sahu, Tr. 1816-17).

1674. When the ECM additive is melt-compounded into the final plastic, the goal is to disperse the additive evenly throughout the plastic, like a colorant (color additive). (Sahu, Tr. 1814-15).

1675. High temperatures or scorching during the manufacturing process render the ECM additive ineffective. (Sahu, Tr. 1815).

1676. If the additive was overheated or scorched, it may not be apparent or obvious to the plastic manufacturer. (Sahu, Tr. 1815).

1677. Companies may leave the additive "on the screw" while manufacturing, which cooks the additive. (Sinclair, Tr. 762).

1678. ECM customers frequently run test samples through a battery of performance testing to ensure proper manufacturing. (Sinclair, Tr. 761-62).

1679. Companies become customers of ECM's additive technology only after months, sometimes years, of negotiation and product testing. (Sinclair, Tr. 761-64).

1680. ECM has to work with customers to get the manufacturing process right, so that customers do not scorch the material or manufacture it improperly. (Sinclair, Tr. 762).

1681. Because of the lengthy testing and verification processes, it takes on average approximately six months to a year (and in some cases several years) for ECM to acquire a customer account. (Sinclair, Tr. 767).

1682. The temperatures used in manufacturing ECM plastics depend on the materials' glass transition and melting temperatures. (Sahu, Tr. 1817).

1683. The temperature will depend on how the manufacturer would like the viscosity properties of the plastic to be during manufacturing, and how they intend to handle the melt after heating. (Sahu, Tr. 1817).

1684. The ECM additive is introduced into the main plastic resin just like any other additive, such as a colorant. (Sahu, Tr. 1818).

1685. Color additives are sometimes not properly mixed with the plastic, and the appearance of the final product clearly shows the inconsistent colors. (Sahu, Tr. 1818).

1686. The "dwell time" during manufacturing refers to the residence time, or how long the additive is exposed to temperatures during manufacturing. (Sahu, Tr. 1836-37).

1687. Because ECM plastics are melt-compounded, longer dwell times can cause the plastic or additive to denature during manufacturing, which must be carefully avoided to ensure additive efficacy. (Sahu, Tr. 1837).

1688. The "load rate" of the ECM additive is the mass or percent of the additive that manufacturers add to a melt. (Sahu, Tr. 1819).

1689. The customary load ratings for color additives are anywhere from 0.5 percent to 2 or 3 percent. (Sahu, Tr. 1819-20).

1690. Plastics made with the ECM additive are manufactured differently than bioplastics. (Sahu, Tr. 1821). Bioplastics are more delicate. (Sahu, Tr. 1821).

1691. The physical properties of a bioplastic also differ in material respects from plastics manufactured with the ECM additive. (Sahu, Tr. 1821).

1692. The crystallinity of the bioplastic differs from the ECM additive. (Sahu, Tr. 1821).

1693. Because bioplastics are designed to rapidly degrade, they are attractive for some uses but unattractive for many other uses. (Sahu, Tr. 1821).

1694. A primary concern when manufacturing plastics is to make the product function for its intended use during the product's lifespan. (Sahu, Tr. 1822).

1695. A "biodegradable" plastic must still function as a consumer good during its ordinary use, effecting a biodegradable property after disposal. (Sahu, Tr. 1822).

1696. Bioplastics may not be appropriate for all consumer uses where, for instance, shelf-life is important, or where product use is intended for environments that could promote biodegradation early. (Sahu, Tr. 1822-23).

1697. One of the advantages of using the ECM additive is that, at a 1% load rating (like a color additive), the additive should not substantially affect the fundamental properties of the plastic product. (Sahu, Tr. 1823).

1698. The ECM additive gives manufacturers the benefit of usability of the article along with biodegradation. (Sahu, Tr. 1823).

C. Dr. Sahu Testified that Many Factors Can Affect the Biodegradable Feature of Plastic Containing the ECM Additive

1699. Many factors affect the ability of a plastic to biodegrade. (Sahu, Tr. 1828).

1700. The inclusion of impurities and other additives in a plastic polymer can influence the ultimate biodegradability of the plastic. (Sahu, Tr. 1828).

1701. Some plastic additives (e.g., colorants) may include components that have an antimicrobial effect. (Sahu, Tr. 1828-29).

1702. Impurities are included in the final plastic unintentionally. (Sahu, Tr. 1829-30).

1703. Impurities may include byproducts from manufacturing. (Sahu, Tr. 1830).

1704. Impurities affect the biodegradability of plastics by providing attack points in the polymer chains. (Sahu, Tr. 1830).

1705. Those impurities become spots where the plastic is weaker than it would be without the impurities, and those weaknesses facilitate microbial attack. (Sahu, Tr. 1831).

1706. Additives are intentionally added to plastics, but they similarly create heterogeneity in the polymer, and create opportunities for biological attack. (Sahu, Tr. 1831).

1707. Additives may include articles like plasticizers, lubricants, impact modifiers, fillers, pigments, flame retardants, stabilizers, and antimicrobial agents. (Sahu, Tr. 1832-33).

1708. There are additives that can have antimicrobial properties but are not specifically introduced to the plastic for antimicrobial purposes. (Sahu, Tr. 1835).

1709. There are some catalysts, including copper- or zinc- or silver-based components that have antimicrobial properties but are not included intentionally as antimicrobials. (Sahu, Tr. 1835).

1710. An antimicrobial additive or impurity would likely reduce or negate biodegradation. (Sahu, Tr. 1836).

1711. Virtually all plastic articles have additives. (Sahu, Tr. 1836).

1712. In all practical applications, many additives are typically present in the final plastic. (Sahu, Tr. 1836).

1713. MSW landfills contain widely variable temperature conditions. (Sahu, Tr. 1842-44).

1714. At a fundamental level, there is no difference in the way thermophilic bacteria metabolize waste versus the way mesophilic bacteria metabolize waste (Sahu, Tr. 1844).

1715. The particular enzymes involved, however, are different, as is the rate of biodegradation. (Sahu, Tr. 1843-44).

1716. All MSW landfills have the potential to produce gases, and those gases are a signature of biological activity. (Sahu, Tr. 1846).

1717. The gases generated from MSW landfills show that there are biological reactions occurring, and so the gases are indicative of underlying biological activity in the landfill. (Sahu, Tr. 1847).

1718. In context with landfill or test gases, there can be no methane without anaerobic biodegradation. (Sahu, Tr. 1848).

1719. Dr. Sahu examined the "threshold question" of whether plastics or polymers are capable of biodegrading. (Sahu, Tr. 1848).

1720. He performed an extensive literature search. (Sahu, Tr. 1848-49).

1721. Dr. Sahu's research was memorialized in his expert report. (Sahu, Tr. 1849; RX 855 at 24-40).

1722. Dr. Sahu has described the mechanism of action by which the ECM additive accelerates biodegradation of plastics. (Sahu, Tr. 1857-58).

1723. The rate of biodegradation of plastic polymers depends on many variables, including the various properties of the base plastic, the presence and types of amounts of biological organisms in the vicinity of the plastic material, and the properties of the local physical environment. (RX 855 at 27).

1724. The ECM additive helps to set in motion the attraction/migration of microbes and biological agents to the plastic, and to the areas of the plastic where weaknesses or hydrophilic defects exist. (RX 855 at 27; Sahu, Tr. 1865-67).

1725. The formation of biofilms near the additive sites promotes the development and growth of bacteria, which spreads to other areas of the plastic. (RX 855 at 27).

1726. Depending on the linear chains and branches within a polymer, biological activity typically begins at the weak points and endings of a polymer chain, and works into the remaining portions of the polymer. (Sahu, Tr. 1866-67).

1727. Microbes secrete enzymes and chemicals that degrade plastic where the biofilms are present, beginning with the weak links in plastic. (RX 855 at 27).

1728. Dr. Sahu relied on peer reviewed literature to demonstrate that plastic polymers biodegrade, including crystalline regions therein. (RX 855 at 24-40).

1729. Dr. Sahu reviewed hundreds of papers in preparation of his expert report, including the eleven that he quoted and relied upon in the text of his report. (RX 855 at 24-40).

1730. Those include: (1) Tokiwa, Y., et al., Biodegradability of Plastics, Int. J. Mol. Sci. 2009, 10, 3722-3742; (2) Tilstra, L., et al., The Biodegradation of Blends of Polycaprolactone and Polyethylene Exposed to a Defined Consortium of Fungi, Journal of Environmental Polymer Degradation, Vol. 1, No. 4, 1993; (3) Zheng, Y., et al., A Review of Plastic Waste Biodegradation, Critical Reviews in Biotechnology, 25:243–250, 2005; (4) Bhardwaj H, Gupta R, Tiwari A (2012) Microbial Population Associated With Plastic Degradation. 1: 272. doi:10.4172/scientificreports; (5) Arutchelvi, J., et. al., Biodegradation of polyethylene and polypropylene, Indian Journal of Biotechnology, Vol. 7, January 2008, p. 9-22; (6) Mueller, R-J., Biological degradation of synthetic polyesters—Enzymes as potential catalysts for polyester recycling, Process Biochemistry, Volume 41, Issue 10, October 2006, p. 2124–2128; (7) Van der Zee, M., Analytical Methods for Monitoring Biodegradation Processes of Environmentally Degradable Polymers, Section 11.4.2; (8) Shah, A.A., et. al., Biological degradation of plastics: A comprehensive review, Biotechnology Advances Vol. 26, 2008, p. 246–265; (9) Pramila, R., et. al., Biodegradation of Low Density Polyethylene (LDPE) by Fungi Isolated from Municipal Landfill Area, J. Microbiol. Biotech. Res., 2011, 1 (4):131-136; (10) Albertsson, A-C., Biodegradation of synthetic polymers. II. A limited microbial conversion of 14C in polyethylene to 14CO2 by some soil fungi, Journal of Applied Polymer Science, Volume 22, Issue 12, p. 3419–3433, December 1978; and (11) Albertsson, A-C., et. al., Biodegradation of synthetic polymers. III. The liberation of 14CO2 by molds like *fusarium redolens* from 14C labeled pulverized high-density polyethylene, Journal of Applied Polymer Science, Volume 22, Issue 12, p. 3435–3447, December 1978.

1731. Based on his experience and research, Dr. Sahu determined that peer reviewed literature demonstrated that beyond aerobic biodegradation, anaerobic processes are capable of biodegrading conventional plastics. (Sahu, Tr. 1858-59).

1732. The biodegradation of plastic polymers involves, *inter alia*, hydrolytic cleavage of polymer bonds. (Sahu, Tr. 1859-60).

1733. The hydroxyl radical (OH radical) is capable of facilitating hydrolytic reactions. (Sahu, Tr. 1860).

1734. Oxidative reactions involve electron transfer. (Sahu, Tr. 1860).

1735. Oxidative reactions need not occur in the presence of oxygen. (Sahu, Tr. 1861).

1736. Oxidative reactions occur in anaerobic systems. (Sahu, Tr. 1862).

1737. Pro-oxidants can facilitate biodegradation, but they are not the only mechanisms that work to degrade polymers. (Sahu, Tr. 1870-73).

1738. Many forms of polymer biodegradation have been documented in the peer reviewed literature. (Sahu, Tr. 1875).

1739. Blending biodegradable and non-biodegradable polymers is one of the means documented in the peer reviewed literature by which polymers can be rendered biodegradable. (Sahu, Tr. 1876; RX 925 at 647).

1740. The scientific literature shows that polymer chains with molecular weights as high as 10,000 can be biodegraded. (Sahu, Tr. 1872-73).

1741. As molecular weights decrease through microbial biodegradation, the susceptibility of polymers to further biodegradation increases. (Sahu, Tr. 1873).

1742. Because the ECM additive is uniformly dispersed throughout an ECM plastic, the additive's effect is not limited to a surface effect. (Sahu, Tr. 1863-64).

1743. Because the ECM additive is uniformly dispersed throughout an ECM plastic, the additive provides a continued food source for microbial growth through plastic degradation. (Sahu, Tr. 1863-64).

1744. The presence of the ECM additive throughout the plastic provides for continued and complete biodegradation of the conventional plastic. (Tr. 1864-65).

1745. MSW landfills contain bacteria, fungi, and other microorganisms that secrete enzymes capable of completing the biodegrading processes that Dr. Sahu identified in his expert report. (Sahu, Tr. 1865-66).

1746. Those microorganisms have evolved over time, and can evolve quickly, to adapt for plastics biodegradation. (Sahu, Tr. 1880-81).

1747. Scientists in the field have published information concerning the types of bacteria and microorganisms that are found in nature (including MSW landfills), which have also been shown to biodegrade conventional plastics. (Sahu, Tr. 1867-68; RX 855 at 34).

1748. Those microorganisms are found in landfills, sewage treatment plants, digesters, and compost piles. (Sahu, Tr. 1869).

1749. Plastic polymers can have amorphous and crystalline regions. (Sahu, Tr. 1883-84). Crystalline portions of the polymer can be biodegraded just as the amorphous regions can, but perhaps at a different rate. (Sahu, Tr. 1884-85).

1750. Crystalline portions of polymers are still fundamentally composed of the same chains. (Sahu, Tr. 1884).

1751. Those polymer regions are actually semi-crystalline. (Sahu, Tr. 1884).

1752. Scientists have examined the biodegradability of crystalline portions of polymers and found that they do in fact biodegrade. (Sahu, Tr. 1885).

1753. Literature in the peer review has discussed the loss of crystallinity or decreases in crystallinity, or loss of the lamellae that are the crystalline subcomponents as indicators that degradation has occurred in the crystalline portions of plastics. (Sahu, Tr. 1885).

1754. In the article titled, Arutchelvi, J., et. al., Biodegradation of polyethylene and polypropylene, Indian Journal of Biotechnology, Vol. 7, January 2008, p. 9-22, the authors focused on polyethylene and polypropylene. (Sahu, Tr. 1885-85; RX 855 at 35; RX 586).

1755. The article included discussion and citations to other literature wherein scientists have observed loss of crystallinity in conventional plastics. (Sahu, Tr. 1885-86; RX 586; RX 855 at 35).

1756. Scientists have posited that biodegradation begins in amorphous regions of the polymers. (RX 586 at 13).

1757. However, the peer reviewed literature also supports that crystalline regions will biodegrade. (RX 855 at 28, 41 n. 62).

1758. The amorphous regions of a polymer are more susceptible to degradation, but while the crystalline sections of a polymer are “more resistant than the amorphous region,” they will also degrade in kind. (RX 855 at 28 (quoting Tokiwa, Y., et al., Biodegradability of Plastics, Int. J. Mol. Sci. 2009, 10, 3722-3742; RX 582).

1759. For example, Tokiwa, Y., et al. (RX 582) have explained that certain enzymes have been shown to biodegrade “both the amorphous and crystalline” portions of plastics. (RX 582 at 3732 (discussing the lipase enzymatic degradation of PCL)).

1760. The degree of crystallinity is merely one of many factors that can influence the biodegradability of plastics. (RX 582 at 3722).

1761. Even plastics with high degrees of crystallinity can be more biodegradable than others with lesser degrees of crystallinity if other factors promote biodegradability, such as surface area, molecular weight distribution, melting point, etc. (Sahu, Tr. 1886; RX 582 at 3722).

1762. It is a scientific error to use the crystallinity of a polymer as the only factor or variable that governs whether a plastic will biodegrade. (Sahu, Tr. 1887).

1763. "Thermoplastics are invariably composed of long, individual molecules that are bonded to each other by secondary chemical bonds, which are much weaker than the primary covalent bonds that hold the molecules together." (RX 855 at 15 (quoting Lampman, S., Characterization and Failure Analysis of Plastics, ASM International, 2003, p.7)).

1764. Thermoplastics "**overall structure is generally amorphous**, but some thermoplastics can become partly crystalline." (RX 855 at 15 (quoting Lampman, S., Characterization and Failure Analysis of Plastics, ASM International, 2003, p.7)) (emphasis added).

1765. Polyethylene, polypropylene, polyvinyl chloride, and polystyrene are all thermoplastics (RX 855 at 31), which have an "overall structure that is generally amorphous" (RX 855 at 15 (quoting Lampman, S., Characterization and Failure Analysis of Plastics, ASM International, 2003, p.7)).

XIII. GAS EVOLUTION TESTS ARE COMPETENT AND RELIABLE EVIDENCE, AND RADIOLABELED TESTING IS NOT REQUIRED

1766. Dr. McCarthy's use of gas evolution tests similar to the D5511 protocol to establish proof or biodegradability in his own technologies is in direct conflict with his testimony offered in this case, wherein he claims that such tests are only screening mechanisms. (Sahu, Tr. 1894-95).

1767. Dr. McCarthy has not used radiolabeled testing to establish proof of biodegradability. (Sahu, Tr. 1895).

1768. Dr. Sahu explained that gas evolution tests are competent and reliable scientific evidence to prove biodegradability. (Sahu, Tr. 1895-96).

1769. Other methods of testing can help to provide supporting evidence, including, for instance, weight loss or gravimetric testing. (Sahu, Tr. 1895-96).

1770. There is no indication in the scientific literature or from scientists in the field that radiolabeled testing is necessary to establish proof of biodegradability. (Sahu, Tr. 1896).

1771. When questioned about the type of evidence required to support biodegradability, Dr. Tolaymat did not mention radiolabeled testing. (Tolaymat, Tr. 112-347).

1772. When assessing the biodegradability of plastic products, Dr. Michel chose to perform several gas evolution tests, but he did not perform radiolabeled testing. (Michel, Tr. 2906).

1773. Dr. Michel has never tested a plastic polymer using radiolabeled testing. (Michel, Tr. 2906).

1774. At his deposition, Dr. Tolaymat explained that radiolabeled testing "could be as expensive as doing it in a landfill – as doing the study in a landfill environment" and that "it's not used frequently." (RX 851 (Tolaymat, Dep. at 256)).

1775. Dr. Michel testified that respirometric testing, like the D5511 test, is generally recognized in the field as competent and reliable evidence to show biodegradation. (Michel, Tr. 2907).

1776. Dr. Sahu found no evidence that radiolabeled testing is generally accepted as a requirement to biodegradability testing for polymers. (Sahu, Tr. 1794-95).

1777. In the pre-complaint phase of this case, Dr. Sahu searched for a commercial laboratory that could perform radiolabeled testing for ECM. (Sahu, Tr. 1897-98).

1778. Dr. Sahu could not find any company able to radiolabel the polymer or create the radiolabeled polymer that would then be subject to further laboratory testing. (Sahu, Tr. 1897).

1779. Many companies could offer radiolabeled pharmaceutical ingredients, but not polymers, which required a different manufacturing process. (Sahu, Tr. 1898-99).

1780. Pharmaceutical ingredients are tested in minute quantities. (Sahu, Tr. 1899).

1781. Radiolabeled testing starts when a laboratory receives a radiolabeled substance which is barium salt. (Sahu, Tr. 1900).

1782. That barium salt is derived from research reactors. (Sahu, Tr. 1900). Only a few research facilities in the world can provide the radioactive source materials. (Sahu, Tr. 1900).

1783. Carbon-14 is evolved from the salt in carbon dioxide. (Sahu, Tr. 1900).

1784. Carbon-14 is then synthesized, and the laboratory will have minute quantities of radiolabeled carbon. (Sahu, Tr. 1900).

1785. In plastics testing, a laboratory must then synthesize monomers with the radiolabeled carbon, then polymerize those monomers into a polymer chain that contains the radiolabeled carbon. (Sahu, Tr. 1900-01).

1786. Most polymers, like polyethylene, are sourced by large scale facilities which derive the feedstock material from petrochemicals. (Sahu, Tr. 1901).

1787. When a source plastic like polyethylene is radiolabeled, the entire source plastic can be radiolabeled. (Sahu, Tr. 1901).

1788. That means both the amorphous and crystalline regions are radiolabeled. (Sahu, Tr. 1901).

1789. The manufacturer must then make the test plastic as it would appear in commerce, but with the radiolabeled base polymer. (Sahu, Tr. 1901).

1790. Once the radiolabeled test plastic is assembled, it must still be tested in a standard biodegradation test. (Sahu, Tr. 1901).

1791. That testing is the same gas evolution testing that would otherwise be done without the radiolabeled polymer. (Sahu, Tr. 1906).

1792. The company that manufacturers the radiolabeled polymer is not the same company that would perform the biodegradation testing. (Sahu, Tr. 1902).

1793. There are difficulties associated with handling radioactive carbon. (Sahu, Tr. 1903).

1794. Aside from the regulatory issues, the laboratory must be capable and prepared to handle the radioactive material and ensuing decontamination. (Sahu, Tr. 1903).

1795. A testing laboratory would require a considerable amount of carbon-14 to test plastics for biodegradation because the manufacturer must create a commercial-scale product for testing. (Sahu, Tr. 1903).

1796. That amount is much more than pharmaceutical companies would use in a test of an active pharmaceutical ingredient. (Sahu, Tr. 1903-04).

1797. Even assuming that Dr. McCarthy's concerns over recalcitrant crystalline sections of the polymers was valid, carbon-14 testing would not address his points. (Sahu, Tr. 1904).

1798. A radiolabeled test would need to have carbon-14 radiolabeled throughout the amorphous and crystalline sections. (Sahu, Tr. 1904-05).

1799. Complaint Counsel's experts provided no testimony or evidence as to how, if at all, a company would radiolabel specifically the crystalline sections but not amorphous sections of a polymer. (McCarthy, Tr. 359–689).

1800. Dr. Sahu testified that it would be impossible to radiolabel only the crystalline sections of a polymer. (Sahu, Tr. 1906).

1801. There is no evidence in the market or in the peer reviewed literature that carbon-14 radiolabeled testing is an industry standard. (Sahu, Tr. 1905).

1802. In-situ landfill studies generally cannot be conducted as gas evolution tests. (Sahu, Tr. 1909).

1803. A landfill test can measure changes to physical properties, but not gas evolution. (Sahu, Tr. 1909).

1804. "Accelerated testing" is scientifically acceptable when trying to mimic a slow natural process in the lab; practicalities require that results come faster than would normally occur in nature. (Sahu, Tr. 1924).

1805. Accelerated testing is done in engineering, biology, drug testing, and many other scientific fields. (Sahu, Tr. 1924).

1806. In engineering studies, for example, abbreviated tests are designed to test against stresses that would be experienced over a lifetime of use. (Sahu, Tr. 1925).

1807. Accelerated testing is appropriate for biodegradation studies because the results under normal time would otherwise require substantially extended test periods. (Sahu, Tr. 1924).

1808. Accelerated laboratory testing is a competent and reliable means to assess intrinsic biodegradability of materials. (Sahu, Tr. 1926-27).

1809. Based on the totality of the scientific evidence, Dr. Sahu testified that conventional plastic containing the ECM additive render the plastic "biodegradable in a landfill." (Sahu, Tr. 1943-44).

XIV. DR. MORTON BARLAZ'S TESTIMONY

A. Dr. Barlaz Testified that Biodegradation Occurs in MSW Landfills

1810. Dr. Morton Barlaz testified that significant anaerobic biodegradation occurs in municipal solid waste landfills, and the prime evidence for that is the production of methane in those landfills. (Barlaz, Tr. 2174).

1811. There are about 2,000 municipal waste landfills in the U.S., and commercial quantities of methane are recovered from at least 600, which evidences the significant anaerobic biodegradation occurring in the landfills. (Barlaz, Tr. 2174).

1812. There is a significant amount of methane emissions that come from municipal solid waste. (Barlaz, Tr. 2174-75).

1813. Methane is the end product of biodegradation in landfills. (Barlaz, Tr. 2174).

1814. Dr. Barlaz testified that, based on his review of laboratory reports relevant to this case, there were numerous examples where specific ECM amended plastics were shown to anaerobically biodegrade to methane. (Barlaz, Tr. 2175).

1815. Municipal solid waste is highly heterogeneous. (Barlaz, Tr. 2175).

1816. Estimates of waste composition should be understood to be rough estimates. (Barlaz, Tr. 2175-76).

1817. EPA's estimates of waste composition should not be considered precise. (Barlaz, Tr. 2177).

1818. MSW is waste that is generated in the residential, commercial, and institutional sectors. (Barlaz, Tr. 2177).

1819. Landfilling is really the only disposal alternative. (Barlaz, Tr. 2178).

1820. Burning or incinerating is not a waste disposal alternative, it is waste treatment. (Barlaz, Tr. 2178).

1821. Combustion and landfilling are the only two viable disposal alternatives. (Barlaz, Tr. 2179).

1822. Some part of the waste stream is recycled, and some is treated biologically either in composting or in a few cases anaerobic digestion. (Barlaz, Tr. 2179).

1823. However, composting is largely confined to yard waste, grass, leaves, and branches, and there are very few communities in the U.S. that separate out compostable waste. (Barlaz, Tr. 2179).

1824. Over the last five to ten years, many residential recycling programs have expanded to accept more materials. (Barlaz, Tr. 2179-80).

1825. Because paper is the largest component of municipal solid waste, the more paper that comes out of the waste stream for disposal means that the waste stream is enriched with other components, like food waste. (Barlaz, Tr. 2180).

1826. Dr. Barlaz has summarized waste sort data from ten states in his published research. (Barlaz, Tr. 2181-82).

1827. Paper still comprises about 20 percent of the total MSW composition, roughly 20 percent is food waste, plastics comprise about 10 percent, and 3 to 5 percent is glass. (Barlaz, Tr. 2181).

1828. Because consumers and commercial entities sort and recycle waste, the composition of waste generated will differ from the composition of waste disposed. (Barlaz, Tr. 2182).

1829. Municipal solid waste contains chemical compounds that have methane potential. (Barlaz, Tr. 2183).

1830. Anaerobically biodegradable materials have the potential to generate methane. (Barlaz, Tr. 2183-84).

1831. Stoichiometry is the relationship between the chemical composition of reactants of an equation (those materials on the left side), and the end products (the materials on the right side). (Barlaz, Tr. 2185).

1832. Principles of stoichiometry deal with conservation of mass, and are applicable to the conversion of substrates to methane during anaerobic biodegradation. (Barlaz, Tr. 2185-86).

1833. To microorganisms, municipal solid waste represents a source of food or energy, so if there is energy to be gained by consuming or attacking a substrate, they will do it. (Barlaz, Tr. 2186).

1834. In general, the process of anaerobic biodegradation involves hydrolysis reactions that eventually produce products such as butyric acid, acetic acid, hydrogen, and carbon dioxide. (Barlaz, Tr. 2186).

1835. Butyric acid is then attacked by microorganisms referred to as acetogenic, which convert the butyric acid to acetic acid and carbon dioxide. (Barlaz, Tr. 2187).

1836. Methanogenic archaea use either the acetic acid or hydrogen plus carbon dioxide and convert either of those substances to methane. (Barlaz, Tr. 2187).

1837. The concerted activity of at least four trophic groups of microorganisms enable the conversion of materials to methane and carbon dioxide. (Barlaz, Tr. 2187).

1838. Microbes may secrete some waste products of metabolism to the environment as a product of biodegradation. (Barlaz, Tr. 2188).

1839. Cell mass is also a product of biodegradation, meaning that carbon extracted from waste may consume the carbon for growth rather than convert carbon to methane or gas. (Barlaz, Tr. 2188).

1840. Methane is only produced in a system that is strictly anaerobic. (Barlaz, Tr. 2188).

1841. In an anaerobic test system, the ratio of methane gas to carbon dioxide is usually in the range of 1:1, but may appear more like 60% methane and 40% carbon dioxide because carbon dioxide can dissolve into the liquid phase. (Barlaz, Tr. 2189).

1842. There is oxygen in landfills, to the extent that it comes from waste materials, water, and other chemicals. (Barlaz, Tr. 2189-90).

1843. For example, there is oxygen in cellulose. (Barlaz, Tr. 2190).

1844. Every reaction in which a microbe gains energy or has a source of energy is an oxidative reaction. (Barlaz, Tr. 2190).

1845. Oxidative reactions need not involve oxygen, and they occur in anaerobic systems. (Barlaz, Tr. 2191-92).

1846. Landfills can produce substantial amounts of methane gas emissions. (Barlaz, Tr. 2192-93).

1847. Dr. Barlaz has seen landfills that make 250 to 500 cubic feet of landfill gas (at 50% methane) per minute. (Barlaz, Tr. 2192).

1848. The EPA's Landfill Methane Outreach Program (LMOP) runs a voluntary database of landfills for recovering methane. (Barlaz, Tr. 2193-94).

1849. Dr. Barlaz has been to landfills making eight to ten thousand cubic feet of landfill gas per minute. (Barlaz, Tr. 2193).

1850. The volume of gas depends on the mass of waste disposed annually and other factors like the moisture content and waste composition. (Barlaz, Tr. 2193).

1851. Dr. Barlaz explained that it is very, very difficult to describe a "typical" landfill. (Barlaz, Tr. 2193).

1852. Dr. Barlaz explained that Dr. Tolaymat's opinion was misleading because Dr. Tolaymat suggested that biodegradation only occurs in bioreactor landfills, and Dr. Tolaymat also adopted a very narrow definition of bioreactor landfill. (Barlaz, Tr. 2196).

1853. The EPA's definition of a bioreactor landfill is very narrow, and it is a misleading definition because Dr. Barlaz has been to many landfills that do not describe themselves as "bioreactors" but still produce substantial methane generation. (Barlaz, Tr. 2196-97).

1854. Dr. Barlaz explained that the simplest analysis is that there are "620 landfills that are generating enough methane for people to make million-dollar investments in equipment to convert that methane to electrical energy or some other beneficial use. And that, to [Dr. Barlaz], contrasts considerably with this notion that there are only 40 landfills with significant biodegradation occurring." (Barlaz, Tr. 2197).

1855. Dr. Barlaz testified that the term "dry tomb landfill" is misused because the implication of the term and the implication of Dr. Tolaymat's report was that if a landfill is not actively adding moisture to a landfill, then it is a dry tomb landfill, which is false. (Barlaz, Tr. 2198).

1856. Dr. Barlaz had been to many landfills that are not actively adding leachate or external liquids to the landfill, and yet by virtue of infiltration of rainwater alone the landfills have considerable moisture, and they are making considerable methane. (Barlaz, Tr. 2198).

1857. The EPA Subtitle D regulations do not specify the hydraulic conductivity of the soil that is used to cover the landfill waste daily or weekly or even annually. (Barlaz, Tr. 2199).

1858. The EPA Subtitle D regulations only specify hydraulic conductivity of the soil that used as a final cover on the landfill. (Barlaz, Tr. 2199).

1859. The hydraulic conductivity is a measure of how much water infiltrates. (Barlaz, Tr. 2199).

1860. There are thus many landfills that by virtue of infiltration alone are not "dry tomb" landfills. (Barlaz, Tr. 2199).

1861. The implication that those landfills are not making methane is misleading and not correct. (Barlaz, Tr. 2199).

1862. More and more landfills are now recirculating leachate or taking in commercial liquids from other sources and adding it to waste. (Barlaz, Tr. 2200).

1863. Those landfills are operating to enhance waste decomposition. (Barlaz, Tr. 2200).

1864. Landfills are also spraying waste with leachate as the waste goes into the landfill, which also accelerates biodegradation. (Barlaz, Tr. 2200).

1865. Dr. Barlaz recently performed a landfill gas study on more than fifteen landfills around the country. (Barlaz, Tr. 2201).

1866. He found that more than two-thirds of those landfills were spray-applying leachate to the working face of the landfill, although those landfills were not calling themselves "bioreactors." (Barlaz, Tr. 2201).

1867. Landfill operators have financial incentives to recycle leachate and increase moisture content. (Barlaz, Tr. 2202-03).

1868. The cost of landfill leachate treatment is substantial, and landfill operators can save those costs by recirculating leachate. (Barlaz, Tr. 2202-03).

1869. Wastewater treatment plants have started informing landfill operators that they will no longer accept landfill leachate, forcing landfill operators to consider alternatives like leachate recirculation. (Barlaz, Tr. 2203).

1870. Some landfill operators must transport leachate hundreds of miles for processing, which adds to operating costs. (Barlaz, Tr. 2203).

1871. Landfills contain pockets of dry and very moist areas. (Barlaz, Tr. 2205).

1872. The range of moisture content in landfills can be considerable. (Barlaz, Tr. 2206).

1873. The range of temperatures in MSW landfills is also significant. (Barlaz, Tr. 2207).

1874. Dr. Barlaz has seen landfills where steam has been emitted from landfills, while on the other side of the same landfill, the temperatures at the gas heads might be in the range of 100 degrees Fahrenheit. (Barlaz, Tr. 2208).

1875. Landfill recirculation increases overall moisture content, and also helps balance the moisture levels in the same landfill. (Barlaz, Tr. 2205).

1876. Landfill leachate is diverse, and contains carboxylic acids, humic matter, ammonia, and other chemicals. (Barlaz, Tr. 2203-04).

1877. Landfill leachate carries microorganisms. (Barlaz, Tr. 2204).

1878. Landfill leachate has nutrients in the form of dissolved ammonia and phosphate, which are major nutrients or macronutrients, and it also contains trace metals which are nutrient sources for microorganisms. (Barlaz, Tr. 2204-05).

1879. A landfill might collect around 300 gallons per acre per day of landfill leachate in a typical MSW landfill. (Barlaz, Tr. 2205-06).

1880. The 300 gallon figure is conservative. (Barlaz, Tr. 2206).

1881. Dr. Barlaz testified that ten years ago the rule was about 1,100 gallons per acre per day. (Barlaz, Tr. 2206).

1882. In the field (in actual landfills), Dr. Barlaz explained that there is no moisture level at which biodegradation would not occur. (Barlaz, Tr. 2208).

1883. Research concerning the microbiology of refuse decomposition in the laboratory is "accelerated." (Barlaz, Tr. 2212).

1884. Without accelerated testing, lab tests for biodegradation could take anywhere from 5 to 500 years. (Barlaz, Tr. 2212).

1885. It is not practical to try to simulate the landfill ecosystem at that time scale in a laboratory. (Barlaz, Tr. 2212).

1886. In a landfill environment, the microorganisms are capable of balancing the ecosystem if it becomes too acidic of basic. (Barlaz, Tr. 2213).

1887. The average landfill accepts waste for about 35 years. (Barlaz, Tr. 2215).

1888. The landfill is then closed with a "final cover" consisting of low-permeability layers to contain gas within the waste and restrict moisture infiltration. (Barlaz, Tr. 2216).

1889. Some landfills will remain open for as long as 50 years, but the final number is site-specific. (Barlaz, Tr. 2216).

1890. Landfills continue to produce gas after closure. (Barlaz, Tr. 2217).

1891. Dr. Barlaz explained that whether and to what extent a material biodegrades can be considered to be an intrinsic property of the material. (Barlaz, Tr. 2217-18).

1892. Dr. Barlaz used the term "intrinsic anaerobic biodegradability" to describe a property of the material, much like its color or weight or density. (Barlaz, Tr. 2218).

1893. The intrinsic biodegradability of a material will not change regardless of where the material is placed. (Barlaz, Tr. 2218).

1894. Changes to environmental temperature or moisture do not change the intrinsic biodegradability of a material. (Barlaz, Tr. 2218).

1895. Dr. Barlaz used the example of a piece of paper which, while biodegradable, would not biodegrade in a courtroom if held there for hundreds of years. (Barlaz, Tr. 2218).

1896. The biodegradable nature of the paper will not change simply because it is in the courtroom setting. (Barlaz, Tr. 2218-19).

1897. The point of biodegradation testing is to put the material in an environment that is favorable for biodegradation. (Barlaz, Tr. 2219).

1898. The ASTM D5511 test method is competent and reliable to test for intrinsic biodegradability. (Barlaz, Tr. 2219).

B. Dr. Barlaz Testified that Gas Evolution Tests are Competent and Reliable to Prove Biodegradability

1899. Dr. Barlaz differentiates between a "BMP" test (or "biochemical methane potential") and "reactor-scale tests." (Barlaz, Tr. 2220).

1900. The BMP test is performed in a small 160 milliliter glass vial, while reactor-scale tests are larger and more dynamic environments. (Barlaz, Tr. 2220).

1901. BMP testing can be modified from lab to lab. (Barlaz, Tr. 2220-21).

1902. Some of the modifications commonly seen involve the preparation of the test sample, or screening the material by passing it through a 1mm screen. (Barlaz, Tr. 2221).

1903. Passing a material through a 1mm screen renders the material the consistency of wheat flour. (Barlaz, Tr. 2221).

1904. Other adaptations to the BMP test include changes to temperature or duration of the test. (Barlaz, Tr. 2221-22).

1905. When running a BMP test, Dr. Barlaz uses about one gram of substrate to a hundred milliliters of liquid, so the environment is essentially "pure liquid," a "liquid phase test." (Barlaz, Tr. 2222).

1906. The ASTM D5511 test is a laboratory-scale reactor test. (Barlaz, Tr. 2222-23).

1907. As compared to the BMP test, a laboratory-scale reactor test is performed in a "high-solids environment," and it is "more representative of a high-solids matrix as we see in a landfill." (Barlaz, Tr. 2224).

1908. Dr. Barlaz testified that "what we see in a reactor is representative of what's possible in a landfill if conditions in the landfill are suitable for anaerobic biodegradation." (Barlaz, Tr. 2224).

1909. The methodology involved in laboratory-scale reactor testing starts with a composition of "inoculum" from well-decomposed refuse or municipal waste. (Barlaz, Tr. 2224-25).

1910. Water is added to the system to achieve the requisite moisture levels. (Barlaz, Tr. 2225).

1911. The laboratory monitors the pH, and other variables in the leachate or solution. (Barlaz, Tr. 2225).

1912. The system is designed to capture gas that is generated in the vessels, including the methane and carbon dioxide in the gas, which is used to calculate the methane generation rate. (Barlaz, Tr. 2225).

1913. Controls are used with the laboratory-scale reactors, including an inoculum blank that includes nothing but the decomposed municipal solid waste so that the laboratory can measure the background methane attributable to the inoculum alone. (Barlaz, Tr. 2225-26).

1914. The laboratory "corrects" for background methane attributable solely to the inoculum by subtracting the amount of gas produced by the inoculum blank. (Barlaz, Tr. 2225-26).

1915. Theoretical methane potential is calculated simply from the chemical formula and the chemical composition of the test materials using stoichiometry. (Barlaz, Tr. 2226).

1916. The Buswell equation is used to calculate methane potential of a substrate. (Barlaz, Tr. 2227).

1917. The Buswell equation is a balanced equation that looks at how much carbon, hydrogen, oxygen, nitrogen and sulfur is in a compound, and it stoichiometrically converts those amounts to methane and carbon dioxide (and ammonia and some hydrogen sulfide). (Barlaz, Tr. 2227).

1918. "Mesophilic" refers to a class of microorganisms that have optimal temperature around 98.6 degrees Fahrenheit. (Barlaz, Tr. 2228).

1919. At temperatures above 43 to 44 degrees, mesophiles are killed off or severely inhibited. (Barlaz, Tr. 2228).

1920. "Thermophiles" have an optimal temperature closer to 60 degrees Centigrade. (Barlaz, Tr. 2228).

1921. The Buswell equation does not factor temperature. (Barlaz, Tr. 2228).

1922. Mesophilic versus thermophilic would primarily influence the rate of degradation. (Barlaz, Tr. 2228).

1923. In a laboratory-scale reactor test, the Buswell equation is used along with the actual methane observed to calculate the percentage of methane realized from the test substrate. (Barlaz, Tr. 2229).

1924. Dr. Barlaz explained that BMP tests are traditionally run for 60 days, however over the years he has come to appreciate that shorter term testing for "more slowly degradable components of the waste" is likely not appropriate. (Barlaz, Tr. 2230).

1925. By performing shorter term studies, the tests are not "in fact measure[ing] the total methane potential" of a substrate. (Barlaz, Tr. 2230).

1926. A difference between a BMP and a reactor test is the frequency of gas measurement. (Barlaz, Tr. 2230).

1927. In a laboratory-scale reactor test, the laboratory is typically measuring the gas weekly. (Barlaz, Tr. 2230).

1928. Dr. Barlaz testified that the challenge with "slowly degradable material" is understanding that it is slowly degradable in designing the test. (Barlaz, Tr. 2231).

1929. There are variables or conditions in laboratory-scale reactor tests, like system pH, that can depress the activity of microorganisms if not controlled. (Barlaz, Tr. 2231-32).

1930. Laboratories must also ensure that they have suitable inoculum that is healthy enough to initiate anaerobic biodegradation. (Barlaz, Tr. 2232).

1931. An inoculum that is over-digested before biodegradation testing would limit biodegradation because there may not be enough substrate to maintain healthy microbial populations and, so, the inoculum would not be effective for initiated tests. (Barlaz, Tr. 2232-33).

1932. The most common compounds inhibitory of microorganisms in the closed-system biodegradation test are the carboxylic intermediates (the propionate, butyrate, and acetate) which can accumulate. (Barlaz, Tr. 2234; RX 853 at 20 (figure 2)).

1933. Another class of inhibitory compounds could be a test substrate that has something inhibitory (e.g., additive or impurity) that leaches out and is a microbial inhibitor. (Barlaz, Tr. 2234; Sahu, Tr. 1836).

C. Dr. Barlaz Testified that Complaint Counsel's Theory on In Situ and Lysimeter Studies is Not Supported

1934. Dr. Barlaz "strongly disagree[d]" with Dr. Tolaymat's opinion that *in situ* landfill testing was important to document the anaerobic biodegradability of a material. (Barlaz, Tr. 2236).

1935. Dr. Barlaz testified that you cannot get quantitative information on anaerobic biodegradability out of an in situ landfill test even if it was done perfectly, and the possibility of doing it perfectly is slight at best. (Barlaz, Tr. 2236).

1936. Dr. Barlaz explained that Dr. Tolaymat had referenced lysimeter testing that Dr. Barlaz himself performed with Chris Bareither at the University of Wisconsin. (Barlaz, Tr. 2236).

1937. Dr. Tolaymat incorrectly implied that Dr. Barlaz and Chris Bareither had measured methane generation in the lysimeter test when in fact they did not measure methane generation at all. (Barlaz, Tr. 2237).

1938. According to Dr. Barlaz, "whether it is that large-scale column [lysimeter] or whether you're burying waste in a landfill, to me, the way that you document anaerobic biodegradability is you measure methane and CO2 production that you can attribute to that material." (Barlaz, Tr. 2237).

1939. When a researcher buries a product in a landfill, you cannot measure methane and CO2 emissions. (Barlaz, Tr. 2237).

1940. In *in situ* studies, "[a]ll you're going to do is put it in the landfill and then at some point later go dig it up and say it's either here or it's not here or it's here and it lost this much weight." (Barlaz, Tr. 2237).

1941. There are many problems with the *in situ* landfill testing, including loss of product samples which frequently occurs. (Barlaz, Tr. 2237).

1942. Also, during in-situ studies, the researcher cannot determine if weight loss was specifically attributed to biodegradation. (Barlaz, Tr. 2238).

1943. Landfill in situ studies therefore allow only for qualitative information about a test sample. (Barlaz, Tr. 2238).

1944. Practical difficulties also limit the availability of landfill in situ testing. (Barlaz, Tr. 2238).

1945. Those difficulties include finding cooperative landfills that will work with researchers to maintain access to landfill sites and samples, and agree not to deposit additional waste on top of the test area. (Barlaz, Tr. 2238).

1946. According to Dr. Barlaz, "to suggest that [in situ landfill studies] are what we have to do to make – to prove a material is biodegradable to me is, number one, technically it's not sound because you can't measure methane and CO2. And even if … technically it were sound, you're imposing this hurdle on people that's completely unrealistic." (Barlaz, Tr. 2238-39).

1947. There is no set definition for a "lysimeter" as used in biodegradation testing. (Barlaz, Tr. 2239).

1948. Dr. Barlaz has not performed lysimeter studies in his laboratory, although he had participated in several lysimeter projects at other sites. (Barlaz, Tr. 2240).

1949. Dr. Barlaz disagreed with Dr. Tolaymat's position that lysimeter studies should be used to test for biodegradation, and Dr. Barlaz "was surprised" that Dr. Tolaymat had used data on settlement and leachate quality to obtain data on the biodegradability of a specific material, which is not scientifically supported. (Barlaz, Tr. 2240-41).

1950. Dr. Barlaz found Dr. Tolaymat's suggested use of lysimeter studies to be unscientific because it would be extremely difficult to gather useable, representative biodegradability data from a large lysimeter design. (Barlaz, Tr. 2241-42).

1951. Assuming it was even possible to get data showing anaerobic biodegradability from a lysimeter test, Dr. Barlaz explained that you would then need to test for multiple years to gather suitable data on a slowly degrading substrate. (Barlaz, Tr. 2242-43).

D. Dr. Barlaz Testified that Complaint Counsel's Reliance on Carbon-14 Testing Is Unsupported

1952. Dr. Barlaz is familiar with carbon-14 testing for biodegradable substances. (Barlaz, Tr. 2243-44).

1953. Dr. Barlaz explained that it is important to recognize that the carbon-14 reactor test has the "exact same premise or exact same conceptual experimental design as a reactor test where you're using regular carbon that's not radiolabeled." (Barlaz, Tr. 2244).

1954. The advantage of using carbon-14 testing goes only to sensitivity of testing where the laboratory is measuring minute amounts of biodegradation. (Barlaz, Tr. 2244).

1955. Dr. Barlaz testified that, where the laboratory is measuring substantial amounts of methane and carbon dioxide, the carbon-14 test does not "buy[] you anything." (Barlaz, Tr. 2244).

1956. Dr. Barlaz also explained that where you have a polymer that consists of more than one compound, you have to carbon-14 label the molecule precisely where you want it, and that is not easy to accomplish. (Barlaz, Tr. 2244-45).

1957. Dr. Barlaz has had people ask for carbon-14 testing, and he has not been able to direct them to a laboratory that can properly synthesize a C-14 labeled compound for plastics biodegradation testing. (Barlaz, Tr. 2245).

1958. Dr. Barlaz would be surprised if any expert had performed C-14 testing on the plastic products at issue in this case, because he testified that it would be hard to find someone who could make the properly radiolabeled plastic for testing. (Barlaz, Tr. 2245-46).

1959. In the mid-1990s, Dr. Barlaz purchased radiolabeled products from a company, American Radiolabeled Chemicals, which company Complaint Counsel suggests was capable of providing radiolabeled polymers for testing. (Barlaz, Tr. 2321-22).

1960. American Radiolabeled Chemicals incorrectly characterized the C-14 that they sold Dr. Barlaz. (Barlaz, Tr. 2322).

1961. Dr. Barlaz discovered after months of testing that the radiolabeled product supplied by American Radiolabeled Chemicals was incorrect by an order of magnitude ten different from what they told Dr. Barlaz that they had sold him. (Barlaz, Tr. 2322).

1962. Dr. Barlaz had used the C-14 radiolabeled product in a test of cellulose polymers—not plastics. (Barlaz, Tr. 2321-22).

1963. Dr. Barlaz testified that C-14 radiolabeled testing is not generally accepted in the relevant scientific community as necessary evidence to show biodegradation of materials. (Barlaz, Tr. 2246).

E. Dr. Barlaz Testified that Gas Evolution Data from ECM Biodegradation Testing Proves that Plastic Containing the ECM additive are Biodegradable

1964. In a gas evolution laboratory-scale reactor test, it is broadly accepted by the scientific community that biodegradation can be proven with data showing that the volume of methane produced in the test vessel is greater than the volume of gas produced in the inoculum. (Barlaz, Tr. 2246).

1965. Dr. Barlaz reviewed many of the gas evolution studies involving ECM amended plastics. (Barlaz, Tr. 2247).

1966. Dr. Barlaz was “surprised” that Drs. McCarthy and Tolaymat were dismissive of gas evolution testing without having examined the data. (Barlaz, Tr. 2247).

1967. Dr. Barlaz examined the raw data produced by certain laboratories, particularly the data concerning methane generation from the test substrate and methane generation from the inoculum that would be the background methane. (Barlaz, Tr. 2247-48).

1968. For those tests where Dr. Barlaz had triplicate data (e.g., raw data), he performed statistical analysis, including T-tests, to determine whether there were statistically significant differences between the methane generation in the reactor with the test substrate and the methane attributable to the inoculum alone. (Barlaz, Tr. 2248).

1969. “In many cases,” Dr. Barlaz determined from the data itself that the results were statistically significant, and that the data suggested that there was anaerobic biodegradability of the test plastic. (Barlaz, Tr. 2248).

1970. For other studies where triplicate data was not available, Dr. Barlaz examined the ratios of methane generation in the test material plus inoculum to methane generation from the inoculum only. (Barlaz, Tr. 2248).

1971. Dr. Barlaz concluded for those studies that ratios varied, but the ratios were generally significant even at the lower end. (Barlaz, Tr. 2248-49).

1972. From those ratios, Dr. Barlaz determined that the methane generation in the test vessels could be attributable to the test substrate, which suggests that the substrate was undergoing anaerobic biodegradation and conversion to methane. (Barlaz, Tr. 2249, 2260-62).

1973. Dr. Barlaz prepared a spreadsheet of his statistical calculations. (Barlaz, Tr. 2250; RX 472).

1974. Dr. Barlaz had also updated his spreadsheet to include additional calculations based on the data. (Barlaz, Tr. 2251; RX 968).

1975. To address the question of whether only the ECM additive had biodegraded, Dr. Barlaz estimated the amount of methane that could theoretically be produced by the ECM additive alone. (Barlaz, Tr. 2251-53).

1976. Dr. Barlaz made certain conservative assumptions about the ECM additive when he calculated the amount of potential methane. (Barlaz, Tr. 2252-53).

1977. Dr. Barlaz’s conservative calculation was that one gram of ECM additive would produce 933 mL of methane gas. (Barlaz, Tr. 2253).

1978. Based on that calculation of 933 mL, Dr. Barlaz looked at the methane yields in the test vessels during biodegradation testing, and determined if the amount of biodegradation exceeded the amount that could potentially be sourced from the additive. (Barlaz, Tr. 2253-54).

1979. Dr. Barlaz's calculation of the potential methane yield of the ECM additive is likely conservative because of the assumptions he made. (Barlaz, Tr. 2254).

1980. Dr. Barlaz assumed the additive was 50% carbon. (Barlaz, Tr. 2254).

1981. Polyethylene, by contrast, is almost 90% carbon. (Barlaz, Tr. 2254).

1982. Dr. Barlaz also calculated the methane yield of the ECM additive based on the formula for the ECM additive that Dr. McCarthy used in his expert report at page 24, footnote 17 of his report. (Barlaz, Tr. 2254-55; CCX 891 at 24 n.17).

1983. Based on Dr. McCarthy's description of the ECM additive allegedly based on reverse engineering, Dr. Barlaz calculated a methane yield for the ECM additive of 838 mL per gram. (Barlaz, Tr. 2255; RX 968).

1984. Thus, using Dr. McCarthy's assumptions, the data produced in the gas evolution tests suggests that even **more** of the substrate plastic (not the additive) biodegraded because the ECM additive would have had a lower potential methane yield. (Barlaz, Tr. 2255-56).

1985. Using the Minigrips NE Lab study as an example (RX 838), Dr. Barlaz explained the arithmetic summarized in his spreadsheet. (Barlaz, Tr. 2256-57; RX 968).

1986. Dr. Barlaz calculates the weight of the ECM additive (in grams) by multiplying the percentage of the ECM additive load rating (in the Minigrips test, 1.5%) by the starting weight of the entire test plastic. (Barlaz, Tr. 2256-57).

1987. Because Dr. Barlaz has calculated the amount of total methane potential from one gram of ECM additive, he can then determine the total amount of methane possible in the ECM additive in each specific test by multiplying the actual weight of the ECM additive by the conservative 933 mL calculation (or 838 mL if using Dr. McCarthy's assumptions). (Barlaz, Tr. 2256-58).

1988. Dr. Barlaz also calculated the net methane for each test vessel, which he did by subtracting the mean triplicate methane data from the inoculum blanks from the test vessels. (Barlaz, Tr. 2257-58; RX 968 (Summary sheet)).

1989. For those studies where Dr. Barlaz had raw data, he calculated T-tests. (Barlaz, Tr. 2257).

1990. The T-statistic is the most common statistical test after a calculation of the average. (Barlaz, Tr. 2259).

1991. Dr. Barlaz also calculated standard deviations for tests where he had triplicate data, however the T-test is superior in that it also takes into consideration the elements of standard deviation. (Barlaz, Tr. 2264).

1992. Dr. Barlaz looked for a 95% certainty in the statistics that he ran, which would mean that the researchers are 95% "certain that you got the right answer." (Barlaz, Tr. 2260).

1993. Dr. Barlaz's t-statistics were generally well below the .05 that indicates statistical significance at the 95% level. (Barlaz, Tr. 2257).

1994. Dr. Barlaz's mathematical process is explained in his testimony. (Barlaz, Tr. 2257-59).

1995. Dr. Barlaz explained that where the methane produced from the test vessel is not attributable to the inoculum, and not attributable to the ECM additive, then the biodegradation must come from the plastic substrate itself. (Barlaz, Tr. 2258).

1996. Dr. Barlaz's calculations are also conservative because "it's not proven" that the ECM additive would completely biodegrade on its own while locked within the plastic without also having the plastic biodegrade along with the additive. (Barlaz, Tr. 2258).

1997. Dr. Barlaz also analyzed the ratios of methane to carbon dioxide in the lab tests. (Barlaz, Tr. 2261-62).

1998. A ratio of methane to carbon dioxide that is greater than 1:1 respectively is a good indication that the anaerobic environment was behaving properly. (Barlaz, Tr. 2262-63).

1999. Gas evolution testing also does not account for carbon that may have been cleaved from the substrate but converted to cell mass instead of gas. (Barlaz, Tr. 2263-64).

2000. Therefore, the biodegradation numbers calculated by the laboratories based on gas data alone are a lower limit of the carbon conversion that was actually realized. (Barlaz, Tr. 2263-64).

2001. Based on his statistical analyses and the test data he reviewed concerning ECM amended plastics, Dr. Barlaz testified that competent and reliable scientific evidence exists to show that plastics manufactured with the ECM additive are anaerobically biodegradable. (Barlaz, Tr. 2264-65).

2002. Dr. Barlaz testified that "there are certainly many tests where there's good scientific evidence that the material – that the material underwent anaerobic [biodegradation]." (Barlaz, Tr. 2265).

2003. Dr. Barlaz also performs commercial BMP testing in his lab for interested companies. (Barlaz, Tr. 2265).

2004. Dr. Barlaz has tested certain plastic articles that contained the ECM additive. (Barlaz, Tr. 2265).

2005. Dr. Barlaz's experience with BMP testing is primarily with cellulosic material, which means that the majority of his testing has involved municipal solid waste testing, and cellulose is a major biodegradable component of same. (Barlaz, Tr. 2266).

2006. Dr. Barlaz's "BMP" studies have been conducted mostly up to 60 days in duration. (Barlaz, Tr. 2267).

2007. Dr. Barlaz testified that, with respect to slowly degrading materials, the BMP test that Dr. Barlaz runs is likely not representative of the total biodegradation expected from the material, and that it is quite possible that the material would have continued to biodegrade after Dr. Barlaz terminated his test. (Barlaz, Tr. 2267-68).

2008. If the experimental goal of the test is to capture the maximum methane yield of a test substrate, then Dr. Barlaz testified that a 60-day test is too short to accomplish that objective. (Barlaz, Tr. 2267).

2009. Document RX 952 represents an example BMP test that Dr. Barlaz performed on an ECM amended plastic. (Barlaz, Tr. 2269-70; RX 952).

F. Dr. Barlaz Testified that the Plateau and Priming Effects are Not Bases to Reject ECM Testing

1. The Plateau Effect

2010. Dr. Barlaz has also reviewed tests in this case that were inconclusive with respect to the amount of biodegradation observed in the test environment. (Barlaz, Tr. 2272).

2011. Inconclusive tests can be the result of an inoculum that is not viable. (Barlaz, Tr. 2272-73).

2012. For slowly degrading substances, there is risk that the inoculum may not remain viable over time in a closed-system laboratory reactor test. (Barlaz, Tr. 2273-74).

2013. The inconclusive test results relevant to this case do not alter Dr. Barlaz's opinion concerning the evidence that shows plastics amended with ECM's additive were shown to biodegrade anaerobically. (Barlaz, Tr. 2274).

2014. Based on the totality of the scientific evidence, Dr. Barlaz concluded that, while there were some tests that did not conclusively show anaerobic biodegradation, "many more" did, and, so, "in totality there's evidence that the material is anaerobically biodegrading." (Barlaz, Tr. 2274).

2. The Priming Effect

2015. The scant information in the peer-reviewed literature concerning the "priming effect" of a substrate in the test environment has generally been limited to rapidly accessible or degrading substrates like glucose. (Sahu, Tr. 1888-89).

2016. There is no consensus in the literature as to what the priming effect is, and the degree to which it could be in action during biodegradation testing of plastics. (Sahu, Tr. 1889).

2017. Dr. Barlaz is familiar with Dr. McCarthy's theory on the "priming effect." (Barlaz, Tr. 2277).

2018. Dr. Barlaz testified that the priming effect theory is based on unsupported assumptions that when the ECM additive is degraded, it stimulates the inoculum and results in an increase in background methane. (Barlaz, Tr. 2277-78).

2019. Dr. Barlaz testified that the priming effect, as described by Complaint Counsel's witnesses, was "speculative," stating that it was "quite a stretch to dismiss … data on the basis of a priming effect." (Barlaz, Tr. 2278).

2020. Dr. Barlaz testified that the "priming effect" theory was first described in the peer reviewed literature in reference to aerobic systems only, and then only with readily degradable substrates. (Barlaz, Tr. 2278).

2021. Dr. Barlaz explained that the priming effect theory described by Complaint Counsel's witnesses has not been reported in the peer-reviewed literature with respect to anaerobic systems and slowly degradable substrates like the ECM additive. (Barlaz, Tr. 2278-79).

2022. Dr. Barlaz explained that, per Dr. McCarthy's report, the ECM additive was mostly polycaprolactone (PCL), and in Dr. Barlaz's own research, the amount of degradation solely from PCL was not that significant to stimulate background methane. (Barlaz, Tr. 2279-80).

2023. Dr. Barlaz explained that, in the absence of any peer reviewed literature or evidentiary support, which Complaint Counsel's experts did not provide, the priming effect theory was "quite speculative as a way to shoot down a test." (Barlaz, Tr. 2280).

2024. Comparing a potential priming effect from a readily degradable substrate in an aerobic environment to a slowly degradable substrate in an anaerobic environment is not an appropriate comparison scientifically. (Barlaz, Tr. 2280-81).

2025. Dr. Barlaz also explained that the amount of biodegradation observed in the ECM tests is much higher than any reasonable interpretation of a priming effect theory and, so, the so-called "priming effect" would need to be massive to swallow the test results. (Barlaz, Tr. 2280).

2026. According to Dr. Barlaz, given the amount of biodegradation observed, "if someone is going to use [the priming effect] to throw out data, I'd like to see something more than this, what to me is [a] theoretical possibility without supporting data." (Barlaz, Tr. 2280).

2027. Dr. Sahu also explained in his testimony that the theory of a "priming effect" presented by Complaint Counsel's witnesses was unsupported. (Sahu, Tr. 1936-37).

2028. Dr. Sahu testified that the amount of methane and carbon dioxide gas emitted from the test vessels far exceeded that which could have been sourced by the inoculum and the ECM additive. (Sahu, Tr. 1936-37).

2029. That amount of gas *has* to come from the test plastic. (Sahu, Tr. 1936).

2030. Furthermore, as a way to check against the priming effect, Dr. McCarthy suggested that the laboratories test the ECM additive by itself to determine how much, if any, methane would be sourced from the additive alone. (McCarthy, Tr. 418, 449).

2031. In one of his BMP tests, Dr. Barlaz actually did test the ECM additive by itself. (CCX 951; Barlaz, Tr. 2312-14).

2032. In that test (CCX 951), Dr. Barlaz reported that the amount of methane produced from the ECM additive alone, under BMP testing conditions that favor biodegradation, was 151.2 mL CH4/g. (CCX 951 at 2).

2033. Thus, the additive itself did not produce a priming effect equivalent to that which Complaint Counsel ascribes to other positive ECM tests. (CCX 951 at 2).

2034. Moreover, the additive produced methane within the range that Dr. Barlaz had calculated based on his Buswell equation memorialized in RX 968. (RX 472; RX 968).

2035. Based on Dr. McCarthy's own suggestion, therefore, the data in CCX 951 contradicts the priming effect theory. (CCX 951 at 2).

2036. Dr. McCarthy himself relied on gas evolution testing (not carbon-14 radiolabeled testing) to demonstrate that his polymer blends were biodegradable. (Sahu, Tr. 1893-94; RX 756 at 8-12).

2037. In his own biodegradation testing, Dr. McCarthy did not account for, or even mention, any biodegradation that might result from the theoretical priming effect. (RX 756).

XV. DR. RYAN BURNETTE TESTIFIED TO THE KINDS, NATURE, AND FUNCTIONS OF MICROBES THAT BIODEGRADE PLASTICS

2038. Dr. Ryan Burnette testified based on his extensive experience as a microbiologist and biochemist. (Burnette, Tr. 2360-71).

2039. Dr. Burnette researched the peer reviewed literature concerning the microbes associated with plastics biodegradation. (Burnette, Tr. 2372).

2040. Dr. Burnette testified that landfills have a wide variety of microorganisms capable of participating in biodegradation processes. (Burnette, Tr. 2372-73).

2041. Dr. Burnette also testified that, while the ASTM D5511 test environment features many conditions similar to those in MSW landfills, the test is also not necessarily representative of all conditions in landfills and, so, the D5511 test environment is not necessarily "optimal" to show the full range of biodegradation that might occur in landfills. (Burnette, Tr. 2373).

2042. Dr. Burnette testified that the D5511 or similar laboratory reactor testing is competent and reliable scientific evidence to assess biodegradability of materials in landfills. (Burnette, Tr. 2373).

2043. However, Dr. Burnette also explained that it would be difficult to maintain adequate biological life in a closed-system laboratory environment for sustained periods of time and, so, the test environments have a finite life span that may not be adequate to assess the full spectrum of biodegradation possible. (Burnette, Tr. 2374-75).

2044. Biodegradation involves microorganisms acting on substrates to break down same. (Burnette, Tr. 2376-77).

2045. Bacteria are the most proliferative, abundant form of life known. (Burnette, Tr. 2377).

2046. Bacteria can be prokaryotes or eukaryotes. (Burnette, Tr. 2377).

2047. Bacteria are very small, single-celled organisms that primarily live in colonies. (Burnette, Tr. 2378).

2048. There are bacteria that are specifically anaerobic, called obligate anaerobes, which can only proliferate in an anaerobic environment. (Burnette, Tr. 2378-79).

2049. There is a broad class of bacteria, called facultative anaerobes, which possess the tools to live, proliferate, reproduce, and feed in both oxygen and non-oxygen containing environments. (Burnette, Tr. 2379).

2050. The types of microorganisms relevant to biodegradation can be facultative anaerobes, obligate anaerobes, methanogens, and archaea bacteria. (Burnette, Tr. 2379-80).

2051. Archaea bacteria are within a subclass of bacteria that contain many types of anaerobic organisms. (Burnette, Tr. 2380).

2052. Enzymes are proteins by definition. (Burnette, Tr. 2380).

2053. Enzymes catalyze reactions or expedite reactions that may move slowly without the enzyme. (Burnette, Tr. 2380).

2054. Enzymes have active sites which structurally favor the substrate in a manner such that the reaction can be facilitated. (Burnette, Tr. 2381).

2055. Enzymes in landfills come primarily from microorganisms, bacteria and fungi. (Burnette, Tr. 2382).

2056. Enzymes in nature are not made without the presence of an organism to make them. (Burnette, Tr. 2382).

2057. In an MSW landfill, with respect to the degradation of food sources, the goal of enzymatic production is to obtain carbon for microbial metabolism. (Burnette, Tr. 2383-84).

2058. There are bacteria that secrete certain chemicals, e.g., polysaccharide in nature, acidic or basic, that would result in chemical degradation of food sources. (Burnette, Tr. 2384).

2059. Methane production is clear evidence that MSW landfills are biologically active because methane is the direct result of anaerobic metabolism. (Burnette, Tr. 2385).

2060. Microbial succession is the lifecycle of microorganisms. (Burnette, Tr. 2385).

2061. In the environment, it would be rare to find a singular species of bacteria. (Burnette, Tr. 2385).

2062. In the natural environment multiple species of bacteria coexist and each has a discrete function in the overall cycle of life. (Burnette, Tr. 2385).

2063. Microbial succession involves the lifecycle of a population of bacteria from initiation through proliferation until death. (Burnette, Tr. 2385).

2064. Dr. Burnette testified to microbial succession in landfills from the initial stages of aerobic metabolism into acetogenesis, and eventually methane production. (Burnette, Tr. 1286-87).

2065. Dr. Burnette testified that, with respect to microbial composition, it would be unreasonable to expect or identify a "one-size-fits-all" description of an MSW landfill because the diversity of potential environments presented in landfills is vast with too many variables, which, in turn, leads to proliferation of many different types of microorganisms. (Burnette, Tr. 2388).

2066. Dr. Burnette explained that it would be scientifically impractical (if not impossible) to design a perfect closed-system test that would be representative of all the potential microenvironments in an MSW landfill. (Burnette, Tr. 2388).

2067. In a laboratory closed-system reactor, the test article is not exposed to all of the conditions which it may be exposed to in an MSW landfill. (Burnette, Tr. 2389).

2068. The closed-system test is also subject to design issues that impart certain limitations. (Burnette, Tr. 2389).

2069. Limitations of the closed-system test environment are significant because, in the natural environment where those limitations are removed, the biodegradation of test substrates could be even greater. (Burnette, Tr. 2389-90).

2070. Researchers have identified many specific microorganisms that populate MSW landfills. (Burnette, Tr. 2390).

2071. Dr. Burnette summarized in his expert report the peer reviewed literature wherein scientists have used DNA sequencing to identify a non-exclusive list of many species existing in landfills which are capable of degrading plastics. (Burnette, Tr. 2390; RX 854 at 10).

2072. Landfills contain species within the phyla Proteobacteria, Firmicutes, and Thermotagae which are large families that contain many forms of individual bacteria. (Burnette, Tr. 2391-92).

2073. There are also fungi present in landfills that have been identified in the peer reviewed literature and are responsible for biodegradation. (Burnette, Tr. 2392, 2394).

2074. The diversity of species in landfills is substantial, and it is likely that many of the bacterial species present in landfills are also present in D5511 test environments, and similarly responsible for biodegradation observed therein. (Burnette, Tr. 2392).

2075. The process of biodegradation and bacterial metabolism can take several paths to access carbon in substrates, including, e.g., hydrolysis reactions, oxidative reactions, and fermentation. (Burnette, Tr. 2396-99).

2076. From a microbiological standpoint, the terms "priming effect" and "plateau effect" have very different meanings from the way in which Complaint Counsel's experts have used them in this case. (Burnette, Tr. 2399-2400).

2077. Dr. Burnette has not seen any evidence in the peer reviewed literature or in his experience as a microbiologist that suggests the priming effect that Dr. McCarthy posited could be responsible for the biodegradation observed in ECM's testing. (Burnette, Tr. 2400).

2078. In terms of a "plateau" effect in the laboratory environment, as that phrase is used in this case, Dr. Burnette testified that the plateau is very likely caused by the test conditions and not the biodegradability of the test plastic. (Burnette, Tr. 2401-02).

2079. No life is designed to live in a closed system for a sustained period of time. (Burnette, Tr. 2401-02).

2080. In the closed-system laboratory there is no way to release or expel the waste products created by the bacterial metabolism. (Burnette, Tr. 2402).

2081. If in a closed-system laboratory reactor the test material is slowly degrading, then you would not be expected to see prolonged biodegradation over time because the microorganisms that would act upon the substrate simply die. (Burnette, Tr. 2403).

2082. Feedback inhibition is a common mechanism by which the product of a biochemical reaction itself will loop back and negatively impact further production of the product, like an accumulation event that prevents the reaction from going forward. (Burnette, Tr. 2403-04; RX 854 at 14 (figure 5)).

2083. The buildup of inhibitory byproducts can begin to occupy binding sites of certain other enzymes. (Burnette, Tr. 2404-05).

2084. When that happens, the byproducts of the microbiological metabolic functions will compete adversely with the substrate for enzymatic binding sites. (Burnette, Tr. 2405).

2085. Virtually all microorganisms are susceptible to feedback inhibition effects. (Burnette, Tr. 2405).

2086. Although the mechanism of feedback inhibition is identical in the natural landfill environment, the difference is that, in a closed system, the inhibitory byproducts cannot be expelled or cleared from the ecosystem, while in a landfill setting the byproducts are dispersed or flushed in an open system. (Burnette, Tr. 2405-06).

2087. A biofilm is the formation of microbial colonies in a somewhat concerted manner which develop into films. (Burnette, Tr. 2406).

2088. Bacteria can adhere to plastics, in part, by secreting polysaccharides which promote bonding to the food source. (Burnette, Tr. 2407-08).

2089. The process of adhering to potential food substrates has been described as "docking and locking." (Burnette, Tr. 2408).

2090. The surface area of a plastic has a substantial influence on the ability of a biofilm to form and adhere. (Burnette, Tr. 2409).

2091. Biofilms can contain hundreds to thousands of bacterial species. (Burnette, Tr. 2410).

2092. Closed system laboratories may restrict the types of conditions that allow certain bacteria to thrive and, thus, the test environment may unintentionally limit the biodegradation that can be observed. (Burnette, Tr. 2412-13).

2093. Dr. Burnette testified that biodegradation seen in a closed laboratory system is expected to be less overall than biodegradation in an open, natural system where the diversity of bacteria and conditions are more substantial. (Burnette, Tr. 2412-13).

2094. Enzymes can weaken or break carbon-carbon bonds in plastic polymers (and other long-chain polymers) by lowering the energy required to break the bonds. (Burnette, Tr. 2414).

2095. For instance, the increase in free chlorine ions in solution during the Environ BioPVC test was a clear indication that the carbon-carbon bonds were either broken or the bond breakage was imminent. (Burnette, Tr. 2415-16).

2096. Dr. Burnette diagrammed his analysis of the PVC degradation extemporaneously at his deposition. (Burnette, Tr. 2415-16; CCX 1081).

2097. When chlorine atoms are present in the solution of the BioPVC test, it indicates that the HCl group was cleaved from the polymer through a nucleophilic attack on the PVC molecule. (Burnette, Tr. 1415-17).

2098. The resulting PVC molecule is substantially weakened in that area, and the carbon-carbon bonds will thus break because the remaining carbon-carbon bond is subject to a hydrolysis reaction that will, in fact, cause bond breakage. (Burnette, Tr. 2417; CCX 1081).

2099. The fact that PVC becomes unstable and degraded after losing the HCl group is a textbook analysis of a nucleophilic attack; it is documented in the peer-reviewed literature, and it is "a fundamental of biochemistry." (Burnette, Tr. 2418).

2100. "Nucleophilic attack" means that the enzyme is looking for a positively charged substance to attack. (Burnette, Tr. 2418).

2101. Depolymerases are a class of enzymes that reduce large polymers into smaller units. (Burnette, Tr. 2418-19).

2102. Depolymerases are also responsible for biodegradation of plastic polymers, and they are ubiquitous in the environment. (Burnette, Tr. 2418-21).

2103. Depolymerases use hydrolysis and nucleophilic attacks to break bonds, and they are involved in the reduction and oxidation reactions. (Burnette, Tr. 2419).

2104. Dr. Burnette's expert report (RX 854) documented several microorganisms that have been identified for their ability to biodegrade plastic polymers. (Burnette, Tr. 2420-21).

2105. For example, *Rhodococcus rubber* uses hydrolases and enzymes called esterases to break apart polyethylene polymers into smaller subunits. (Burnette, Tr. 2421).

2106. Oxidation reactions are simply reactions that involve the addition of electrons. (Burnette, Tr. 2421).

2107. An oxidative reaction can occur in anaerobic systems. (Burnette, Tr. 2421-22).

2108. Oxidative reactions can play a role in anaerobic biodegradation of polymers. (Burnette, Tr. 2422).

2109. Anaerobic and aerobic metabolisms in microorganisms are different concepts, but they share many key similarities, including certain Bs of action used to achieve the breakdown of substrates. (Burnette, Tr. 2423-25).

2110. For example, the use of pyruvate dehydrogenase is a key ingredient and factor in both aerobic and anaerobic metabolism. (Burnette, Tr. 2424-25).

2111. Dr. Burnette explained that one documented pathway to polyethylene biodegradation includes a common mechanism applicable to both aerobic and anaerobic systems,

including the cofactor NAD, and the oxidative reactions that occur in both environments. (Burnette, Tr. 2426).

2112. The mechanisms of aerobic biodegradation are therefore useful to interpreting anaerobic biodegradation of polymers like polyethylene. (Burnette, Tr. 2426).

2113. Dr. Burnette identified and testified to other mechanisms of enzymatic degradation of plastic polymers, including the degradation of polyethylene terephthalate, a more difficult to digest polymer, using the cutinase enzyme. (Burnette, Tr. 2428).

2114. Hydrolysis reactions are not limited to environments with high moisture contents. (Burnette, Tr. 2429).

2115. Digestion of certain polymer chains may require just a few molecules of water. (Burnette, Tr. 2429).

2116. Dr. Burnette testified that mesophilic and thermophilic bacteria function at different temperatures and pace, but they use common and universal mechanisms of action to gain access to food sources. (Burnette, Tr. 2430-31).

2117. Dr. Burnette explained that many bacteria identified in the peer reviewed literature as responsible for biodegrading plastics fall within the mesophilic range. (Burnette, Tr. 2432).

2118. Therefore, because bacteria capable of degrading plastics are mesophilic, test conditions (like the D5511) that promote only thermophilic bacteria may not provide a truly "optimal" environment for assessing total biodegradability. (Burnette, Tr. 2432-33).

2119. Certain mesophiles will die at higher temperatures, or become ineffective. (Burnette, Tr. 2432).

2120. Dr. Burnette testified that the ECM additive likely promotes biodegradation in two ways: first by serving as an attractant for microbial growth on and within plastics; and second, by weakening or perturbing the carbon-carbon bonds through weaknesses in the chain or the addition of more weak points in the form of the additive. (Burnette, Tr. 2435-37).

2121. Dr. Burnette testified that the D5511 test is a good measure of biodegradability in an MSW landfill because the biodegradation observed in the D5511 test has occurred despite the limitations of a closed-system, ecologically limited test environment. (Burnette, Tr. 2438-39).

2122. In the open landfill environment, while biodegradation may be at varying rates, the total biodegradation should be expected to increase or, at least, continue onward absent the limitations of a closed-system test. (Burnette, Tr. 2437-40).

2123. The D5511 test represents still a subset of the conditions found in MSW landfills. (Burnette, Tr. 2439-40).

2124. Dr. Burnette testified that "negative" tests are not the same thing as "inconclusive" tests, and a test is not truly "negative" until all of the variables have been explored and you still have replicability of results. (Burnette, Tr. 2442).

2125. Dr. Burnette considers the likelihood of cell death in a closed-system laboratory test to be probable without refreshing the system with new nutrients or expelling the waste. (Burnette, Tr. 2442-43).

2126. The untimely death of the microorganisms in the closed-system laboratory test makes for an inconclusive test with respect to biodegradation testing, and not a negative outcome adverse to the test article. (Burnette, Tr. 2443).

2127. Dr. Burnette also testified that a direct comparison of the rate or extent of biodegradation in cellulose to the rate or extent of biodegradation in the test plastic is not appropriate scientifically because: (a) cellulose is degraded by an entirely different, and very ubiquitous enzyme called cellulace; and (b) cellulose is chosen as a positive control because it is rapidly degradable, while plastics with the ECM additive are comparatively slow degrading products. (Burnette, Tr. 2444-45).

2128. In context with a discussion about microbiological pathways involved in polymer biodegradation, the persistent set of positive ECM test results reveals that the additive is, in fact, enhancing the biodegradation of the plastic itself. (Burnette, Tr. 2446).

XVI. TESTING PROVES THAT PLASTIC CONTAINING THE ECM ADDITIVE IS BIODEGRADABLE

2129. Numerous gas evolution tests have shown that plastics manufactured with ECM's additive, which otherwise do not biodegrade, have biodegraded to a degree that is substantially more than biodegradation that could have been sourced solely by the ECM additive. (Barlaz, Tr. 2175).

A. Aerobic Testing

2130. Dr. Barlaz testified that a portion of the "biodegradation" in MSW landfills occurs through aerobic processes. (Barlaz, Tr. 2214-15).

2131. Complaint Counsel's experts Drs. Tolaymat and McCarthy testified that conventional plastics such as polyethylene are otherwise not biodegradable without the ECM additive. (Tolaymat, Tr. 245; McCarthy, Tr. 414).

2132. Dr. Sahu explained that both aerobic and anaerobic studies are useful when evaluating whether the ECM additive renders conventional plastics biodegradable. (Sahu, Tr. 1917-18).

1. RX 465, 2009 SSCCP Aerobic Test

2133. In 2009, the Stazione Sperimental Carta, Cartoni e Paste per Carta (SSCCP), or Pulp and Paper Experimental Station (an agency of the Chamber of Commerce in Milan), conducted an aerobic composting test of an ECM Plastic. (RX 465)

2134. The 2009 SSCCP test was performed under ISO 14855, a standard titled "Determination of the ultimate aerobic biodegradability of plastic materials under controlled composing conditions—Method by analysis of evolved carbon dioxide." (RX 827)

2135. ISO 14855 describes a "solid-phase respirometric test system based on mature compost…" (RX 827 at v).

2136. The method is "designed to simulate typical aerobic composting conditions for the organic fraction of solid mixed municipal waste." (RX 827 at 1).

2137. The test assesses biodegradation by measure of carbon dioxide emitted, adjusted for the amount of carbon dioxide produced in the "blank" vessels. (RX 827 at 9).

2138. RX 465 involved a test PVC sample, a sample PET, and a sample "orange film." (RX 465 at 114990).

2139. Biodegradation of the test sample under aerobic conditions was recorded, including a substantial increase in biodegradation beginning, generally, after the twentieth day of the 90-day compost test. (RX 465 at 114990).

2140. The average biodegradation among the triplicate data recorded for the PVC sample over the 90 day test period was more than 50%. (RX 465 at 114989).

2141. The average biodegradation among the triplicate data recorded for the orange film sample was 4.8%. (RX 465 at 114989).

2142. The average biodegradation among the triplicate data recorded for PET sample was 4.95%. (RX 465 at 114989).

2143. The SSCCP test marked as RX 465 involved an ECM additive at a 1% load rating. (CCX 202 at 1).

2144. Dr. Tolaymat testified that PVC, without the ECM additive, is not biodegradable under either aerobic or anaerobic conditions. (Tolaymat, Tr. 288).

2. RX 467, 2012 SSCCP Aerobic Test

2145. In 2012, the Stazione Sperimental Carta, Cartoni e Paste per Carta (SSCCP), or Pulp and Paper Experimental Station (an agency of the Chamber of Commerce in Milan), conducted another aerobic composting test of an ECM Plastic under ISO 14855 (RX 827), on behalf of Colplast Srl. (RX 467).

2146. The test was performed on a sample marked for identification as "BR-2010." (RX 467).

2147. Test results were reported on January 8, 2013. (RX 467).

2148. The test marked RX 467 revealed average biodegradation among the triplicate data of approximately 12% over the 90-day test period. (RX 467 at 112490).

2149. The SSCCP test marked as RX 467 involved an ECM additive at a 1% load rating. (CCX-196 at 2).

3. RX 468, 2012 SSCCP Aerobic Test

2150. In 2012, the Stazione Sperimental Carta, Cartoni e Paste per Carta (SSCCP), or Pulp and Paper Experimental Station (an agency of the Chamber of Commerce in Milan), conducted another aerobic composting test of an ECM Plastic under ISO 14855 (RX 827), on behalf of Colplast Srl. (RX 468).

2151. The test was performed on a sample marked for identification as "PR-2011." (RX 468).

2152. Test results were reported on August 1, 2013. (RX 468).

2153. The SSCCP test marked as RX 468 reflected an average biodegradation among the triplicate data of approximately 6.9% over the 90-day test period. (RX 268 at 4).

2154. The SSCCP test marked as RX 468 involved an ECM additive used at 1.1% load rating. (CCX 196 at 4).

4. RX 273, 2010 Ecologia Applicata Aerobic Test

2155. In November 2010, Ecologia Applicata Srl., a laboratory based in Milano, Italy, reported results from an aerobic test of an ECM-amended plastic artifact (a full coffee capsule). (RX 273).

2156. The test marked as RX 273 involved a polypropylene plastic with 1% ECM additive. (RX 273).

2157. The test marked as RX 273 followed the international ISO 14855 standard for aerobic compostability testing. (RX 273 at 2; RX 827 (ISO standard)).

2158. The test marked as RX 273 reported 19.3% biodegradation of the ECM amended plastic after 180 days of testing. (RX 273 at 3).

2159. The test further calculated, based on the data observed, that the ECM-amended plastic would be biodegraded to more than 77% after approximately 2 years. (RX 273 at 3).

2160. In the test marked RX 273, substantial biodegradation did not begin until after 30 days of aerobic testing. (RX 273 at 3).

2161. The rate of biodegradation, as measured through carbon dioxide emissions, revealed that at the close of testing on day 180, biodegradation was still continuing. (RX 273 at 3).

5. RX 276, 2011 Ecologia Applicata Aerobic Test

2162. In January 2012, Ecologia Applicata Srl., a laboratory based in Milano, Italy, reported results from an aerobic test of an ECM-amended plastic artifact (polyamide nylon resin with ECM additive). (RX 276).

2163. The 2011 Ecologia test marked as RX 276 involved an ECM additive at a 1% load rating. (CCX-196 at 2).

2164. The 2011 Ecologia test marked as RX 276 followed the international ISO 14855 standard for aerobic compostability testing. (RX 276; RX 827 (ISO standard)).

2165. In the test marked RX 276, substantial biodegradation did not being until after 20 days of aerobic testing. (RX 276 at 9).

2166. The 2011 Ecologia test marked as RX 276 was conducted under 62.47% dry solids content, or about 38% moisture. (RX 276 at 4).

2167. The test marked as RX 276 reported 46.67% biodegradation of the ECM amended plastic after 180 days of aerobic testing. (RX 276 at 11).

2168. The test further calculated, based on the data observed, that the ECM-amended plastic would be biodegraded to more than 88% after approximately 900 days (or about 2.5 years). (RX 276 at 11).

6. RX 263, 1998 OWS Aerobic Test

2169. In August 1998, O.W.S. Inc. reported test results from an aerobic test involving a 5% ECM film and a 5% Natural Film (load ratings relating to the amount of ECM added by weight). (RX 263 at 1).

2170. The test was stopped at 45 days. (RX 263 at 3).

2171. The test was labeled by OWS as "OWS PFR-1," and it was an aerobic biodegradation under controlled composing conditions. (RX 263 at 1).

2172. In the test marked RX 263, the 5% ECM film showed 4.5% biodegradation, based on carbon dioxide readings, after 45 days. (RX 263 a 3).

2173. The 5% ECM Natural Film showed 2.6% biodegradation over the 45 day period. (RX 263 at 3).

2174. In the test marked RX 263, the average biodegradation of all three cellulose reactors reached only 61.1% after 45 days of testing. (RX 263 at 25).

2175. The biodegradation of the cellulose samples plateaued around the sixth day of testing, with the three cellulose vessels demonstrating no more than sixty percent biodegradation. (RX 263 at 29).

7. RX 266, 2000 OWS Aerobic Test

2176. In March 2000, O.W.S. Inc. reported test results from an aerobic test involving 40-gallon trash bags amended with the ECM additive. (RX 266 at 1).

2177. The test was stopped at 45 days. (RX 266 at 3).

2178. OWS labeled the test "PFR-5," and it was an "aerobic biodegradation under controlled composting conditions." (RX 266 at 1).

2179. In the test marked RX 266, the 40-gallon trash bag amended with the ECM trash bag biodegraded 5.2% in 45 days of testing. (RX 266 at 3).

B. Anaerobic Testing

1. Eden Laboratories ("ERL") Testing Generally

2180. Eden Laboratories ("ERL") is a laboratory in New Mexico, owned and operated by Thomas Poth. (Poth, Tr. 1440-41).

2181. Thomas Poth performs scientific studies alongside Dr. Brian Esau. (Poth, Tr. 1440-41).

2182. Dr. Esau has a master's degree and a Ph.D. in biochemistry from the University of Illinois at Champaign-Urbana. (Poth, Tr. 1441).

2183. Dr. Brian Esau participates in daily operation of the laboratory, and performs testing of products. (Poth, Tr. 1441).

2184. ERL performs D5511 biodegradation testing for clients. (Poth, Tr. 1447-48).

2185. ERL follows the D5511 protocol, but has made adjustments to that protocol to more closely simulate a landfill. (Poth, Tr. 1449-50).

2186. ERL has increased the solids content in its D5511 test. (Poth, Tr. 1450).

2187. Other than the adjustment to solids content (or moisture content), ERL does not alter the D5511 test protocol in any substantial way. (Poth, Tr. 1450).

2188. ERL increased the solids content of its test so that its D5511 test would look more like a landfill as opposed to a digester. (Poth, Tr. 1450).

2189. ERL explained to its customers that ERL's testing is not performed at optimal moisture contents and, as a consequence, the performance of test samples in biodegradation testing are not going to be optimal. (Poth, Tr. 1451-52).

2190. ERL explained that the higher solid content involved in ERL D5511 testing would be more appropriate because the testing was more indicative of performance in a landfill. (Poth, Tr. 1452).

2191. ERL prepares its test "inoculum" with compost obtained from a local facility. (Poth, Tr. 1457-58).

2192. ERL conditions its inoculum in an incubator to climatize it to temperature and promote selection of anaerobic microbes. (Poth, Tr. 1459-60).

2193. ERL combines its compost with sewage sludge to form the final inoculum. (Poth, Tr. 1461).

2194. Sewage sludge, as used by ERL, consists of the solids that come from the digester in ERL's laboratory. (Poth, Tr. 1461).

2195. ERL determines the moisture content of its inoculum, and adjusts the liquid added to the inoculum before placing it in the incubator, which helps control the specific moisture content in the final, test-ready inoculum. (Poth, Tr. 1463).

2196. ERL reviews and controls for the carbon to nitrogen levels, the ammonia levels, and the pH. (Poth, Tr. 1463-64).

2197. ERL runs all D5511 tests in triplicate, using three separate test vessels for each of the three controls in the D5511 standard, the two additional controls that ERL relies on, and the test vessels. (Poth, Tr. 1466).

2198. ERL uses a gas chromatograph to analyze the gas emissions produced during the D5511 test. (Poth, Tr. 1468-69).

2199. ERL calibrates its gas chromatograph monthly and as appropriate. (Poth, Tr. 1469).

2200. ERL uses a graduated cylinder to record total gas volume and collect gas during the D5511 test. (Poth, Tr. 1468).

2201. ERL does not use Mylar or Kevlar bags for gas collection because ERL previously determined that those bags leaked methane, and because the bags made gas transfer difficult. (Poth, Tr. 1468).

2202. ERL calculates the percentage of biodegradation observed in a D5511 test by performing the necessary calculations of theoretical gas yields, and comparing those to the gas yield of the sample (excluding the gas produced by the inoculum blanks). (Poth, Tr. 1469-71).

2203. ERL's method of calculating the percentage of biodegradation follows the ASTM D5511 standard. (RX 356 at 4).

2204. ERL has had difficulties in testing certain plastic polymers in the laboratory reactor tests. (Poth, Tr. 1472-73).

2205. For example, with plastic foams, ERL testified that it was difficult to have decent surface area contact with the inoculum. (Poth, Tr. 1473).

2206. ERL testified that the foam products frequently consumed too much space in the test vessel. (Poth, Tr. 1473).

2207. ERL's testing protocols, which follow the D5511 test, are not suitable for plastics that have components inhibitory to microorganisms. (Poth, Tr. 1471).

2208. ERL does not refresh inoculum during D5511 tests that are run over a long duration. (Poth, Tr. 1474).

2209. ERL has seen plateaus in the biodegradation in long term tests, which last for a period of up to two months before biodegradation in the test system sometimes resumes. (Poth, Tr. 1474).

2210. ERL uses a standard format for reporting data in a D5511 test. (Poth, Tr. 1480-81).

2211. Dr. Barlaz visited Eden Laboratories in about December 2012 for a meeting. (Barlaz, Tr. 2274).

2212. His visit to ERL predated and was unrelated to his participation as an expert witness in this case. (Barlaz, Tr. 2274-75).

2213. Having reviewed ERL's biodegradation testing, Dr. Barlaz was comfortable that ERL's testing was strictly under anaerobic conditions and that Eden Labs had the appropriate capability to monitor gas volume and composition. (Barlaz, Tr. 2275).

2214. Dr. Barlaz observed ERL's test reactors. (Barlaz, Tr. 2275).

2215. Dr. Barlaz reviewed ERL's testing process with ERL's owner, Thomas Poth. (Barlaz, Tr. 2275).

2216. Dr. Barlaz was comfortable that ERL's biodegradation testing was "legitimate anaerobic testing." (Barlaz, Tr. 2275).

a. RX 248, Eden Laboratories No. 092511B

2217. In September 2011, Eden Laboratories reported test data from an anaerobic D5511 biodegradation test in laboratory reactors. (RX 248).

2218. ERL performed the test on behalf of FP International, using test samples that were provided by FP. (RX 248 at 1).

2219. The test marked RX 248 followed the ASTM D5511 protocol. (RX 248 at 1).

2220. The solid content of the test was 48.4%. (RX 248 at 1).

2221. The study authors recorded gas evolution data on a weekly basis. (RX 248 at 2-4).

2222. The study authors calculated pH volumes, volatile fatty acids, and ammonium nitrogen levels. (RX 248 at 1).

2223. The test marked RX 248, as with all ERL D5511 tests, included the use of an inoculum blank, a negative control (polyethylene), a positive control (cellulose), a negative control consisting of an untreated plastic, and two test samples, all of which were run in triplicate. (RX 248; Poth, Tr. 1466-67).

2224. The test marked RX 248 included two "test" plastic samples both amended with the ECM additive at 1% by weight. (RX 248 at 1-2).

2225. The two test samples, marked "ERL #223" and "ERL #224" in RX 248, were polyethylene "airbags." (Blood, Dep. at 166-169)

2226. The test marked RX 248 involved a negative control that was an "airbag control," a plastic that was not amended with the ECM additive. (RX 248).

2227. The test marked RX 248 revealed biodegradation of the two ECM amended plastics in the amount of **11.5%** for sample "223" and **15.2%** for sample "224" after 120 days of anaerobic testing. (RX 248 at 5).

2228. In the test marked RX 248, the amount of methane recorded in sample 223 was 3,884.2 mL. (RX 248 at 5).

2229. The amount of methane recorded from sample 224 was 4,761.8 mL. (RX 248 at 5).

2230. In the test marked RX 248, the total mass of the sample "223" was 20 grams. (RX 248 at 5).

2231. The ECM additive, at 1% by weight, had a mass of 0.2 grams. (RX 248).

2232. Based on Dr. Barlaz's conservative calculation, the total theoretical yield of methane from 0.2 grams of the ECM additive is 186.6 mL of methane, calculated by multiplying the grams of ECM additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM additive in the sample. (RX 968).

2233. At 3,884.2 mL, the amount of methane recorded from test sample "223" in RX 248 was nearly twenty times the biodegradation that could have been sourced from the ECM additive alone. (RX 248 at 5; RX 968; Barlaz, Tr. 2252-58).

2234. In the test marked RX 248, the total mass of the sample marked "224" was 20 grams. (RX 248).

2235. The ECM additive, at 1% by weight, had a mass of 0.2 grams. (RX 248).

2236. Based on Dr. Barlaz's conservative calculation, the total theoretical yield of methane from the 0.2 grams of the ECM additive is 186.6 mL of methane, calculated by multiplying the grams of ECM additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM additive in the sample. (RX 968).

2237. At 4,761.8 mL, the amount of methane recorded from the test sample "224" is more than twenty five times the amount of biodegradation that could have been sourced from the ECM additive alone. (RX 248 at 5; RX 968; Barlaz, Tr. 2252-58).

2238. The cumulative amount of methane collected from test RX 248 represented about fifty percent of the total gas emissions. (RX 248 at 5).

2239. The study author, Eden Laboratories, reported that it was "obvious that biodegradation has occurred on the treated sample. (RX 248 at 6).

2240. Based on the data collected, the study author reported that, as if the date of the report, "the treated sample is continuing to biodegrade." (RX 248).

b. RX 839, Eden Laboratories No. 070312C

2241. In July 2012, Eden Laboratories reported test data from an anaerobic D5511 biodegradation test in laboratory reactors. (RX 839).

2242. ERL performed the test on behalf of Shields Bag & Printing. (RX 839 at 113977).

2243. The test marked RX 839 followed the ASTM D5511 protocol. (RX 839 at 113977). The solid content of the test was 48.4%. (RX 839 at 113977).

2244. The study authors recorded gas evolution data on a weekly basis. (RX 839 at 113978-80).

2245. The study authors calculated pH volumes, volatile fatty acids, and ammonium nitrogen levels. (RX 839 at 113977).

2246. The test marked RX 839, as with all ERL D5511 tests, included the use of an inoculum blank, a negative control (polyethylene), a positive control (cellulose), a negative control consisting of an untreated plastic, and one test sample, all of which were run in triplicate. (RX 839 at 113982; Poth, Tr. 1466-67).

2247. The test marked RX 839 included a "test" plastic sample amended with the ECM additive at 1% by weight. (RX 839 at 113978).

2248. The test sample, marked "476A" was a clear film. (RX 839 at 113982).

2249. The test marked RX 839 involved a negative control that was a "control film," a plastic that was not amended with the ECM additive. (RX 839 at 113982).

2250. The test marked RX 839 revealed biodegradation of the ECM amended plastic in the amount of **7.9%** after 22 weeks of anaerobic testing. (RX 839 at 113982).

2251. In the test marked RX 839, the amount of methane recorded in sample 476A was 2,053.2 mL. (RX 839 at 113982).

2252. In the test marked RX 839, the total mass of the sample "476A" was 20 grams. (RX 839 at 113982).

2253. The ECM additive, at 1% by weight, had a mass of 0.2 grams. (RX 839; Barlaz, Tr. 2252-58).

2254. Based on Dr. Barlaz's conservative calculation, the total theoretical yield of methane from 0.2 grams of the ECM additive is 186.6 mL of methane, calculated by multiplying the grams of ECM additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM additive in the sample. (RX 968; Barlaz, Tr. 2252-58).

2255. At 2,053.2 mL, the amount of methane recorded from test sample "476A" in RX 839 was eleven times the amount of biodegradation that could have been sourced from the ECM additive alone. (RX 839 at 113982; RX 968; Barlaz, Tr. 2252-58).

2256. The amount of methane recorded in the inoculum blanks was just 792.7 mL. (RX 839 at 113982).

2257. The study author, Eden Laboratories, reported that it was "obvious that biodegradation has occurred on the treated sample." (RX 839 at 113982).

2258. Based on the data collected, the study author reported that, as if the date of the report, "the treated sample is continuing to biodegrade." (RX 839 at 113982).

c. RX 403, Eden Laboratories Fellows Test

2259. In October 2012 through February 2013, Eden Laboratories reported test data from an anaerobic D5511 biodegradation test in laboratory reactors. (RX 403).

2260. ERL performed the test on behalf of Fellows. (RX 403 at 001048).

2261. The test marked RX 403 followed the ASTM D5511 protocol. (RX 403 at 001048).

2262. The test report is an ERL "update." (RX 403).

2263. ERL produces update reports to keep customers abreast of the status of testing. (Poth, Tr. 1477).

2264. Update reports do not include all of the information relevant to the test, or all of the information included in a final report. (Poth, Tr. 1475).

2265. The test marked RX 403, as with all ERL D5511 tests, included the use of an inoculum blank, a negative control (polyethylene), a positive control (cellulose), two negative controls consisting of an untreated plastics, and two test samples, all of which were run in triplicate. (RX 403 at 001048; Poth, Tr. 1466-67).

2266. The test marked RX 403 included two "test" plastic samples amended with the ECM additive at 1% by weight. (RX 403 at 001048).

2267. One test sample designated “568-P1004” included a “1% ECM BioFilm Resin.” (RX 403 at 001048).

2268. One test sample designated “570-TPU” included a “1% ECM BioFilm Resin Pink.” (RX 403 at 001048).

2269. The test marked RX 403 involved negative controls that were control resins, plastics that was not amended with the ECM additive and contained “0% ECM.” (RX 403 at 001052).

2270. ERL recorded data for the test marked RX 403 through 197 days. (RX 403 at 001052).

2271. In the test marked RX 403, ERL recorded biodegradation of the ECM amended sample “568-P1004” in the amount of 71.8% after 197 days of anaerobic testing. (RX 403 at 001052).

2272. For the sample marked 568-P1004, Dr. Barlaz calculated a net methane yield of 7,548.9 mL, meaning that the test produced 7,548.9 mL more than the inoculum blanks. (RX 403; RX 968; Barlaz, Tr. 2252-58).

2273. The total mass of the sample “568-P1004” was 20 grams. (RX 403 at 001052).

2274. The ECM additive, at 1% by weight, had a mass of 0.2 grams. (RX 403; Barlaz, Tr. 2252-58).

2275. Based on Dr. Barlaz’s conservative calculation, the total theoretical yield of methane from 0.2 grams of the ECM additive is 186.6 mL of methane, calculated by multiplying the grams of ECM additive by Dr. Barlaz’s calculation of the mL of methane per gram of ECM additive in the sample. (RX 968; Barlaz, Tr. 2252-58).

2276. At a net methane production of 7,548.9 mL, the amount of methane recorded from test sample “568-P1004” in RX 403 was more than forty times the amount that could have theoretically been sourced from the ECM additive. (RX 403 at 113982; RX 968; Barlaz, Tr. 2252-58).

2277. In the test marked RX 403, ERL recorded biodegradation of the ECM amended sample “570-TPU” in the amount of 16.1% after 197 days of anaerobic testing. (RX 403 at 001052).

2278. For the sample marked 570-TPU, Dr. Barlaz calculated a net methane yield of 2,337.5 mL, meaning that the test produced 2,337.5 mL more than the inoculum blanks. (RX 403; RX 968; Barlaz, Tr. 2252-58).

2279. The total mass of the sample “570-TPU” was 20 grams. (RX 403 at 001052).

2280. The ECM additive, at 1% by weight, had a mass of 0.2 grams. (RX 403; Barlaz, Tr. 2252-58).

2281. Based on Dr. Barlaz's conservative calculation, the total theoretical yield of methane from 0.2 grams of the ECM additive is 186.6 mL of methane, calculated by multiplying the grams of ECM additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM additive in the sample. (RX 968; Barlaz, Tr. 2252-58).

2282. At 2,337.5 mL, the amount of methane recorded from test sample "570-TPU" in RX 403 was more than twelve times the amount of biodegradation that could have been sourced from the ECM additive alone. (RX 403 at 113982; RX 968; Barlaz, Tr. 2252-58).

2283. The ratio of mean substrate methane to mean inoculum methane was more than 5:1, indicating that the biodegradation observed in the test environment was confidently ascribed to the test article. (RX 968; Barlaz, Tr. 2247-50).

d. RX 402, Eden Laboratories FP International Testing

2284. In October 2013 through February 2014, Eden Laboratories reported test data from an anaerobic biodegradation test in laboratory reactors. (RX 402).

2285. ERL performed the test on behalf of FP International. (RX 402 at 001046).

2286. The test marked RX 402 followed a modernized and more recent ASTM protocol. (RX 402 at 001046).

2287. The test report is an ERL "update." (RX 402).

2288. ERL produces update reports to keep customers abreast of the status of testing. (Poth, Tr. 1477).

2289. Update reports do not include all of the information relevant to the test, or all of the information included in a final report. (Poth, Tr. 1475).

2290. The test marked RX 402, as with ERL biodegradation tests modeled after D5511, included the use of an inoculum blank, a negative control (polyethylene), a positive control (cellulose), a negative control consisting of an untreated plastic, and two test samples, all of which were run in triplicate. (RX 402 at 001046; Poth, Tr. 1466-67).

2291. The test marked RX 402 included two "test" plastic sample amended with the ECM additive at 1% and 1.75% by weight. (RX 402 at 001046).

2292. One test sample designated "726" included a "Film with 1% ECM." (RX 402 at 001046).

2293. One test sample designated "727" included a "Film with 1.75% ECM." (RX 402 at 001046).

2294. The test marked RX 402 involved a negative control that was a control film containing "0% ECM." (RX 402 at 001046).

2295. ERL recorded data for the test marked RX 402 through 290 days. (RX 402 at 001042).

2296. There is no provision of D5511 that limits the amount of time under which a D5511 test can be run. (RX 356).

2297. In the test marked RX 402, ERL recorded biodegradation of the ECM amended sample "728" in the amount of 11.5% after 290 days of anaerobic testing. (RX 402 at 1042).

2298. For the sample marked 727, Dr. Barlaz calculated a net methane yield of 1,352.2 mL, meaning that the test produced 1,352.2 mL more than the inoculum blanks. (RX 402; RX 968; Barlaz, Tr. 2252-58).

2299. The total mass of the sample "727" was 20 grams. (RX 402 at 001042; RX 968).

2300. The ECM additive, at 1% by weight, had a mass of 0.35 grams. (RX 402; RX 968; Barlaz, Tr. 2252-58).

2301. Based on Dr. Barlaz's conservative calculation, the total theoretical yield of methane from 0.35 grams of the ECM additive is 326.55 mL of methane, calculated by multiplying the grams of ECM additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM additive in the sample. (RX 968; Barlaz, Tr. 2252-58).

2302. At a net methane production of 1,352.2 mL, the amount of methane recorded from test sample "727" in RX 402 was more than four times the amount of biodegradation that could have theoretically been sourced from the ECM additive alone. (RX 402 at 001042; RX 968; Barlaz, Tr. 2252-58).

e. CCX-548, Eden Laboratories FP International Testing

2303. In October 2013 through February 2014, Eden Laboratories reported test data from an anaerobic biodegradation test in laboratory reactors. (CCX 548).

2304. ERL performed the test on behalf of FP International. (CCX 548 at 1).

2305. The test marked CCX 548 followed a modernized and more recent ASTM protocol. (CCX 548 at 1).

2306. The test report is an ERL "update." (CCX 548).

2307. ERL produces update reports to keep customers abreast of the status of testing. (Poth, Tr. 1477).

2308. Update reports do not include all of the information relevant to the test, or all of the information included in a final report. (Poth, Tr. 1475).

2309. The test marked CCX 548, as with other ERL biodegradation tests modeled after D5511, included the use of an inoculum blank, a negative control (polyethylene), a positive control (cellulose), a negative control consisting of an untreated plastic, and a test sample, all of which were run in triplicate. (CCX 548 at 1; Poth, Tr. 1466-67).

2310. The test marked CCX 548 included a "test" plastic amended with the ECM additive and labeled "723 – Biodegradable EPS FloPak." (CCX 548 at 1).

2311. ERL recorded data for the test marked CCX 548 through 291 days. (CCX 548 at 1).

2312. There is no provision of D5511 that limits the amount of time under which a D5511 test can be run. (RX 356).

2313. In the test marked CCX 548, ERL recorded biodegradation of the ECM amended sample "723" in the amount of 30.4% after 291 days of anaerobic testing. (CCX 548 at 1).

2314. For the sample marked 723, ERL reported 2,705.9 mL of total methane, compared to just 383.4 mL of methane in the inoculum blank. (CCX 548 at 1).

2315. The net methane is therefore 2322.5 mL in the "723" sample vessels. (CCX 548 at 1).

2316. The sample mass of the "723" test sample was 7.5 grams. (CCX 548 at 1).

2317. The amount of the ECM additive is not provided in the report marked CCX 548. (CCX 548 at 1).

2318. FP International testified at deposition that FP had manufactured a polystyrene product containing the ECM additive at 1% by weight. (RX 871 (Blood, Dep. at 57-58)).

2319. Even assuming that the ECM additive was introduced at 5% by weight, the weight of the ECM additive in the 7.5 gram "723" sample tested in CCX 548 would have been 0.375 grams. (CCX 548; RX 968; Barlaz, Tr. 2252-58).

2320. Based on Dr. Barlaz's conservative calculations, the total theoretical yield of methane from 0.375 grams of the ECM additive is 349.875 mL of methane, calculated by multiplying the grams of ECM additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM additive in the sample. (RX 968; Barlaz, Tr. 2252-58).

2321. At a net methane production of 2322.5 mL, the amount of methane recorded from test sample "723" in CCX 548 was more than 6.5 times the amount of biodegradation that could have theoretically been sourced from the ECM additive alone. (CCX 548 at 1; RX 968; Barlaz, Tr. 2252-58).

f. CCX 546, Eden Laboratories FP International Testing

2322. In November 2013, Eden Laboratories reported test data from an anaerobic D5511 biodegradation test in laboratory reactors. (CCX 546).

2323. ERL performed the test on behalf of FP International. (CCX 546 at 1).

2324. The test marked CCX 546 is an ERL "update." (CCX 546).

2325. ERL produces update reports to keep customers abreast of the status of testing. (Poth, Tr. 1477).

2326. Update reports do not include all of the information relevant to the test, or all of the information included in a final report. (Poth, Tr. 1475).

2327. The test marked CCX 546, as with other ERL biodegradation tests modeled after D5511, included the use of an inoculum blank, a negative control (polyethylene), a positive control (cellulose), a negative control consisting of an untreated plastic, and two test samples, all of which were run in triplicate. (CCX 546 at 1; Poth, Tr. 1466-67).

2328. The test marked CCX 546 included two "test" plastic containing the ECM additive, labeled "223A-TKN Green" and "224A-HOP Green." (CCX 546 at 1).

2329. The ERL test marked CCX 546 does not report the amount of ECM additive included in the test samples. (CCX 546 at 1).

2330. James Blood, FP International, testified at deposition that the test would have involved a 1% ECM additive product. (RX 871 (Blood, Dep. at 164-65)).

2331. James Blood of FP International testified that the primary difference between the test samples marked "TKN" and "HOP" was the location or factory where the samples were manufactured. (RX 871 (Blood, Dep. at 164-65)).

2332. ERL recorded data for the test marked CCX 546 through 977 days. (CCX 546 at 1).

2333. There is no provision of D5511 that limits the amount of time under which a D5511 test can be run. (RX 356).

2334. In the test marked CCX 546, ERL recorded biodegradation of the ECM amended sample "223A" in the amount of 36.7% after 977 days of anaerobic testing. (CCX 546 at 1).

2335. In the test marked CCX 546, ERL recorded biodegradation of the ECM amended sample "224A" in the amount of 39.8% after 977 days of anaerobic testing. (CCX 546 at 1).

2336. For the sample marked 223A, ERL reported 9,268.8 mL of total methane, compared to just 1,805.9 mL of methane in the inoculum blank. (CCX 546 at 1).

2337. The net methane is therefore 7,462.9 mL in the "223A" sample vessels. (CCX 546 at 1; RX 968; Barlaz, Tr. 2252-58).

2338. For the sample marked 224A, ERL reported 9,970.8 mL of total methane, compared to just 1,805.9 mL of methane in the inoculum blank. (CCX 546 at 1; RX 968; Barlaz, Tr. 2252-58).

2339. The net methane is therefore 8,164.9 mL in the "224A" sample vessels. (CCX 546 at 1; RX 968; Barlaz, Tr. 2252-58).

2340. The sample mass of the "223A" test sample was 20 grams. (CCX 546 at 1).

2341. The sample mass of the "224A" sample was 20 grams. (CCX 546 at 1).

2342. At 1% by weight, the sample mass of the ECM additive in the 223A and 224A samples was 0.20 grams. (RX 968; Barlaz, Tr. 2252-58).

2343. Based on Dr. Barlaz's conservative calculations, the total theoretical yield of methane from 0.2 grams of the ECM additive is 186.6 mL of methane, calculated by multiplying the grams of ECM additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM additive in the sample. (RX 968; Barlaz, Tr. 2252-58).

2344. At a net methane production of 7,462.9 mL, the amount of methane recorded from test sample "223A" in CCX 546 was about forty (40) times the amount that could have possibly been sourced from the ECM additive. (CCX 546 at 1; RX 968; Barlaz, Tr. 2252-58).

2345. At a net methane production of 8,164.9 mL, the amount of methane recorded from test sample "224A" in CCX 546 was about forty-four (44) times the amount of biodegradation that could have possibly been sourced from the ECM additive. (CCX 546 at 1; RX 968; Barlaz, Tr. 2252-58).

g. CCX 534, Eden Laboratories MicroTek Testing

2346. In May 2012 through March 2013, Eden Laboratories reported test data from an anaerobic D5511 biodegradation test in laboratory reactors. (CCX 534).

2347. ERL performed the test on behalf of MicroTek. (CCX 534 at 009017).

2348. The test marked CCX 534 was performed on a polyethylene film. (CCX 534 at 009017).

2349. The test marked CCX 534 is an ERL "update." (CCX 534). ERL produces update reports to keep customers abreast of the status of testing. (Poth, Tr. 1477).

2350. Update reports do not include all of the information relevant to the test, or all of the information included in a final report. (Poth, Tr. 1475).

2351. The test marked CCX 534, as with other ERL biodegradation tests modeled after D5511, included the use of an inoculum blank, a negative control (polyethylene), a positive control (cellulose), a negative control consisting of an untreated plastic, and a test sample, all of which were run in triplicate. (CCX 534 at 009017; Poth, Tr. 1466-67).

2352. The test marked CCX 534 included a "test" plastic amended with the ECM additive, labeled "BIO10115 ECM FILM." (CCX 534 at 009017).

2353. The ERL test marked CCX 534 does not report the amount of ECM additive included in the test samples. (CCX 534 at 009017).

2354. ERL recorded data for the test marked CCX 534 through 485 days. (CCX 534 at 009017).

2355. There is no provision of D5511 that limits the amount of time under which a D5511 test can be run. (RX 356).

2356. In the test marked CCX 534, ERL recorded biodegradation of the ECM amended sample "BIO10115" in the amount of 45.2% after 485 days of anaerobic testing. (CCX 534 at 009017).

2357. For the sample marked BIO10115, ERL reported 7,588.2 mL of total methane, compared to just 1,781.7 mL of methane in the inoculum blank. (CCX 534 at 009017).

2358. The net methane is therefore 5,806.5 between the test vessels and the inoculum vessels. (CCX 534 at 009017; RX 968; Barlaz, Tr. 2252-58).

2359. The sample mass of the "BIO10115" test sample was 13 grams. (CCX 534 at 009017).

2360. Even assuming that the ECM additive was included at 5% by weight, the sample mass of the ECM additive in the BIO10115 sample would have been 0.65 grams. (CCX 534 at 009017; RX 968; Barlaz, Tr. 2252-58).

2361. Based on Dr. Barlaz's conservative calculations, the total theoretical yield of methane from 0.65 grams of the ECM additive is 606.45 mL of methane, calculated by multiplying the grams of ECM additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM additive in the sample. (RX 968; Barlaz, Tr. 2252-58).

2362. At a net methane production of 5,806.5 mL, the amount of methane recorded from test sample "BIO10115" in CCX 534 was about nine and one half (9.5x) times the amount of biodegradation could have possibly been sourced from the ECM additive. (CCX 534 at 009017; RX 968; Barlaz, Tr. 2252-58).

h. CCX 547, Eden Laboratories EcoLab Testing

2363. In March 2013 through September 2013, Eden Laboratories reported test data from an anaerobic D5511 biodegradation test in laboratory reactors. (CCX 547).

2364. ERL performed the test on behalf of EcoLab. (CCX 547 at 009008).

2365. The test marked CCX 547 is an ERL "update." (CCX 547).

2366. ERL produces update reports to keep customers abreast of the status of testing. (Poth, Tr. 1477).

2367. Update reports do not include all of the information relevant to the test, or all of the information included in a final report. (Poth, Tr. 1475).

2368. The test marked CCX 547, as with other ERL biodegradation tests modeled after D5511, included the use of an inoculum blank, a negative control (polyethylene), a positive control (cellulose), and a test sample, all of which were run in triplicate. (CCX 547 at 009017; Poth, Tr. 1466-67).

2369. The test marked CCX 547 included two "test" plastic containing the ECM additive, on sample labeled "538A BIO10115 ECM Film," and another sample labeled "539A BIO10115 ECM Film." (CCX 547 at 009008).

2370. ERL recorded data for the test marked CCX 547 through 452 days. (CCX 547 at 009004-08).

2371. There is no provision of D5511 that limits the amount of time under which a D5511 test can be run. (RX 356).

2372. In the test marked CCX 547, ERL recorded biodegradation of the ECM amended sample “538A” in the amount of 19.6% after 452 days of anaerobic testing. (CCX 547 at 009008).

2373. In the test marked CCX 547, ERL recorded biodegradation of the ECM amended sample “539A” in the amount of 46.5% after 452 days of anaerobic testing. (CCX 547 at 009008).

2374. The ERL test marked CCX 547 does not report the amount of ECM additive included in the test samples. (CCX 547 at 009008).

2375. For the sample marked 538A, ERL reported 5,356.4 mL of total methane, compared to just 1093.3 mL of methane in the inoculum blank. (CCX 547 at 009008).

2376. The net methane for sample 538A is therefore 4,263.1 mL between the test vessels and the inoculum vessels. (CCX 547 at 009008; RX 968; Barlaz, Tr. 2252-58).

2377. For the sample marked 539A, ERL reported 9,778.7 mL of total methane, compared to 1093.3 mL of methane in the inoculum blank. (CCX 547 at 009008).

2378. The net methane for sample 539A is therefore 8,685.4 mL between the test vessels and the inoculum vessels. (CCX 547 at 009008; RX 968; Barlaz, Tr. 2252-58).

2379. The sample masses of the “538A” and “539A” test samples were 20 grams each. (CCX 547 at 009008).

2380. Even assuming that the ECM additive was included at 5% by weight in the 538A sample (an amount higher than the 1-2% that customers ordinarily use), the sample mass of the ECM additive in the 538A sample would have been 1 gram. (CCX 547 at 009008; RX 968; Barlaz, Tr. 2252-58).

2381. Even assuming that the ECM additive was included in the 539A sample at 15% (an amount substantially higher than the 1-2% that customers ordinarily use), the sample mass of the ECM additive in the 539A sample would have been 3 grams. (CCX 547 at 009008; RX 968; Barlaz, Tr. 2252-58).

2382. Based on Dr. Barlaz’s conservative calculations, the total theoretical yield of methane from 1 gram of the ECM additive is 933 mL of methane, calculated by multiplying the grams of ECM additive by Dr. Barlaz’s calculation of the mL of methane per gram of ECM additive in the sample. (RX 968; Barlaz, Tr. 2252-58).

2383. The total theoretical yield of methane from 3 grams of the ECM additive is 2,799 mL, calculated by multiplying the grams of ECM additive by Dr. Barlaz’s calculation of the mL of methane per gram of ECM additive in the sample. (RX 968; Barlaz, Tr. 2252-58).

2384. At a net methane production of 4,263.1 mL, the amount of methane recorded from test sample "538A" in CCX 547 was more than four and one half (4.5x) times the amount of biodegradation (933 mL) that could have possibly been sourced from the ECM additive assuming even a 5% load rate for same. (CCX 547 at 009008; RX 968; Barlaz, Tr. 2252-58).

2385. At a net methane production of 8,685.4 mL, the amount of methane recorded from test sample "539A" in CCX 547 was more than three (3x) times the amount of biodegradation (2,799 mL) that could have possibly been sourced from the ECM additive assuming even a 15% load rate for same. (CCX 547 at 009008; RX 968; Barlaz, Tr. 2252-58).

1. Northeast Laboratories Testing Generally

2386. Alan Johnson testified as the owner of Northeast Laboratories ("NE Labs") in Berlin, Connecticut. (Johnson, Tr. 1554-57).

2387. Alan Johnson serves as the current laboratory director at Northeast Laboratories. (Johnson, Tr. 1554).

2388. Mr. Johnson has a bachelor's of science from the University of Connecticut where he majored in biology and minored in chemistry. (Johnson, Tr. 1555).

2389. Northeast Laboratories houses several laboratory divisions at its offices, including chemistry and microbiology labs. (Johnson, Tr. 1556-58).

2390. NE Labs environmental and chemistry laboratory divisions have been certified by several governmental bodies, including the EPA, FDA, CDC, and the State of Connecticut. (Johnson, Tr. 1558).

2391. NE Labs' biodegradation testing is a branch of NE Lab's testing services, however NE Labs relies on its other laboratory divisions, including its chemistry lab, for portions of the biodegradation testing work. (Johnson, Tr. 1560-61).

2392. With respect to its certifications, NE Labs has been inspected by governmental bodies, and NE Labs passed those inspections. (Johnson, Tr. 1559-61).

2393. NE Labs began performing biodegradation testing around 2005. (Johnson, Tr. 1560).

2394. NE Labs' biodegradation testing business was initiated and operated by Dr. William Ullmann. (Johnson, Tr. 1560).

2395. Dr. Ullmann founded NE Labs in 1977. (Johnson, Tr. 1562).

2396. He was the former director of the State of Connecticut's Public Health Laboratory. (Johnson, Tr. 1562).

2397. Dr. Ullmann had a Ph.D. in microbiology. (Johnson, Tr. 1562).

2398. Dr. Ullmann was responsible for developing NE Lab's biodegradation testing protocols, and he performed those studies until he passed away in 2011. (Johnson, Tr. 1563).

2399. NE Labs would begin biodegradation testing by obtaining test samples directly from customers, and then calculating the carbon content of same. (Johnson, Tr. 1564).

2400. NE Labs generally follows the ASTM D5511 protocol, but NE Labs uses metal canisters as reactor vessels instead of glass vessels. (Johnson, Tr. 1565).

2401. NE Labs metal canisters are specially manufactured for biodegradation testing. (Johnson, Tr. 1565).

2402. NE Labs drills into the metal canisters and threads a fitting into the can so that the test tubing is airtight and feeds directly from the reactor into the graduated cylinder, where gas volume is measured. (Johnson, Tr. 1565-1566).

2403. The ASTM D5511 method specifically calls for the use of a graduated cylinder to measure total gas volume. (RX 356, at 2 § 6.1).

2404. NE Labs uses lined paint cans to prevent corrosion. (Johnson, Tr. 1566).

2405. The issue of corrosion was never an issue in NE Lab's shorter-duration studies. (Johnson, Tr. 1565-66).

2406. In longer duration studies during the early years when NE Labs used unlined canisters, corrosion may have been an issue to the extent that NE Labs observed rust forming on the can. (Johnson, Tr. 1566).

2407. NE Labs seals its canisters with silicone caulking and then seals each container with a resin. (Johnson, Tr. 1567).

2408. NE Labs never had any indications that its test systems leaked or were not gas tight. (Johnson, Tr. 1566-67).

2409. A canister that was leaking would be quite obvious. (Johnson, Tr. 1567-68).

2410. NE Labs could determine whether its test vessels leaked or were airtight because if the canisters had leaked, then the water level in the graduated cylinder (used for gas collection) would be lowered. (Johnson, Tr. 1566-67).

2411. NE Labs could determine that the test environment was not aerobic (or gaining oxygen) because the test vessels were producing methane, and the D5511 tests used methane as a marker for biodegradation. (Johnson, Tr. 1566-67).

2412. The presence of methane means that the test environment is anaerobic. (Johnson, Tr. 1566-67, 1570).

2413. NE Labs extracted gas from the cylinder through an extraction valve in the test tubing. (Johnson, Tr. 1568-69).

2414. NE Labs uses a Quantek analyzer to analyze carbon dioxide. (Johnson, Tr. 1569).

2415. NE Labs uses an infrared ("IR") spectrometer to measure methane content. (Johnson, Tr. 1569).

2416. The precision of the IR spectrometer varies depending on the amount of methane detected in the system. (Johnson, Tr. 1586-87).

2417. However, for the higher readings of methane that NE Labs was looking at, the precision of the instrument was probably around plus or minus 1 percent. (Johnson, Tr. 1587).

2418. Because NE Lab's test vessels have "head space" at the top of the canisters, the canisters contain ambient gases that are not produced from the biological processes in the tests. (Johnson, Tr. 1591-92).

2419. The ambient gases in the headspace are also collected in the graduated cylinder so that the gas composition would include a percentage of ambient gas unassociated with the inoculum or biota. (Johnson, Tr. 1591-92).

2420. The biodegradation process produces carbon dioxide and methane, the presence of the latter in relatively equal proportions to the carbon dioxide is an indication that the test environment is anaerobic (as opposed to aerobic). (Johnson, Tr. 1566-67; Barlaz, Tr. 2188-89).

2421. NE Labs uses a standard format for its biodegradation test reports. (Johnson, Tr. 1571). Mr. Johnson testified that the reports in evidence from NE Labs are in the format of NE Lab's standard reports. (Johnson, Tr. 1571-72).

2422. NE Labs performed "extension" biodegradation testing for certain customers. (Johnson, Tr. 1573).

2423. For longer-term extension testing over 45 days past the planned termination date, NE Labs would assess whether the activity in the triplicate vessels had levelled off. (Johnson, Tr. 1573-74).

2424. If the activity in the test vessels had leveled, and the positive control had already been digested, NE Labs would remove the test materials and negative controls from the stale testing environment, and place those materials into a new reactor canister with fresh inoculum. (Johnson, Tr. 1573-74).

2425. To maintain anaerobic conditions during a long-term extension test, NE Labs would sparge (or flush) the new canisters with nitrogen to remove excess atmospheric gases. (Johnson, Tr. 1573-74).

2426. When using fresh canisters with fresh inoculum to extend tests, NE Labs would always use fresh inoculum blanks, and often fresh negative control vessels. (Johnson, Tr. 1574-75).

2427. There is no evidence in the record that NE Labs changed canisters during biodegradation testing of ECM amended plastics. (Johnson, Tr. 1560-1596).

2428. There is no evidence in the record that corrosion of canisters occurred in biodegradation testing of ECM amended plastics. (Johnson, Tr. 1557-96).

2429. There is no evidence in the record of leakage in the metal canisters that NE Labs used in biodegradation testing of ECM amended plastics. (Johnson, Tr. 1560-96).

2430. Dr. Barlaz reviewed NE Lab's testing protocol. (Barlaz, Tr. 2276).

2431. Dr. Barlaz testified that NE Lab's use of metal canisters in D5511 testing would not affect the validity of NE Lab's test results. (Barlaz, Tr. 2276).

2432. With respect to NE Lab's use of metal canisters, Dr. Barlaz explained that "you either have a leak in your system or you don't have a leak in your system, and if you don't have a leak in your system, then a metal can should be fine." (Barlaz, Tr. 2276).

2433. "And the fact that [NE Labs] were getting methane generation from their positive controls indicate[d] to [Dr. Barlaz] that [NE Labs] have an ability to make a gas-tight system out of a metal can." (Barlaz, Tr. 2276).

2434. The presence of methane in NE Labs testing proves that the test environment was anaerobic "because oxygen kills methanogens" responsible for producing methane. (Barlaz, Tr. 2277).

2435. Complaint Counsel presented no evidence through their experts that NE Labs use of metal canisters resulted in a methodologically flawed test. (Tolaymat, Tr. 112-213; McCarthy, Tr. 359-480).

2436. With respect to D5511 tests that showed ECM amended plastics were biodegradable, Dr. McCarthy testified in vague and general terms simply that "there are some tests

that were conducted well and some tests that were conducted poorly." (McCarthy, Tr. 452).

2437. He also testified vaguely that the tests that are problematic "are the ones that are the 5511 that were conducted at the very, very long periods of time and indicate a lot of leakage." (McCarthy, Tr. 452).

2438. Dr. McCarthy did not identify which tests he thought exhibited any leakage. (McCarthy, Tr. 452-54).

2439. He did not identify any evidence of "leakage" in any of ECM's supportive tests. (McCarthy, Tr. 359-480).

2440. He rejected tests outright because they were run for periods of time longer than 30 days. (McCarthy, Tr. 454-55).

2441. Dr. Tolaymat, by contrast, testified that a D5511 test could be conducted for several years while remaining viable. (Tolaymat, Tr. 251).

2442. Complaint Counsel's rebuttal expert, Dr. Michel, performed biodegradation gas evolution studies in his laboratory that exceeded 500 days. (Michel, Tr. 2899).

2443. Dr. McCarthy provided no evidence or explanation for how a small leakage in the NE Lab's system, even assuming that occurred, would affect the evidence of biodegradation observed. (McCarthy, Tr. 359-480).

2444. Dr. McCarthy did not explain whether a small leak in the NE Labs system would actually minimize the data on biodegradation, logically lowering the appearance of any observable affect. (McCarthy, Tr. 359-480).

2445. Dr. McCarthy apparently failed to understand NE Labs' display of averaged gas readings when he criticized test readings that were "exactly the same." (McCarthy, Tr. 454).

2446. NE Labs used weekly gas measurements and would report the data for individual days based on an average from the weekly readings. (RX 873 (Ullmann, Dep. at 61)).

2447. The percentage of total biodegradation is based on total gas volume, which would not be influenced by NE Labs decision to display weekly gas readings in that fashion. (RX 356).

2448. Dr. McCarthy criticized ECM studies, including NE Lab's studies, because there were no "error bars or standard deviations or standard error given" in the tests. (McCarthy, Tr. 454-55).

2449. Although NE Labs raw data was available to Dr. McCarthy, he offered no statistical assessment of the data, and made no attempt to base his testimony on a specific review of the gas evolution data generated in the tests. (McCarthy, Tr. 359-480).

2450. Dr. Sahu testified that he had no concerns with NE Lab's methodology. (Sahu, Tr. 1933-34).

2451. Dr. Sahu was not concerned with the process of reinoculating the test vessels in long-term D5511 studies. (Sahu, Tr. 1933-34).

2452. Dr. Sahu was satisfied that the amount of biogas produced in the ECM tests that was in excess of that which could come from the inoculum was sufficient to show that the plastic itself had been rendered biodegradable. (Sahu, Tr. 1934-35).

2453. With respect to NE Labs testing, or any gas evolution testing relevant to the case, Dr. McCarthy did not perform statistical analyses of the data. (McCarthy, Tr. 359-480).

2454. Although Dr. McCarthy possessed Dr. Barlaz's statistical analyses of the data, Dr. McCarthy offered no evidence or testimony concerning Dr. Barlaz's analysis of the gas evolution data. (McCarthy, Tr. 359-480).

2455. Dr. McCarthy did not even mention Dr. Barlaz's analysis of data. (McCarthy, Tr. 359-480).

a. RX 836, NE Labs N1048340 (PPC Industries, Inc.) Testing

2456. From September 2010 through November 2013, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors. (RX 836).

2457. NE Labs performed the test on behalf of PPC Industries, Inc. (RX 836 at 1).

2458. The test marked RX 836 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 836; Johnson, Tr. 1571).

2459. The test marked RX 836, as with other NE Labs ASTM D5511 biodegradation tests, included the use of an inoculum blank, a negative control (untreated plastic), a positive control (cellulose), and a test sample, all of which were run in triplicate. (RX 836 at 2; Johnson, Tr. 1575).

2460. The test marked RX 836 included a plastic amended with 1% ECM additive. (RX 155; RX 156; RX 157).

2461. The plastic sample was labeled “EP Flex Renew Green Poly Bags Treated,” and the test involved an untreated “Clear Poly Bag” sample as a negative control. (RX 836 at 2).

2462. NE Labs recorded data for the test marked RX 836 through 900 days. (RX 836 at 126 (10/21/2013 Report)).

2463. There is no provision of D5511 that limits the amount of time under which a D5511 test can be run. (RX 356).

2464. In the test marked RX 836, NE Labs recorded biodegradation of the ECM amended sample “EP Flex Renew Green Poly Bags Treated” in the amount of 49.28% after 900 days of anaerobic testing. (RX 836 at 126 (10/21/2013 Report)).

2465. The negative control in RX 836 revealed just 0.1152% total biodegradation after 900 days of anaerobic biodegradation testing. (RX 836 at 126 (10/21/2013 Report)).

2466. Dr. Barlaz reviewed the raw data provided by NE Labs, including data pertaining to RX 836. (RX 836; RX 968; Barlaz, Tr. 2252-58).

2467. For the sample “EP Flex Renew Green Poly Bags Treated,” NE Labs reported 4,716 mL of total methane, compared to just 1,854 mL of methane in the inoculum blank. (RX 836; RX 472; RX 968).

2468. The net methane yield between the inoculum and the test vessel in RX 836 was 2,862.4 mL. (RX 836; RX 472; RX 968).

2469. Dr. Barlaz calculated the mean substrate to inoculum ratio at 2.5 for this test, affirming that the methane content observed in the test vessels was from the test substrate (the plastic). (RX 836; RX 968; Barlaz, Tr. 2247-49, 2260-63).

2470. Dr. Barlaz calculated methane and carbon dioxide t-statistics, and determined that the results of RX 836 were statistically significant. (RX 968; Barlaz, Tr. 2259-60).

2471. The mass of the test sample in RX 836 was 20 grams. (RX 836 at 1).

2472. At 1% by weight, the mass of the ECM additive in the sample test was approximately 0.2 grams. (RX 836; RX 968; Barlaz, Tr. 2251-54).

2473. Based on Dr. Barlaz’s conservative calculations, the total theoretical yield of methane from the 1% ECM additive tested in RX 836 is 186.6 mL of methane, calculated by multiplying the weight of ECM additive by Dr. Barlaz’s calculation of the mL of methane per gram of ECM additive (933 mL). (RX 968; Barlaz, Tr. 2252-58).

2474. At a net methane yield of 2,862.4 mL, the biodegradation of the test substrate in RX 836 was more than fifteen (15x) times the amount of biodegradation that could have

possibly been sourced from the ECM additive alone. (RX 836; RX 968; Barlaz, Tr. 2252-58).

2475. Dr. Barlaz also calculated standard deviations for RX 836, which were within reasonable limits as expressed by the t-statistics. (RX 968; RX 472; Barlaz, Tr. 2264).

2476. Based, in part, on RX 836, Dr. Barlaz testified that the scientific evidence showed that plastic containing the ECM additive anaerobically biodegraded. (RX 968; Barlaz, Tr. 2274).

b. RX 838, NE Labs 1149980 (MINIGRIP) Testing

2477. From May 2011 through August 2012, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors. (RX 838).

2478. NE Labs performed the test on behalf of Minigrips in Kennesaw, GA. (RX 838 at 1).

2479. The test marked RX 838 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 838; Johnson, Tr. 1571).

2480. The test marked RX 838, as with other NE Labs ASTM D5511 biodegradation tests, included the use of an inoculum blank, a negative control (untreated plastic), a positive control (cellulose), and a test sample, all of which were run in triplicate. (RX 838 at 2; Johnson, Tr. 1575).

2481. The test marked RX 838 included a plastic amended with 1.5% ECM additive. (RX 838).

2482. The plastic sample was labeled "#1149980-01 Zip Bags, Green Line LDPE/LLDPE Treated, 1.5% ECM (25 Grams)," and the test involved an untreated control labeled "#1149980-02 Zip Bags, Red Line LDPE/LLDPE Untreated (25 Grams). (RX 838 at 1).

2483. NE Labs recorded data for the test marked RX 838 through 365 days. (RX 838 at 72 (6/4/2012 Report)).

2484. There is no provision of D5511 that limits the amount of time under which a D5511 test can be run. (RX 356).

2485. In the test marked RX 838, NE Labs recorded biodegradation of the ECM amended sample "#1149980-01" in the amount of 17.069% after 365 days of anaerobic testing. (RX 838 at 72 (6/4/2012 Report)).

2486. The negative control in RX 838 revealed just 0.1009% total biodegradation after 365 days of anaerobic biodegradation testing. (RX 838 at 72 (6/4/2012 Report)).

2487. Dr. Barlaz reviewed the raw data provided by NE Labs, including data pertaining to RX 838. (RX 838; RX 968; Barlaz, Tr. 2252-58).

2488. For the sample "#1149980-01," NE Labs reported 5,197 mL of total methane, compared to just 1,360 mL of methane in the inoculum blank. (RX 838; RX 472; RX 968).

2489. The net methane yield between the inoculum and the test vessel in RX 838 was 3,837.3 mL. (RX 838; RX 472; RX 968).

2490. Dr. Barlaz calculated the mean substrate to inoculum ratio at 3.8 for this test, affirming that the methane content observed in the test vessels was from the test substrate (the plastic). (RX 838; RX 968; Barlaz, Tr. 2247-49, 2260-63).

2491. Dr. Barlaz calculated methane and carbon dioxide t-statistics, and determined that the results of RX 838 were statistically significant. (RX 472; RX 968; Barlaz, Tr. 2259-60).

2492. The mass of the test sample in RX 838 was 25 grams. (RX 838 at 1).

2493. At 1.5% by weight, the mass of the ECM additive in the sample test was approximately 0.375 grams. (RX 838; RX 968; Barlaz, Tr. 2251-54).

2494. Based on Dr. Barlaz's conservative calculations, the total theoretical yield of methane from the 1.5% ECM additive tested in RX 838 is 349.875 mL of methane, calculated by multiplying the weight of ECM additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM additive (933 mL). (RX 968; Barlaz, Tr. 2252-58).

2495. At a net methane (CH4) yield of 3,837.3 mL, the biodegradation of the test plastic in RX 838 was about eleven (11x) times the amount of biodegradation that could have possibly been sourced from the ECM additive alone. (RX 838; RX 968; Barlaz, Tr. 2252-58).

2496. Dr. Barlaz also calculated standard deviations for RX 838, which were within reasonable limits as expressed by the t-statistics. (RX 968; RX 472; Barlaz, Tr. 2264).

2497. Based in part on RX 838, Dr. Barlaz testified that the scientific evidence showed that plastic containing the ECM additive anaerobically biodegraded. (RX 968; Barlaz, Tr. 2274).

2498. Along with its RX 838 test, NE Labs also performed an Analytical Report under ASTM D6579 to determine the molecular weight averages and molecular weight distribution of the test sample after completion of the biodegradation test. (RX 838 at 73 (8/1/2012 Report)).

2499. In its August 1, 2012 Analytical Report (RX 838), NE Labs demonstrated that the plastic "zip bags" treated with the 1.5% ECM additive had lost molecular weight after biodegradation testing. (RX 838 at 73 (8/1/2012 Report)).

2500. Both the "number average" and the "weight average" molecular weights of the 1.5% ECM treated plastic had declined by about 16%, as measured using a different ASTM standard, ASTM D6579. (RX 838 at 73 (8/1/2012 Report)).

2501. For comparison, the biodegradation percentage recorded by NE Labs at the end of the RX 838 testing, measured by methane conversion, was listed at about 17%. (RX 838 at 72 (6/4/2012 Report)).

2502. In comments written on NE Lab's certificate of analysis, NE Labs explained that "change in molecular weight is a measure of bulk deterioration.

2503. As an analytical method it indicates that polymer chains are breaking down or cleaving during biodegradation." (RX 838 at 73 (8/1/2012 Report)).

2504. The NE Labs Minigrips test (RX 838) demonstrated about 6% biodegradation based on methane conversion after 30 days of testing, before ultimately continuing to biodegrade to more than 17% after 365 days of testing. (RX 838 at 6 (6/13/2011 Report)).

2505. Having reviewed the Minigrips data, Mr. Johnson testified that by the end of the test there was virtually no activity of any kind occurring in any of the test vessels. (Johnson, Tr. 1589-90).

c. RX 398, NE Labs N0946510-01 (Masternet I) Testing

2506. In December 2009, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors. (RX 398).

2507. NE Labs performed the test on behalf of Masternet Ltd. in Mississauga, Ontario, Canada. (RX 398 at 1).

2508. The test marked RX 398 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 398; Johnson, Tr. 1571).

2509. The test marked RX 398, as with other NE Labs ASTM D5511 biodegradation tests, included the use of an inoculum blank, a negative control (untreated plastic, here

polyethylene), a positive control (cellulose), and a test sample, all of which were run in triplicate. (RX 398 at 2; Johnson, Tr. 1575).

2510. The test marked RX 398 included a polyethylene plastic amended with 1% ECM additive. (RX 398 at 1).

2511. The plastic test sample had an initial weight of 25 grams. (RX 398 at 2).

2512. NE Labs recorded data for the test marked RX 398 through 15 days. (RX 398 at 4).

2513. In the test marked RX 398, NE Labs recorded biodegradation of the ECM amended polyethylene in the amount of 4.91% after 15 days of anaerobic testing. (RX 398 at 4).

2514. The 4.91% biodegradation within 15 days of anaerobic testing, calculated based on methane conversion, is more than the 3.65% biodegradation observed in the first 15 days of testing in NE Labs RX 838, which test would later produce more than 17% biodegradation over 365 days. (RX 398 at 4; RX 838 at 6 (6/13/2011 Report)).

2515. Dr. Barlaz reviewed the raw data provided by NE Labs, including data pertaining to RX 398. (RX 398; RX 472; RX 968; Barlaz, Tr. 2252-58).

2516. For the ECM amended plastic, NE Labs reported 2,628 mL of total methane, compared to 1,554 mL of methane in the inoculum blank. (RX 398; RX 472; RX 968).

2517. The net methane yield between the inoculum and the test vessel in RX 398 was 1,074.3 mL. (RX 398; RX 472; RX 968).

2518. Dr. Barlaz calculated methane and carbon dioxide t-statistics, and determined that the results of RX 398 were statistically significant. (RX 472; RX 968; Barlaz, Tr. 2259-60).

2519. The mass of the 1% ECM amended polyethylene sample in RX 398 was 25 grams. (RX 398 at 1).

2520. At 1% by weight, the mass of the ECM additive in the sample test was approximately 0.25 grams. (RX 398; RX 968; Barlaz, Tr. 2251-54).

2521. Based on Dr. Barlaz's conservative calculations, the total theoretical yield of methane from the 1% ECM additive tested in RX 398 is 233.25 mL of methane, calculated by multiplying the weight of ECM additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM additive (933 mL). (RX 968; Barlaz, Tr. 2252-58).

2522. At a net methane (CH4) yield of 1,074.3 mL, the biodegradation of the test plastic in RX 398 was more than four and one half (4.5x) times the amount of biodegradation

that could have possibly been sourced from the ECM additive alone, all during the short fifteen (15) day test window. (RX 398; RX 968; Barlaz, Tr. 2252-58).

d. RX 405, NE Labs 1048742-01 (Eco SmartPlastics) Testing

2523. In November 2010, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors. (RX 405).

2524. NE Labs performed the test on behalf of Eco SmartPlastics in Bohemia, New York. (RX 405 at 1).

2525. The test marked RX 405 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 405; Johnson, Tr. 1571).

2526. The test marked RX 405, as with other NE Labs ASTM D5511 biodegradation tests, included the use of an inoculum blank, a negative control (untreated plastic, here polypropylene), a positive control (cellulose), and a test sample, all of which were run in triplicate. (RX 405 at 2; Johnson, Tr. 1575).

2527. The test marked RX 405 included a low-density polyethylene plastic (LDPE) amended with 1.5% ECM additive. (RX 405 at 1).

2528. The plastic test sample had an initial weight of 25 grams. (RX 405 at 1).

2529. NE Labs recorded data for the test marked RX 405 through 45 days. (RX 405 at 3).

2530. In the test marked RX 405, NE Labs recorded biodegradation of the ECM amended low-density polyethylene in the amount of 7.37% after 45 days of anaerobic testing. (RX 405 at 3).

2531. The 7.37% biodegradation within 45 days of anaerobic testing, calculated based on methane conversion, is roughly equal to the 7.53% biodegradation observed in the first 45 days of testing in NE Labs RX 838 (Minigrips Test), which latter test would reveal more than 17% biodegradation over 365 days. (RX 405 at 3; RX 838 at 9 (7/5/2011 Report)).

2532. The 17% biodegradation of the test substrate in the NE Labs RX 838 Minigrips test was confirmed through molecular weight testing, and far exceeded the amount of biodegradation that could have been sourced from the ECM additive alone. (RX 838; RX 968; Barlaz, Tr. 2252-58).

e. RX 396, NE Labs 1048819 (Eco SmartPlastics) Testing

2533. In December 2010, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors. (RX 396).

2534. NE Labs performed the test on behalf of Eco SmartPlastics in Bohemia, New York. (RX 396 at 1).

2535. RX 396 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 396; Johnson, Tr. 1571).

2536. The test marked RX 396, as with other NE Labs ASTM D5511 biodegradation tests, included the use of an inoculum blank, a negative control (untreated plastic, here polypropylene), a positive control (cellulose), and a test sample, all of which were run in triplicate. (RX 396 at 1-2; Johnson, Tr. 1575).

2537. The test marked RX 396 included a polyethylene terephthalate (PET) plastic amended with the ECM additive. (RX 396 at 1; CCX 413).

2538. The plastic test sample had an initial weight of 25 grams. (RX 396 at 1).

2539. The test report (RX 396) does not specify the amount of ECM additive included in the test plastic. (RX 396).

2540. Eco SmartPlastics used a 1.5% load rate for the ECM additive in other plastic applications. (RX 405 at 1).

2541. NE Labs recorded data for the test marked RX 396 through 43 days. (RX 396 at 3).

2542. In the test marked RX 396, NE Labs recorded biodegradation of the ECM amended polyethylene in the amount of 7.01% after 45 days of anaerobic testing. (RX 396 at 4).

2543. The 7.01% biodegradation within 45 days of anaerobic testing, calculated based on methane conversion, is roughly equal to the 7.53% biodegradation observed in the first 45 days of testing in NE Labs RX 838 (Minigrips Test), which latter test would reveal more than 17% biodegradation over 365 days. (RX 396 at 4; RX 838 at 9 (7/5/2011 Report)).

2544. For the ECM amended plastic, NE Labs reported 3,496 mL of total methane, compared to 1,821 mL of methane in the inoculum blank. (RX 396 at 4).

2545. The net methane yield between the inoculum and the test vessel in RX 396 was therefore 1,675 mL. (RX 396 at 4).

2546. Even assuming Eco Smartplastics included the ECM additive in the test PET plastic at an amount as high as 2%, a load rate higher than Eco SmartPlastics previously used, the mass of the sample would have been 0.5 grams. (Barlaz, Tr. 2251-54).

2547. Based on Dr. Barlaz's conservative calculations, the total theoretical yield of methane from a 2% ECM additive (0.5 grams) tested in RX 396 is 466.5 mL of methane,

calculated by multiplying the weight of the ECM additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM additive (933 mL). (RX 968; Barlaz, Tr. 2252-58).

2548. At a net methane (CH4) yield of 1,675 mL, the biodegradation of the test plastic in RX 396 was more than three and on half (3.5x) times the amount of biodegradation that could have possibly been sourced from the ECM additive alone, all during the short forty five (45) day test window. (RX 396; RX 968; Barlaz, Tr. 2252-58).

f. RX 395, NE Labs 1150851 (Sweet Tape Enterprise) Testing

2549. In September 2011, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors. (RX 395).

2550. NE Labs performed the test on behalf of Sweet Tape Enterprise (M) Sdn. Bhd., in Malaysia. (RX 395 at 1).

2551. RX 395 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 395; Johnson, Tr. 1571).

2552. The test marked RX 395, as with other NE Labs ASTM D5511 biodegradation tests, included the use of an inoculum blank, a negative control (untreated plastic, here polyethylene), a positive control (cellulose), and a test sample, all of which were run in triplicate. (RX 395 at 1-2; Johnson, Tr. 1575).

2553. The test marked RX 395 included a polypropylene (PP) clear tape plastic amended with the ECM additive. (RX 395 at 1; CCX 413).

2554. The plastic test sample had an initial weight of 25 grams. (RX 395 at 1).

2555. The test report (RX 395) does not specify the amount of ECM additive included in the test plastic. (RX 395).

2556. NE Labs recorded data for the test marked RX 395 through 45 days. (RX 395 at 3).

2557. In the test marked RX 395, NE Labs recorded biodegradation of the ECM amended PP sample in the amount of 4.54% after 45 days of anaerobic testing. (RX 395 at 3).

g. RX 394, NE Labs 1150851 (Tycoplas Sdn. Bhd.) Testing

2558. In October 2011, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors. (RX 394).

2559. NE Labs performed the test on behalf of Tycoplas Sdn Bhd. (RX 394 at 1).

2560. The test marked RX 394 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 394; Johnson, Tr. 1571).

2561. The test marked RX 394, as with other NE Labs ASTM D5511 biodegradation tests, included the use of an inoculum blank, a negative control (untreated polyethylene), a positive control (cellulose), and a test sample, all of which were run in triplicate. (RX 394 at 1; Johnson, Tr. 1575).

2562. The test marked RX 394 included a plastic amended with the ECM additive. (RX 394).

2563. The plastic sample was labeled PS Foam Lunch Boxes with ECM Additive." (RX 394 at 1).

2564. NE Labs recorded data for the test marked RX 394 through 15 days. (RX 394 at 3).

2565. In the test marked RX 394, NE Labs recorded biodegradation of the ECM amended polystyrene sample in the amount of 5.89% after just 15 days of anaerobic testing. (RX 394 at 3).

2566. Dr. Barlaz reviewed the raw data provided by NE Labs, including data pertaining to RX 394. (RX 394; RX 968; Barlaz, Tr. 2252-58).

2567. For the test PS sample in RX 394, NE Labs reported 1,962 mL of total methane, compared to just 621 mL of methane in the inoculum blank. (RX 394 at 3; RX 472; RX 968).

2568. The net methane yield between the inoculum and the test vessel in RX 394 was 1,340.6 mL. (RX 394; RX 472; RX 968).

2569. Dr. Barlaz calculated the mean substrate to inoculum ratio at 3.2 for this test (RX 394), affirming that the methane content observed in the test vessels was from the test substrate (the plastic). (RX 394; RX 968; Barlaz, Tr. 2247-49, 2260-63).

2570. Dr. Barlaz calculated methane and carbon dioxide t-statistics, and determined that the results of RX 394 were statistically significant. (RX 472; RX 968; Barlaz, Tr. 2259-60).

2571. The mass of the test sample in RX 394 was 25 grams. (RX 394 at 1).

2572. The test report (RX 394) does not specify the load rate of the ECM additive in the test polystyrene product. (RX 394 at 3).

2573. However, even assuming the additive was included at a 2% load rating, an amount higher than the 1.0-1.5% customers ordinarily use, the mass of the ECM additive would be 0.5 grams. (RX 394 at 3; RX 968; Barlaz, Tr. 2251-54).

2574. Based on Dr. Barlaz's conservative calculations, the total theoretical yield of methane from 0.5 grams of the ECM additive is 466.5 mL of methane, calculated by multiplying the weight of ECM additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM additive (933 mL). (RX 968; Barlaz, Tr. 2252-58).

2575. At a net methane (CH4) yield of 1,340.6 mL, the biodegradation of the test plastic in RX 394 was about three (3x) times the amount of biodegradation that could have possibly been sourced from the ECM additive alone. (RX 394; RX 968; Barlaz, Tr. 2252-58).

2576. Dr. Barlaz also calculated standard deviations for RX 394, which were within reasonable limits as expressed by the t-statistics. (RX 968; RX 472; Barlaz, Tr. 2264).

2577. Based in part on RX 394, Dr. Barlaz testified that the scientific evidence showed that plastic containing the ECM additive anaerobically biodegraded. (RX 968; Barlaz, Tr. 2274).

2578. The NE Labs Minigrips test (RX 838) demonstrated about 6% biodegradation based on methane conversion after 30 days of testing, before ultimately continuing to biodegrade to more than 17% after 365 days of testing. (RX 394 at 6 (6/13/2011 Report)).

2579. The NE Labs Tycoplas test (RX 394) exhibited nearly 6% biodegradation in roughly half the time, much of which could not have come from the ECM additive. (RX 394).

h. RX 393, NE Labs 1253020 (National Tree Co.) Testing

2580. In April 2012, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors. (RX 393).

2581. NE Labs performed the test on behalf of National Tree Co. in Cranford, New Jersey. (RX 393 at 1).

2582. RX 393 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 393; Johnson, Tr. 1571).

2583. The test marked RX 393, as with other NE Labs ASTM D5511 biodegradation tests, included the use of inoculum blanks, negative controls (untreated plastic, PVC and PE), a positive control (cellulose), and two test samples, all of which were run in triplicate. (RX 393 at 1-2; Johnson, Tr. 1575).

2584. The test marked RX 393 included two test samples amended with the ECM additive. (RX 393 at 1-2).

2585. One test sample was “PVC, Treated,” the other test sample was “PE, Treated.” (RX 393 at 2).

2586. Both test samples were 25 grams at the start of testing. (RX 393 at 2).

2587. The negative controls involved untreated plastics, “PVC, Untreated” and “PE, Untreated.” (RX 393 at 2).

2588. NE Labs recorded data for the test marked RX 393 through 15 days of anaerobic testing. (RX 393 at 4).

2589. In RX 393, NE Labs recorded biodegradation of the ECM amended PVC sample in the amount of 9.89% after 15 days of anaerobic testing. (RX 393 at 4).

2590. NE Labs recorded biodegradation of the ECM amended PE sample in the amount of 5.75% after 15 days of anaerobic testing. (RX 393 at 4).

2591. For the ECM amended PVC sample, NE Labs reported 1119 mL of total methane, compared to 254 mL of methane in the inoculum blank. (RX 393 at 4).

2592. The net methane yield between the inoculum and the treated PVC sample in RX 393 was therefore 865 mL. (RX 393 at 4).

2593. For the amended PE sample, NE Labs reported 1451 mL of total methane, compared to 254 mL of methane in the inoculum blank. (RX 393 at 4).

2594. The net methane production in the PE treated sample was therefore 1,197 mL of methane gas. (RX 393 at 4).

2595. The negative controls for PVC and PE reported 238 mL and 219 mL of methane respectively, which is consistent with the 254 mL of methane produced in the inoculum blank. (RX 393 at 4).

2596. The test report (RX 393) does not specify the amount of ECM additive included in the test plastic. (RX 393).

2597. ECM recommends that its customers use close to 1% load rating. (CCX 10; Sinclair, Tr. 787-88).

2598. Even assuming National Tree Co. included the ECM additive in the test plastics at an amount as high as 2%, a load rate higher than ECM recommended and higher than other customers ordinarily used, the mass of the additive in the samples would have been 0.5 grams. (Barlaz, Tr. 2251-54).

2599. Based on Dr. Barlaz’s conservative calculations, the total theoretical yield of methane from 0.5 grams of the ECM additive is 466.5 mL of methane, calculated by

multiplying the weight of the ECM additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM additive (933 mL). (RX 968; Barlaz, Tr. 2252-58).

2600. At a net methane (CH4) yield of 865 mL, the biodegradation of the treated PVC plastic in RX 393 was almost twice (2x) the amount of biodegradation that could have possibly been sourced from the ECM additive alone, all during the short fifteen (15) day test window. (RX 393; RX 968; Barlaz, Tr. 2252-58).

2601. Similarly, at a net methane (CH4) yield of 1,197 mL, the biodegradation of the treated PE plastic sample in RX 393 was more than two and one half (2.5x) the amount of biodegradation that could have possibly been sourced from the ECM additive alone, all during the short fifteen (15) day test window. (RX 393; RX 968; Barlaz, Tr. 2252-58).

i. RX 392, NE Labs 1048036 (Transilwrap Co.) Testing

2602. In April 2011, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors. (RX 392).

2603. NE Labs performed the test on behalf of Transilwrap Co. in Richmond, Indiana. (RX 392 at 1).

2604. RX 392 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 392; Johnson, Tr. 1571).

2605. The test marked RX 392, as with other NE Labs ASTM D5511 biodegradation tests, included the use of inoculum blanks, negative controls (here polyethylene), a positive control (cellulose), and two test samples, all of which were run in triplicate. (RX 392 at 1-2; Johnson, Tr. 1575).

2606. The test marked RX 392 included two test samples amended with the ECM additive. (RX 392 at 1-2).

2607. One test sample was a Thin HIPS (High Impact Polystyrene) Based Sheet, the other test sample was a "Two Layer Laminating Film." (RX 392 at 1; CCX 273).

2608. Both test samples were 25 grams at the start of testing. (RX 392 at 1).

2609. Transilwrap described the samples as a "HIPS sheet allow with the ECM additive, and a thin film PETG coated with EVA (also both having [the ECM] additive)." (CCX 273 at 3).

2610. NE Labs recorded data for the test marked RX 392 through 233 days of anaerobic testing. (RX 392 at 4).

2611. In RX 392, NE Labs recorded biodegradation of the ECM amended HIPS polystyrene sample in the amount of 7.85% after 233 days of anaerobic testing. (RX 392 at 4).

2612. NE Labs recorded biodegradation of the ECM amended Two Layer Laminating Film sample in the amount of 8.53% after 233 days of anaerobic testing. (RX 392 at 4).

2613. The test report (RX 392) does not specify the amount of ECM additive included in the test plastic. (RX 392).

2614. ECM recommends that its customers use close to 1% load rating. (CCX 10; Sinclair, Tr. 787-88).

j. RX 399, NE Labs N0843980 (Bio-Tec Environmental, LLC) Testing

2615. In December 2008, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors. (RX 399).

2616. NE Labs performed the test on behalf of Bio-Tec Environmental, LLC in Albuquerque, New Mexico. (RX 399 at 1).

2617. RX 399 is an NE Labs analytical report similar to the type ordinarily supplied by NE Labs. (RX 399; Johnson, Tr. 1571).

2618. The test marked RX 399, as with other NE Labs ASTM D5511 biodegradation tests, included the use of an inoculum blank (called "sludge control"), a negative control, a positive control (cellulose), and a test sample, all of which were run in triplicate. (RX 399 at 1-2; Johnson, Tr. 1575).

2619. The test marked RX 399 included a polypropylene plastic sheet amended with the ECM additive. (RX 399 at 1; CCX 413).

2620. The plastic test sample had an initial weight of 100 grams. (RX 399 at 1).

2621. The test report (RX 399) does not specify the amount of ECM additive included in the test plastic. (RX 399).

2622. ECM recommends that its customers use just above a 1% load rating. (CCX 10; Sinclair, Tr. 787-88).

2623. NE Labs recorded data for the test marked RX 399 through 14 days. (RX 399 at 2).

2624. In RX 399, one of the earlier NE Labs biodegradation tests, NE Labs used two endpoints to assess biodegradation, methane gas conversion and gravimetric weight loss. (RX 399 at 2).

2625. Although gas data was not available, NE Labs concluded in RX 399 that, based on the average weight loss of the triplicate test samples and the methane gas conversion, the "results indicate[d] that the treated PP Sheets was biodegradable." (RX 399 at 2).

3. Other Anaerobic Gas Evolution Testing

a. CCX 952, NC State 2010 StarchTech BMP Testing

2626. In March 2010, Dr. Barlaz reported his results from a biochemical methane potential (BMP) test involving recycled polystyrene loosefill peanuts with the ECM additive. (CCX 952 at 1).

2627. The test was on behalf of StarchTech. (CCX 952).

2628. Dr. Barlaz performed his BMP test as he did other BMP tests performed at his NC State laboratory. (Barlaz, Tr. 2220-22, 2269-72).

2629. In the test memorialized as CCX 952, Dr. Barlaz tested two materials, a recycled polystyrene loosefill plastic with the ECM additive, and a starch-based biodegradable loosefill product. (Barlaz, Tr. 2270).

2630. Dr. Barlaz's results showed significant methane generation that was attributed to the test substrate, to wit, the plastic. (Barlaz, Tr. 2270; CCX 952).

2631. Dr. Barlaz calculated the percent that each material was converted to methane, subtracting the methane produced from the inoculum blanks. (Barlaz, Tr. 2270-71; CCX 952).

2632. Dr. Barlaz calculated the percentage of biodegradation by examining the percent loss of volatile solids, which was 7.4% of the ECM-amended polystyrene loosefill product in 60 days. (CCX 952; Barlaz, Tr. 2271).

2633. Although Dr. Barlaz terminated his BMP test on day 60, he observed that the short term, laboratory scale biodegradation test was not an accurate representation of the biodegradation potential of the sample. (Barlaz, Tr. 2271-74).

2634. Dr. Barlaz's test report included methane production data at day 30 and day 60. (CCX 952 at 2).

2635. Dr. Barlaz explained that "the methane generation on day 60 is double that of the methane generation on day 30, so there – the implication is that the measured methane is a lower limit and more methane would have been produced had we run the test for longer than 60 days." (Barlaz, Tr. 2271).

2636. The fact that methane generated during days 31-60 was equal to or more than methane generated on days 1-30 was scientifically significant because it demonstrates that the test sample was likely to evidence more biodegradation than the 60-day BMP test would suggest. (Barlaz, Tr. 2271-72).

2637. According to Dr. Barlaz, there was "no evidence that methane generation is slowing down, whereas, if you look at the second material [Starch-based product] there's considerable evidence that methane generation is slowing down." (Barlaz, Tr. 2271-72).

2638. Dr. Barlaz has concluded that this observed phenomena "speaks to the BMP as I've been using it with cutting it off at 60 days is perhaps imperfect or not appropriate if I have a slowly degradable substrate." (Barlaz, Tr. 2272).

b. RX 265, OWS Microtech Research Inc. Anaerobic Testing (Feb 1999)

2639. In February 1999, O.W.S. Inc. reported the results of anaerobic testing on the ECM additive pellets. (RX 265 at 6).

2640. OWS performed the test titled "High Solids Anaerobic Digestion (HSAD) Test of ECM pellets," on behalf of Patrick F. Riley of Microtech Research. (RX 265).

2641. The OWS test marked RX 265 was performed under the ASTM D5511-94 method. (RX 265).

2642. The substance tested were the ECM pellets by themselves. (RX 265).

2643. At the time, in 1999, the ECM pellets were comprised of approximately 50% active biodegradable components, and 50% of a traditionally non-biodegradable "carrier" resin. (CCX 818 (Sinclair, Dep. at 116)).

2644. ECM would later change its "load rating" to a 70% load of the actively biodegradable components. (CCX 818 (Sinclair, Dep. at 118-20)).

2645. OWS, like Eden Laboratories and Northeast Labs, measured total gas volume using a graduated cylinder. (RX 265 at 8).

2646. The OWS RX 265 test was conducted at a 34.1% solids content (63.9% moisture). (RX 265 at 12).

2647. After 15 days, the ECM pellets anaerobically biodegraded 24%. (RX 265 at 17).

2648. The test was terminated after 15 days. (RX 265).

c. RX 268, OWS Covidien Anaerobic Testing (May 2010)

2649. In May 2010, O.W.S. Inc. reported the results of anaerobic testing on polypropylene (PP) product labeled "polypropylene plaques." (RX 268 at 6).

2650. OWS performed the test titled "High Solids Anaerobic Digestion (HSAD) Test," on behalf of Covidien in Mansfield, MA. (RX 268 at 1).

2651. The OWS test marked RX 268 was performed under the ASTM D5511-02 method. (RX 268 at 3).

2652. In the OWS test marked RX 268, the positive control, cellulose, reached a plateau at 69.5%. (RX 268 at 4).

2653. The failure to achieve 70% biodegradation in the positive control is an indication that the test environment was not suitable for biodegradation testing. (RX 356 at 3 § 11.2.1.1).

2654. The OWS test marked RX 268 revealed 3.9% biodegradation of the test sample in 15 days of anaerobic degradation. (RX 268 at 7).

2655. The test indicated that the sample vessels plateaued around the same time as the cellulose vessels plateaued at 69.5%. (RX 268 at 5-7).

2656. In another OWS test in 1999 (RX 265), OWS wrote that cellulose should biodegrade at least to 85% through gas evolution, while at most 15% of the cellulose can be assimilated by microorganisms or left as other byproduct. (RX 265 at 16-17).

2657. In the NE Labs Minigrips test (RX 838), 3.65% biodegradation of the test samples were observed after 15 days of D5511 anaerobic testing. (RX 838 at 3).

2658. The 3.9% biodegradation observed in the OWS RX 268 test, before the entire system plateaued, is consistent with the test data observed after 15 days in RX 838. (RX 838 at 3; RX 265 at 7).

2659. The NE Labs Minigrips test (RX 838) reflected more than 17% biodegradation of the test sample after one year of sustained testing, based on gas conversion. (RX 838).

C. Qualitative Testing

2660. Qualitative testing is part of the totality of the scientific evidence in the case. (Sahu, Tr. 1910).

2661. The qualitative studies provide multiple lines of proof. (Sahu, Tr. 1910-11).

2662. In the Environ BioPVC study, the measurement of free chloride ions was a significant element. (Sahu, Tr. 1912-13).

2663. In the Environ test marked RX 254, Dr. Barber observed that the presence of chlorine atoms in solution had increased along with biodegradation of the polyvinyl chloride (PVC) substrate. (Sahu, Tr. 1912-13; RX 254).

2664. The molecular weight of the PVC is due to the molecular weight of chlorine, which is heavy. (Sahu, Tr. 1912).

2665. If the PVC molecule loses chloride, there would be an alteration of the chemical structure of PVC that indicates the carbon backbone will also degrade. (Sahu, Tr. 1912-13).

2666. Hydrogen chloride (HCl) is actually the group that is lost due to degradation. (Sahu, Tr. 1913).

2667. If the molecule loses the HCl, the underlying carbon backbone is unavoidably altered too. (Sahu, Tr. 1913).

2668. Double bonds are formed in the carbon backbones that are unavoidably reformed when the HCl group drops out. (Sahu, Tr. 1914).

2669. Dr. Barber concluded in his published reports that the ECM additive would render plastics such as PVC fully degradable with a 1.9 year half-life. (RX 254 at 1).

2670. He confirmed his gravimetric endpoints by looking at free chloride content in the test solution, noting that the chloride ions would have come from the degraded sections of the PVC plastic and that "an increase in soil leachate chloride content and reduction in tensile strength was observed, indicat[ing] the PVC molecules were being effectively degraded." (RX 370 at 6; RX 259).

2671. Dr. Barber also reviewed test data from other laboratories concerning ECM's additive technology. (RX 269).

2672. Dr. Barber had explained that ASTM protocols that are available are inappropriate for to test slowly degrading material and, so, he had to create his own test model. (Barber, Tr. 2062:8-9).

2673. Conventional plastics are challenging materials that may take many years to biodegrade. (Barber, Tr. 2057:5-6).

2674. ASTM did not conceive of this type of material when they were developing their standards, and these materials must be tested for longer periods of time. (Barber, Tr. 2062:9-11).

2675. Therefore, an in-house method of testing with similar reliability safeguards to ASTM (i.e., positive and negative control, and a significant level of replication and statistical testing) must be developed for these materials. (Barber, Tr. 2062:12-2063:3).

2676. Dr. Barber testified that to see if a slowly degrading material fully biodegrades in a lab, you would have to run a test for ten, fifteen, or twenty years. (Barber, Tr. 2057:7-11).

2677. Running a test for ten to twenty-five years would be very expensive. (Barber, Tr. 2058:3-4).

2678. In some cases, testing requires daily monitoring or interaction with the sample, and doing this for tens of years would be prohibitively expensive. (Barber, Tr. 2058:4-8).

2679. A bigger issue with running tests of this duration is maintaining a viable culture for such a long period of time. (Barber, Tr. 2058:9-11).

2680. Maintaining a viable culture requires monitoring of temperature, water, pH, and nutrients for ten or more years would be extremely difficult. (Barber, Tr. 2058:17-23).

2681. Dr. Barber found it very difficult to maintain a real active biological system longer than twelve to eighteen months, and the concept of maintaining this level of activity for tens of years in a laboratory is next to impossible. (Barber, Tr. 2059:5-9).

2682. Therefore, a test must be run for a discrete, reasonable period of time. (Barber, Tr. 2057:12-13).

2683. The tester must ensure that that the amount of material that has been biodegraded is much higher than the amount of additive to show that it isn't just the additive that is biodegrading. (Barber, Tr. 2057:13-16).

2684. This would indicate that the microbes are attacking the base polymer, and there would be no reason to believe this would not continue until the base material is completely biodegraded. (Barber, Tr. 2057:16-20).

2685. Dr. Barber was convinced based on the test results that ECM's technology produced a biodegradable plastic. (RX 870 (Barber, Dep. at 90)).

2686. Dr. Barber has performed tests for five or six ECM customers concerning the biodegradability of ECM plastics that they manufacture. (Barber, Tr. 2028).

2687. Dr. Barber had to create a testing methodology similar to the ASTM testing protocols but on a timescale more appropriate for conventional plastics testing (9 to 18 months) and using slightly different leachate. (Barber, Tr. 2030–31, 2034).

2688. Dr. Barber's tests were designed to simulate landfill conditions as closely as possible. (Barber, Tr. 2034, 2044–45).

2689. Dr. Barber's tests use special containers to maintain anaerobic conditions, and pH, temperature, and moisture content were monitored to maintain optimal levels. (Barber, Tr. 2037–39).

2690. Dr. Barber's tests, like ASTM protocols, utilized both positive and negative controls. (Barber, Tr. 2036).

2691. Dr. Barber performed testing for FP International to determine the biodegradability of their plastics when infused with the ECM additive under both aerobic and anaerobic conditions. (Barber, Tr. 2034. 2041, 2051, 2065, 2148).

2692. The FP International Report summarized the findings of Dr. Barber's tests, stating that ECM plastic "is biodegradable under laboratory conditions that simulate conditions expected to occur in a composting operation or in a municipal landfill managed to promote biological activity." (Barber, Tr. 2047–48; RX 275).

2693. Dr. Barber performed weight-loss testing for BioPVC to determine the biodegradability of their plastics when infused with the ECM additive under anaerobic conditions. (Barber, Tr. 2048–49; RX 120).

2694. Dr. Barber's testing showed weight loss of the ECM material, but not the negative control, indicating that the ECM material was biodegrading. (Barber, Tr. 2055; RX 120).

2695. Dr. Barber also had tensile strength and free chloride testing done on the material after nine months in a simulated landfill environment. (Barber, Tr. 2053–55).

2696. Dr. Barber's testing showed reduced tensile strength as compared to the negative control, indicating that the material was biodegrading. (Barber, Tr. 2055).

2697. Dr. Barber's testing also showed a higher free chloride concentration as compared to the negative control, indicating the breaking of covalent bonds by organic processes. (Barber, Tr. 2056).

2698. Dr. Barber drafted a report summarizing the findings of his tests. (2049; RX 254).

2699. Dr. Barber also provided analytical consulting for BIOtech Products, LLC, an ECM customer, of their test data on the biodegradability of the ECM infused plastics they produce. (Barber, Tr. 2056–57).

2700. Dr. Barber stated in an email to BIOtech Products, LLC explaining his conclusions:

> After a significant level of biodegradation, five to ten times the level of the additive, the only reasonable assumption, assuming conditions supportive of biological activity continue, is that all of the base polymer will biodegrade.

(Barber, Tr. 2056–57; RX 426).

2701. Dr. Barber was contacted by Bill Walters of QC Product Development, an ECM customer, and asked to determine whether their polyethylene product infused with the ECM additive would biodegrade. (Barber, Tr. 2064–65; RX 430).

2702. Dr. Barber, based on his findings for FP International and their polyethylene product, informed Mr. Walters that "PE film with ECM additive is biodegradable." (Barber, Tr. 2065; RX 430).

2703. ECM employees, including Mr. Sinclair, also performed tests of the ECM additive in gardens, backyard soils, and in 50-gallon drums to assess biodegradation in real-time. (CCX 818 (Sinclair, Dep. at 63-69); CCX 820 (Sullivan, Dep. at 8-9); Sullivan, Tr. 725–728; Sinclair, Tr. 755–56).

2704. Environ had also demonstrated through testing similar to the BioPVC work that polyethylene amended with a 1% ECM additive was biodegradable. (RX 275).

2705. ECM also received microscopy with images that reflected changes to plastic and biodegradation after plastic articles had been exposed to test environments. (RX 254; RX 269; RX 270; RX 271).

2706. Other companies and customers have similarly applied qualitative endpoints to verify that plastics made with the ECM additive had biodegraded. (RX 274; 277; RX 388-91).

XVII. DR. TOLAYMAT'S OPINIONS ARE NOT CREDIBLE

2707. In drafting his expert opinion in this case, Complaint Counsel's witness Dr. Tolaymat rejected dozens of scientific tests (including gas evolution tests) because he deemed them to be unreliable or methodologically flawed. (Tolaymat, Tr. 296; CCX 893 at 39-46).

2708. Dr. Tolaymat is an employee of the EPA, a sister agency of the FTC. (Tolaymat, Tr. 216-17).

2709. Dr. Tolaymat was paid an EPA salary for the work he performed in this case. (Tolaymat, Tr. 118-19, 215-16).

2710. He worked on this case during regular business hours, from his EPA office. (Tolaymat Tr. 215-16).

2711. Despite working on the case as an EPA employee, Dr. Tolaymat did not share his report or opinions with any other EPA employee or official before submitting them in this case. (Tolaymat, Tr. 216).

2712. Dr. Tolaymat did not consult any other colleagues or persons at the EPA concerning his opinions in this case. (Tolaymat, Tr. 216-17).

2713. The EPA has other individuals in their ranks that are considered landfill gas experts. (Tolaymat, Tr. 217).

2714. One of those persons is Susan Thorneloe in the EPA's Officer of Research and Development, who has more than 25 years of experience with landfills and landfill gas. (Tolaymat, Tr. 217).

2715. Dr. Tolaymat has been with the EPA for eleven years. (Tolaymat, Tr. 217).

2716. Dr. Tolaymat did not share his opinions in this case with Susan Thorneloe, or anyone at the EPA's ORD, to determine whether his position was consistent with theirs or scientifically reasonable. (Tolaymat, Tr. 217).

2717. Dr. Tolaymat was retained by Complaint Counsel as early as 2010 to assist with this case. (Tolaymat, Tr. 214).

2718. From 2010 through the time when he testified at deposition, Dr. Tolaymat had performed just 80 hours of work on this case total. (Tolaymat, Tr. 214).

2719. Most of his 80 hours were spent drafting his expert report. (Tolaymat, Tr. 214).

2720. Dr. Tolaymat did not perform significant research into plastics before preparing his expert opinion. (Tolaymat, Tr. 214).

2721. Although he had recommended to Complaint Counsel that they perform BMP testing on ECM plastics, Dr. Tolaymat did not test the Plastic containing the ECM additive or plastics made with same. (Tolaymat, Tr. 356, 214).

2722. Dr. Tolaymat was unable to specifically identify what type of tests or testing would be considered competent and reliable evidence to show biodegradation in landfills. (Tolaymat, Tr. 218).

2723. Dr. Tolaymat proposed an in-situ landfill study (Tolaymat, Tr. 218), which Dr. Barlaz later explained is impractical and erroneous. (Barlaz, Tr. 2237).

2724. Dr. Tolaymat recognizes Dr. Barlaz as an authority in the field. (Tolaymat, Tr. 233).

2725. Dr. Tolaymat has consulted Dr. Barlaz on a number of questions concerning landfill biodegradation, and Dr. Barlaz has been hired by the EPA as a consultant on biodegradation. (Tolaymat, Tr. 233).

2726. Dr. Tolaymat has asked Dr. Barlaz to comment and review on Tolaymat's work. (Tolaymat, Tr. 234).

2727. Dr. Tolaymat has asked Dr. Barlaz to revise his work. (Tolaymat, Tr. 234).

2728. No other expert in the case suggested that an in situ landfill study was required to show biodegradation. (Tr. 1-3005).

2729. Dr. Tolaymat admitted that his proposal to use *in situ* landfill studies to measure biodegradation would not be appropriate because researchers would not be able to quantify or determine a specific amount of biodegradation. (Tolaymat, Tr. 222).

2730. Dr. Tolaymat later testified that, in his proposed *in situ* landfill study, "weight loss" would be an appropriate measurement of biodegradation, because gas evolution data would not be possible. (Tolaymat, Tr. 224).

2731. However, when attacking studies favorable to ECM, like the Environ tests, just hours before testifying on cross, Dr. Tolaymat was convinced that "mass loss as an indicator for biodegradation" was not appropriate. (Tolaymat, Tr. 183-84).

2732. In fact, one of Dr. Tolaymat's principle reasons for rejecting the Environ testing was because the study relied on mass loss as an indicator of biodegradation. (Tolaymat, Tr. 182-84).

2733. Dr. Tolaymat had never encountered an *in situ* landfill experiment that tested a specific commercial product as opposed to waste generally. (Tolaymat, Tr. 224).

2734. Dr. Tolaymat had never heard of any company specifically performing an *in situ* study for purposes of evaluating biodegradation claims. (Tolaymat, Tr. 224-25).

2735. Dr. Tolaymat admitted that *in situ* studies carry substantial difficulties and risks that complicate the ability to perform a successful test. (Tolaymat, Tr. 225-26).

2736. Dr. Tolaymat testified that landfill *in situ* studies are "rarely" performed. (Tolaymat, Tr. 237).

2737. Dr. Tolaymat also testified that lysimeter studies are possible. (Tolaymat, Tr. 228-29).

2738. Dr. Tolaymat stated that, to perform an adequate lysimeter study, he would make 12 percent of the lysimeter composed of ECM amended plastics. (Tolaymat, Tr. 229).

2739. Dr. Tolaymat could not explain how a lysimeter test composed of fully twelve percent ECM plastic would be representative of the typical landfill environment, particularly after he testified that plastics generally (not just ECM) ordinarily comprise twelve percent of the total waste. (Tolaymat, Tr. 229).

2740. Dr. Tolaymat's proposed lysimeter study would not rely on gas evolution data, but rather a series of qualitative endpoints like leachate quality and quantity. (Tolaymat, Tr. 230).

2741. Dr. Tolaymat did not explain how, if at all, he could calculate the percentage of biodegradation in a landfill based on those endpoints he posited for the lysimeter study. (Tolaymat, Tr. 230).

2742. In fact, although Dr. Tolaymat rejected entirely the Environ BioPVC study (and similar Environ studies) because Environ relied on weight loss as an endpoint, Dr. Tolaymat himself suggested that weight loss was an acceptable measurement when used in his *in situ* landfill studies. (Tolaymat, Tr. 279-80).

2743. He testified that weight loss was an appropriate endpoint for *in situ* studies, but not for the Environ study, even though he agreed that for the *in situ* landfill studies there are more variables as far as possible confounders than in the laboratory test performed by Dr. Barber at Environ. (Tolaymat, Tr. 281).

2744. In fact, Dr. Tolaymat testified that there are more concerns with "things that could go wrong" in an *in situ* landfill study than there would be in the Environ BioPVC study, which Dr. Tolaymat rejected outright. (Tolaymat, Tr. 281).

2745. Without supporting data, Dr. Tolaymat testified that he could use mass loss endpoints for an *in situ* study, but not for a laboratory study. (Tolaymat, Tr. 282).

2746. When specifically asked about what type of competent and reliable scientific evidence would be appropriate to prove that a product biodegrades at a certain rate in a landfill, Dr. Tolaymat explained that he would accept a "combination of tests." (Tolaymat, Tr. 262).

2747. He explained that, under the totality of scientific evidence, whether a biodegradation claim was supported was entirely a matter of scientific judgment. (Tolaymat, Tr. 262).

2748. Dr. Tolaymat has himself relied on less than perfect scientific data in his research. (Tolaymat, Tr. 262).

2749. The EPA has guidance documents addressing how to glean information from less than perfect scientific information. (Tolaymat, Tr. 262-63).

2750. Dr. Tolaymat did not consult the EPA's guidance documents concerning data validation and verification before authoring his report. (Tolaymat, Tr. 262-63).

2751. When specifically asked about what type of competent and reliable scientific evidence would be appropriate to prove that a product biodegrades at a certain rate in a landfill, Dr. Tolaymat explained that "one of the tests would be the biochemical methane potential test" or BMP. (Tolaymat, Tr. 218-19).

2752. The BMP test is a gas evolution test performed in a laboratory. (Tolaymat, Tr. 219).

2753. Dr. Tolaymat attempted to describe in vague terms how he would calculate a rate of biodegradation in an MSW landfill using a BMP test. (Tolaymat, Tr. 220-21).

2754. Dr. Tolaymat acknowledged that the rate of degradation would be "slower" in a landfill than in a BMP test. (Tolaymat, Tr. 221).

2755. When asked how he could then determine the specific rate of biodegradation in the landfill from the BMP, in other words, how much slower the degradation would be, Dr. Tolaymat testified that he "would be speculating if I tell you." (Tolaymat, Tr. 221).

2756. The BMP test does not "replicate or simulate" landfill conditions, as Dr. Tolaymat uses that phrase, because it does not have the same moisture content as many landfills, it is usually conducted at higher temperatures, the test is enriched with nutrients, and the test samples are often ground or passed through screens. (Tolaymat, Tr. 220, 237-38).

2757. Dr. Tolaymat specifically testified that the BMP test "does not simulate" a landfill, and that the environment is optimized to show biodegradation. (Tolaymat, Tr. 237-38).

2758. Dr. Tolaymat testified that the BMP differs "dramatically" from the typical U.S. landfill. (Tolaymat, Tr. 238).

2759. Dr. Tolaymat still testified that "the BMP test provides [competent and reliable] data to shed light on the degradation in a landfill." (Tolaymat, Tr. 218).

2760. He explained that, "if you run the appropriate controls, yes, the BMP could be a suitable test." (Tolaymat, Tr. 237-38).

2761. Dr. Tolaymat recommended to Complaint Counsel that they perform a BMP test to assess the biodegradability of plastics made with the ECM additive. (Tolaymat, Tr. 356-57).

2762. At hearing, Dr. Tolaymat deviated from prior testimony and testified that he could not have tested the ECM additive because of hardship. (Tolaymat, Tr. 353-54).

2763. Contrary to his hearing testimony, Dr. Tolaymat testified at deposition that he offered to perform product testing of the ECM plastics for Complaint Counsel. (RX 851 (Tolaymat, Dep. at 39)).

2764. Specifically, Dr. Tolaymat testified as follows:

> Q: Do you have the capability of performing product testing of ECM's products?
> A: Yes.
> Q: You could run any of the tests that you did that you cite to in the peer-reviewed literature, right?
> A: Given enough time, we have the capability to run any tests we deem necessary.
> …

Q: Did you ask to perform any of those tests?
A: I suggested one time that it may be beneficial to do it, but that was it.
…
Q: What kind of test did you suggest?
A: Whatever anaerobic tests we were conducting at the time, so it probably would be the biochemical methane potential test.

(RX 851 (Tolaymat, Dep. at 38-39).

2765. Then, at the hearing, Dr. Tolaymat testified contrary to his deposition that EPA could not have performed testing because they "would have to open it up for any other company out there that has a product that they claim is biodegradable." (Tolaymat, Tr. 353).

2766. Dr. Tolaymat conceded that the test protocol for a BMP test is not standardized and it varies considerably from one laboratory to another. (Tolaymat, Tr. 239).

2767. Dr. Tolaymat stated that the deviation from one laboratory to another in the operation of the BMP study did not render data unreliable. (Tolaymat, Tr. 239).

2768. Dr. Tolaymat himself chose to perform a BMP test to evaluate the biodegradability of commercial plastic products in about 2010. (Tolaymat, Tr. 238-39).

2769. The point of Dr. Tolaymat's BMP study was specifically to draw conclusions about "the performance of the plastics in a landfill environment." (Tolaymat, Tr. 243).

2770. At the same time, Dr. Tolaymat rejected "dozens" of favorable ECM D5511 gas evolution studies because, according to Dr. Tolaymat, they did not "simulate" landfill conditions. (Tolaymat, Tr. 235-37).

2771. He testified that he rejected "all of … ECM's D5511 studies because they don't simulate the landfill environment." (Tolaymat, Tr. 243).

2772. But Dr. Tolaymat himself relied on that same type of scientific information in his own assessments of plastics biodegradability in landfills. (Tolaymat, Tr. 243).

2773. Despite that fact, Dr. Tolaymat testified that a test which deviates in any respect from a landfill environment through, e.g., temperature or moisture, is not competent and reliable scientific evidence to show that a product will biodegrade in a typical municipal solid waste landfill. (Tolaymat, Tr. 236-37).

2774. Dr. Tolaymat agreed that biodegradation tests can be accelerated, but he did not know and would have needed to "speculate" how a researcher would accelerate the tests. (Tolaymat, Tr. 244).

2775. Dr. Tolaymat was not sure whether a plastic that biodegraded in a landfill in twenty years was environmentally beneficial. (Tolaymat, Tr. 245-46).

2776. In his expert report, Dr. Tolaymat did not understand how half-lives operate, and he repeatedly calculated the time for complete biodegradation of a material to be simply twice the half-life. (CCX 893 at 16 n.9, 27 ¶67).

2777. He later corrected himself at the hearing after being confronted with his erroneous understanding of half-lives during his deposition. (RX 851 (Tolaymat, Dep. at 97-99); Tolaymat, Tr. 246-47).

2778. Based on Dr. Tolaymat's insistence that a test must replicate or simulate a landfill environment, Dr. Tolaymat admitted that, to satisfy his standard, a test would need to be run for decades in order to show that a degradable plastic, which could reasonably biodegrade over 20 years, was completely biodegraded. (Tolaymat, Tr. 245-50).

2779. Dr. Tolaymat testified that a test must precisely simulate the landfill environment to be competent and reliable, but, he also accepted that a biodegradation test could be "accelerated" so that it would not be required to run for decades. (Tolaymat, Tr. 249).

2780. When asked how tests could be accelerated while at the same time simulating a landfill environment, Dr. Tolaymat stated, "that is an open-ended question. I mean, we can spend hours and hours talking about it" and "it's going to take more than this court has time to allow." (Tolaymat, Tr. 250).

2781. Dr. Tolaymat testified that the D5511 test is not an "accelerated" test. (Tolaymat, Tr. 250-51).

2782. He testified that a laboratory could conduct a D5511 test for several years while maintaining test conditions. (Tolaymat, Tr. 251).

2783. However, Dr. Tolaymat rejected certain ECM D5511 tests that were longer in duration because, according to Dr. Tolaymat, they did not follow the D5511 method precisely. (Tolaymat, Tr. 251-52).

2784. Dr. Tolaymat offered no explanation for why a D5511 test of longer duration would not follow the D5511 method. (Tolaymat, Tr. 250-53).

2785. The ASTM D5511 method does not specify a cutoff time or duration for the test and, in fact, the method specifically contemplates tests of varying durations: "The incubation time shall be run **until** no net gas production is noted for at least five days from both the positive control and the test substance reactors." (RX 356 at 3 § 11.2.1.2) (emphasis added).

2786. Although Dr. Tolaymat entirely rejected ECM D5511 tests that were run longer than 60 days because those tests did not "follow the standard test method," he offered no scientific basis to reject data on those grounds alone, and he acknowledged that the BMP test, upon which he himself used and recommended, did not even have a standard test method. (Tolaymat, Tr. 252-54).

2787. Dr. Tolaymat admitted that he excluded "an entire class of studies" solely because they did not "simulate the landfill" and that he excluded those studies "**regardless of how well-conducted those studies [were]**." (Tolaymat, Tr. 296) (emphasis added).

2788. On that basis, he rejected "dozens" of positive ECM studies. (Tolaymat, Tr. 296).

2789. Dr. Tolaymat performed no research and reviewed no studies or articles concerning the limitations of closed-system laboratories. (Tolaymat, Tr. 290).

2790. He reviewed no articles or literature on the principle of feedback inhibition. (Tolaymat, Tr. 290).

2791. Dr. Sahu, by contrast, testified that extending the duration of a D5511 test does not render the data unreliable. (Sahu, Tr. 1928).

2792. Dr. Sahu testified that, consistent with the D5511 standard itself, as long as the conditions of the test are maintained, then there is no reason to simply reject a test based on an increase in study duration. (Sahu, Tr. 1928).

2793. Dr. Sahu had no concerns with the methodology of the various laboratory reactor tests performed on ECM plastics. (Sahu, Tr. 1932-33).

2794. In his expert report, Dr. Tolaymat wrote that the conditions in a D5511 gas evolution test will cause activity by "different bacterial communities" in landfills. (Tolaymat, Tr. 263).

2795. Dr. Tolaymat presented no data in his report or testimony concerning an assessment of bacterial communities in landfills. (Tolaymat, Tr. 264).

2796. Dr. Tolaymat does not consider himself to be an expert in the kinds of microbial species that exist in landfills. (Tolaymat, Tr. 264).

2797. Dr. Tolaymat was not aware of the type of enzymes produced by microbial species that might cause biodegradation. (Tolaymat, Tr. 264).

2798. Dr. Tolaymat could not identify or explain the mechanisms of action used by microbes and colonies of microbes to biodegrade plastics. (Tolaymat, Tr. 264).

2799. Dr. Tolaymat did not know whether there is an overlap in the temperatures where mesophilic and thermophilic bacteria function. (Tolaymat, Tr. 266).

2800. Dr. Tolaymat did not evaluate whether thermophilic and mesophilic bacteria would use similar forms of enzymatic degradation or metabolism to break down substrates. (Tolaymat, Tr. 266).

2801. Dr. Tolaymat could not name a single phyla of bacteria that exist in landfills. (Tolaymat, Tr. 266).

2802. Dr. Tolaymat could not name a single phyla of fungi that exist in landfills. (Tolaymat, Tr. 266).

2803. Dr. Tolaymat could not state whether types of bacteria in a D5511 test environment also exist in the MSW landfills. (Tolaymat, Tr. 266-67).

2804. Dr. Tolaymat rejected the Environ BioPVC study (CCX 739) because, according to him, it contained several methodological flaws. (Tolaymat, Tr. 268-69).

2805. He rejected the study (CCX 739) because the moisture content was too high. (Tolaymat, Tr. 268-69).

2806. However, Dr. Tolaymat himself had relied on BMP studies that had higher moisture levels than the Environ BioPVC study, and Dr. Tolaymat testified that those BMP studies were competent and reliable. (Tolaymat, Tr. 218-19, 268-69).

2807. Dr. Tolaymat also conceded that landfill systems are highly variable and have many different moisture levels throughout a single landfill, including pockets were waste is saturated. (Tolaymat, Tr. 270-71).

2808. Dr. Tolaymat conceded that landfills have "ponding" or ponded areas where water content is saturated above the fifty percent (50%) mark. (Tolaymat, Tr. 273-74).

2809. He admitted that a landfill could be almost dry on one side and then very wet on the other side. (Tolaymat, Tr. 274-75).

2810. He also conceded that landfills receive moisture that infiltrates from rainwater, and that landfill moisture content varies considerable by geographic location. (Tolaymat, Tr. 276-77).

2811. Dr. Tolaymat was also aware that certain landfills practice spray application of liquid to waste. (Tolaymat, Tr. 277-78).

2812. In rejecting the Environ BioPVC study (CCX 739), Dr. Tolaymat testified that it was more likely that the mass loss resulted from fragmentation of the BioPVC than from biodegradation. (Tolaymat, Tr. 282).

2813. However, Dr. Tolaymat observed no evidence that suggested fragmentation was possible or likely, such as agitation of the test vessels. (Tolaymat, Tr. 282).

2814. Dr. Tolaymat could not explain the type of mechanical processes that he thought were responsible for fragmentation of the BioPVC in lieu of biodegradation. (Tolaymat, Tr. 283).

2815. Dr. Tolaymat never determined whether the PVC plastic would be susceptible to fragmentation based on the PVC's molecular structure. (Tolaymat, Tr. 283).

2816. He never considered the PVC molecule's melting point, glass transition temperature, crystallinity, or modulus of elasticity. (Tolaymat, Tr. 283).

2817. He was not aware whether the negative controls displayed similar results. (Tolaymat, Tr. 284).

2818. Dr. Tolaymat was aware that Dr. Barber at Environ also relied on the presence of free chloride ions in solution to show that the PVC molecule had broken down. (Tolaymat, Tr. 284-85).

2819. Dr. Tolaymat agreed that the BioPVC molecule would have originally contained chloride. (Tolaymat, Tr. 284).

2820. Dr. Tolaymat was also aware that the negative control did not display a similar increase in chloride ions. (Tolaymat, Tr. 285).

2821. Dr. Tolaymat dismissed the significance of the chloride ions. (Tolaymat, Tr. 285).

2822. Dr. Tolaymat suggested that "the free chloride could have come from the ECM additive that was used since there was no ECM control by itself." (Tolaymat, Tr. 285).

2823. However, he testified immediately thereafter that the ECM additive "**shouldn't**" contain polyvinyl chloride. (Tolaymat, Tr. 285).

2824. In fact, Dr. Tolaymat conceded that "if the ECM additive we are sure does not contain chloride, then t**he chloride obviously would be coming from potentially the degradation of the PVC**." (Tolaymat, Tr. 286) (emphasis added).

2825. Dr. McCarthy, in his report at page 24 n.17, reported that the ECM additive contains polyethylene vinyl acetate (EVA), polycaprolactone (PCL), linear low-density polyethylene (LLDPE), calcium stearate, and starch, none of which contain chloride (CCX 891 at 24 n.17).

2826. Dr. Tolaymat also concluded that a plateau in the test environment is evidence that the test plastic is no longer biodegradable. (Tolaymat, Tr. 287).

2827. Dr. Tolaymat, without evidentiary support or a basis in fact, testified that exposing a partially biodegraded test sample to the atmosphere would render that product incapable of further biodegradation testing. (Tolaymat, Tr. 287).

2828. Dr. Tolaymat conceded, however, that the test plastic is exposed to the atmosphere before biodegradation testing. (Tolaymat, Tr. 288).

2829. He also conceded that if a test sample were returned to a test vessel, the production of methane gas would indicate the presence of continued anaerobic biodegradation. (Tolaymat, Tr. 289).

2830. Dr. Tolaymat's theory on the "plateau effect" is that once a plateau is observed, the ECM additive has been exhausted and there is nothing left to biodegrade. (Tolaymat, Tr. 289).

2831. Without any scientific basis, Dr. Tolaymat rejected the logical idea that a lab could retest the partially degraded sample to test whether any portion remains biodegradable after the first test. (Tolaymat, Tr. 289).

2832. Dr. Tolaymat conceded and agreed that, "if the additive is … exhausted and there's biodegradation, that would be reflective that the test article, the plastic, is degrading." (Tolaymat, Tr. 289).

2833. Dr. Tolaymat considers cellulose to be a "fully degradable material." (Tolaymat, Tr. 290).

2834. Laboratories use cellulose as a positive control in gas evolution testing precisely because the product should be fully biodegradable. (Tolaymat, Tr. 291).

2835. Dr. Tolaymat conceded that in studies that are in the record, evidence suggests that cellulose "plateaued" or stopped degrading well below 90% and in at least one test it plateaued under 50%. (Tolaymat, Tr. 292-93).

2836. Dr. Tolaymat conceded that the material may have stopped biodegrading because "the environment that it is in [was] not conducive for complete biodegradation…" (Tolaymat, Tr. 292).

2837. Dr. Tolaymat also rejected many positive ECM D5511 tests because, according to Dr. Tolaymat, they did not provide a means to distinguish biodegradation of the plastics and the additive. (Tolaymat, Tr. 296).

2838. He could not explain how plastics are manufactured with the ECM additive. (Tolaymat, Tr. 297-98).

2839. Dr. Tolaymat agreed that other additives, like colorants, which are introduced into the plastics in a similar method and at similar percentages as the ECM additive (Sahu, Tr. 1818-20), appear to be mixed throughout the plastic uniformly. (Tolaymat, Tr. 298-99).

2840. Dr. Tolaymat had no reason to think that the ECM additive is not uniformly mixed throughout the plastic if manufactured as intended. (Tolaymat, Tr. 299).

2841. He agreed that the goal of manufacturing the ECM plastic is to achieve a uniform distribution throughout the plastic. (Tolaymat, Tr. 299).

2842. Dr. Tolaymat testified that much of the ECM additive will not, therefore, be accessible to the microbes at once. (Tolaymat, Tr. 299).

2843. Dr. Tolaymat agreed that the methane sourced from a D5511 test can only be sourced from anaerobic biodegradation. (Tolaymat, Tr. 302).

2844. He testified that the presence of methane in the test environment is an indication that there is anaerobic biodegradation. (Tolaymat, Tr. 302).

2845. The point of a D5511 test, or a "gas evolution" test, is to calculate a percentage of biodegradation based on the gas emissions. (Tolaymat, Tr. 303).

2846. That percentage is calculated by first determining the theoretical yield of gas that could possibly be sourced from the test article, assuming complete conversion of carbon to gas. (Tolaymat, Tr. 303).

2847. Dr. Tolaymat agreed that the theoretical yields are appropriate endpoints because "there can only be so much carbon in a test sample based on weight." (Tolaymat, Tr. 305).

2848. He also agreed that it would be scientifically appropriate to calculate a maximum theoretical yield of gas from the ECM additive alone. (Tolaymat, Tr. 305).

2849. Dr. Tolaymat did not attempt to calculate a theoretical yield of methane or gas from the ECM additive alone. (Tolaymat, Tr. 306).

2850. Dr. Tolaymat did not consider whether the amount of methane recorded in ECM's gas evolution tests would have been greater than the maximum amount of methane theoretically possible from the ECM additive alone. (Tolaymat, Tr. 308-10).

2851. Dr. Tolaymat testified that a D5511 test of sound methodological quality that revealed a percentage of biodegradation in the range of 50%, with just 1% of the additive, would be evidence that the plastic was biodegrading and not the additive. (Tolaymat, Tr. 314).

2852. Dr. Tolaymat's statement that a methodologically sound D5511 test could produce evidence that the plastic and not the additive was degrading conflicts with his testimony and expert report where he testified that the D5511 test does not allow researchers to determine if the plastic degraded above the additive. (Tolaymat, Tr. 296, 313-14).

2853. Dr. Tolaymat did not perform any statistical analyses of the test data. (Tolaymat, Tr. 314-15).

2854. With respect to NE Labs testing, or any gas evolution testing relevant to the case, Dr. Tolaymat did not perform statistical analyses of the data. (Tolaymat, Tr. 316-17).

2855. Dr. Tolaymat testified that the same raw data available to Dr. Barlaz was also available to him. (Tolaymat, Tr. 317).

2856. He testified that he was aware of Dr. Barlaz's statistical calculations, but he did not perform the same calculations on his own, or any similar calculations. (Tolaymat, Tr. 317).

2857. Dr. Tolaymat was aware of Dr. Barlaz's statistical calculations based on gas evolution data, but Dr. Tolaymat did not review Dr. Barlaz's statistical calculations. (Tolaymat, Tr. 316-17).

2858. Dr. Tolaymat claimed to have reviewed test data after his deposition, but before the hearing, but he testified that he "didn't do any calculations." (Tolaymat, Tr. 317).

2859. Although the raw data was available to him, Dr. Tolaymat did not calculate the ratio of methane yield of the substrate to the inoculum yield. (Tolaymat, Tr. 320-21).

2860. Dr. Tolaymat did not calculate the mean methane in milliliters for the inoculum. (Tolaymat, Tr. 320).

2861. He did not calculate t-statistics for the methane or carbon dioxide readings. (Tolaymat, Tr. 321).

2862. He did not calculate standard deviations. (Tolaymat, Tr. 321).

2863. He did not calculate ranges. (Tolaymat, Tr. 321).

2864. He did not calculate the theoretical yield of methane from the ECM additive (Tolaymat, Tr. 321-22), yet he testified that the D5511 tests cannot show that the biodegradation occurring from the test sample is from the additive. (Tolaymat, Tr. 207).

2865. Even when accepting the premise behind Dr. Barlaz's opinion, and accepting that the amount of methane gas stemming from the additive is limited, Dr. Tolaymat still insisted that he could not determine whether biodegradation exceeded the maximum amount potentially supplied by the ECM additive. (Tolaymat, Tr. 307-10).

2866. Dr. Tolaymat also rejected aerobic studies of ECM amended plastics solely because they were conducted under aerobic conditions. (Tolaymat, Tr. 324).

2867. Dr. Tolaymat rejected the Ecologicia Applicata aerobic test which revealed 47% biodegradation over 180 days, solely because the test did not simulate landfill conditions. (Tolaymat, Tr. 324; RX 276).

2868. Dr. Tolaymat had no basis to conclude that the test reported as RX 276 did not adhere to the IS0 14855 standard that was described in the report. (Tolaymat, Tr. 325; RX 276).

2869. He testified that he had no reason to think that the test marked RX 276 was methodologically flawed. (Tolaymat, Tr. 326).

2870. Dr. Tolaymat had no specific belief that the polyamide nylon plastic polymer tested in RX 276 was a product that would be aerobically biodegradable but not anaerobically biodegradable. (Tolaymat, Tr. 326-27).

2871. Dr. Tolaymat also rejected all biodegradation studies that did not show "complete" biodegradation because, according to Dr. Tolaymat, the only way to prove complete biodegradation is to test and actually witness complete biodegradation. (Tolaymat, Tr. 329-30).

2872. Dr. Tolaymat also rejected ASTM D5511 tests because the laboratories measured gas weekly. (Tolaymat, Tr. 329).

2873. He provided no scientific basis to conclude that weekly gas measurements would render the data or study conclusions unreliable. (Tolaymat, Tr. 329-31).

2874. In fact, Dr. Tolaymat himself published two peer reviewed articles wherein he employed gas evolution tests and recorded gas readings even less frequent than weekly. (Tolaymat, Tr. 330-32).

2875. Although Dr. Tolaymat testified that he did not "see any scientific issues affecting the data from once-per-week gas measurement[s]," he rejected ECM tests that relied on weekly measurements. (Tolaymat, Tr. 329-31).

2876. Dr. Tolaymat did not reject his own study data when he relied on weekly gas measurements and, in fact, he relied on that data to support his writings in the peer reviewed literature. (Tolaymat, Tr. 332-33).

2877. The EPA's Landfill Methane Outreach Program (LMOP) has a mission to reduce methane emissions from landfills. (RX 967).

2878. One of the ways LMPO tries to accomplish its mission is by promoting successful recovery of landfill gas emissions. (RX 967).

2879. In 2013, the EPA had estimated that landfills were supplying already over 102 billion cubic feet of usable methane landfill gas per year. (RX 967).

2880. Dr. Tolaymat conceded that the amount of methane identified by LMOP mostly came from those landfills Dr. Tolaymat had described as "dry tomb" landfills. (Tolaymat, Tr. 343).

2881. Dr. Tolaymat also accepted that the EPA LMOP has identified another 600 potential landfills for methane gas recovery for beneficial use, most of which would also be "dry tomb" landfills as Dr. Tolaymat described them. (Tolaymat, Tr. 343).

2882. Dr. Tolaymat conceded that the presence of landfill gas, specifically methane, is an indication of biological activity because, in part, "methane can only be sourced in a landfill from anaerobic biodegradation." (Tolaymat, Tr. 340).

2883. Dr. Tolaymat never discussed his position concerning "dry tomb" landfills with colleagues in the EPA's LMOP. (Tolaymat, Tr. 344).

2884. Dr. Tolaymat did not share his report with any person in the EPA's LMOP. (Tolaymat, Tr. 344).

2885. Dr. Tolaymat did not consult with anyone in the EPA's LMOP when preparing his opinion in this case. (Tolaymat, Tr. 344).

XVIII. AN INCONCLUSIVE TEST IS NOT PROOF OF A NEGATIVE TEST

2886. Any laboratory test used to measure real-world phenomena is an approximation of the real-world situation and, so, scientists must accept that the real world is more complex and subject to more factors that cannot be controlled for in the laboratory environment. (Sahu, Tr. 1915).

2887. Dr. Sahu explained that because MSW landfills are so heterogeneous, and that the range of conditions are so vast, it would be impossible to "replicate" in one laboratory test the conditions present in landfills generally. (Sahu, Tr. 1915-16).

2888. Gas evolution tests cannot scientifically be rejected simply because they do not perfectly replicate all conditions (or even average conditions) found in MSW landfills. (Sahu, Tr. 1016-17).

2889. Many laboratories deviate slightly from the ASTM D5511 protocol. (Sahu, Tr. 1922-23). Variations of the testing protocol do not render the test data unreliable. (Sahu, Tr. 1922-23).

2890. Dr. Sahu testified that there are concerns with running a closed-system laboratory test over longer periods of time. (Sahu, Tr. 1928-29). The test ecosystem must be maintained, which is challenging. (Sahu, Tr. 1928-29).

2891. Unlike in a landfill where biological systems are being replenished and renewed and have a greater propensity to thrive, a lab environment can quickly lose activity if the biota die. (Sahu, Tr. 1929).

2892. Biological systems produce waste, and the closed-system laboratory test does not permit that waste to be rejected or expelled. (Sahu, Tr. 1930).

2893. The closed-system laboratory test vessel is also limited in that there may be less biological diversity in the test sample than what might exist in the natural environment. (Sahu, Tr. 1931).

2894. Evidence that a plateau has formed in the laboratory tests can signal that the test environment is no longer conductive to biodegradation testing. (Sahu, Tr. 1929). That is particularly evident where the plateau forms in the positive control, an article known to be biodegradable. (Sahu, Tr. 1929-30).

2895. Dr. Sahu testified that the presence of a "plateau effect" in the closed-system laboratory tests does not mean that biodegradation of the test substrate is no longer possible, or that the test substrate is finished biodegrading. (Sahu, Tr. 1931).

2896. Dr. Sahu explained that there are multiple candidate answers to explain the plateau effect, and one of which is that the article has seemingly stopped biodegrading because the biological activity in the test vessel has diminished or is no longer present. (Sahu, Tr. 1931-32).

2897. Dr. Sahu reviewed biodegradation tests of ECM plastics that were inconclusive with respect to biodegradation. (Sahu, Tr. 1937).

2898. Dr. Sahu explained that there are many reasons that might point to the cause of an inconclusive test. (Sahu, Tr. 1938-39).

2899. To properly understand an inconclusive test, the scientist must understand, inter alia, the biological activity in the test vessels; know whether the additive as in fact properly mixed and present in the plastic; know whether the plastic was manufactured with the additive properly such that the additive was not rendered ineffective; and know whether the presence of other additives or impurities may have hindered biodegradation. (Sahu, Tr. 1938-39).

2900. For instance, Dr. Barber at Environ explained that polystyrene foams did not test well in his methodology that is based on weight loss because the foams collect and retain too much environmental material. Dolco and EDS produce products that use expanded polystyrene. (Barber, Tr. 2148:16-18, 2149:5-11, 2148:6-7).

2901. Expanded polystyrene has a lot of pore space that can trap dirt and microorganisms, and flushing these materials out can be problematic. (Barber, Tr. 2148:16-18, 2149:5-11).

2902. The inability to clear out the dirt, bacteria and other materials from these pores can result in negative weight loss or weight gain during the exposure period. (Barber, Tr. 2149:8-12).

2903. Dispoz-o products are made of both expanded polystyrene and molded polystyrene. (Barber, Tr. 2148:8-9).

2904. FP International produces a product that uses a combination of polyethylene film and expanded polystyrene. (Barber, Tr. 2148:10-12).

2905. The manufacturing process with the ECM additive is subject to complexities that must be controlled for. (Sahu, Tr. 1938-39).

2906. In the inconclusive studies, the laboratories generally did not follow-up or investigate why the study may have been inconclusive. (Sahu, Tr. 1939).

2907. Even assuming that Complaint Counsel's priming effect theory is supportable, that priming effect would be expected in all ECM studies because the ECM additive itself is biodegradable. (Sahu, Tr. 1942).

2908. If a test shows no biodegradation, or very little biodegradation, then that data is inconsistent with Complaint Counsel's theory on the priming effect. (Sahu, Tr. 1942-43). That data is also consistent with the implication that manufacturing errors or other variables limited the ECM additive's efficacy or presence in the final product. (Sahu, Tr. 1942-43).

XIX. THIS COURT SANCTIONED COMPLAINT COUNSEL FOR A DISCOVERY OBLIGATION

2909. On February 28, 2014, Respondent filed a Motion for Sanctions, asserting that FTC Complaint Counsel failed to supplement its document production "in a timely manner," pursuant to FTC Rule 3.31(e)(2). (Order Granting in part and Denying in part Resp. Mot. for Sanctions, Dkt. 9358 (March 21, 2014)).

2910. Complaint Counsel filed an opposition to the Motion on March 10, 2014, and a Clarification Regarding Respondent's Motion for Sanctions on March 13, 2014. (Order Granting in part and Denying in part Resp. Mot. for Sanctions, Dkt. 9358 (March 21, 2014)).

2911. On March 21, 2014, the Court granted in part Respondent's Motion for Sanctions, because "Complaint Counsel violated its discovery obligation." (Order Granting in part and Denying in part Resp. Mot. for Sanctions, Dkt. 9358 (March 21, 2014)).

XX. DR. MICHEL, A LAST MINUTE SURPRISE REBUTTAL WITNESS, LACKED CREDIBILITY

2912. On July 9, 2014, Respondent moved to exclude testimony of surprise Complaint Counsel Expert witness, Dr. Frederick Michel, to strike his rebuttal report, and for sanctions against Complaint Counsel under Rule 3.38(b). (Resp. Mot. for Sanctions 1-3, (July 9, 2014)).

2913. Respondent alleged that Complaint Counsel had failed to comply with discovery obligations imposed by the rules, and that such conduct was sanctionable under Rule 3.38(b).

2914. Dr. Michel co-authored a study entitled "Biodegradation of Conventional and Bio-Based Plastics and Natural Fiber Composites During Composting, Anaerobic Digestion and Long-Term Soil Incubation" ("Dr. Michel's study"). (Michel, Tr. 2903–04).

2915. In Dr. Michel's study, he assessed the anaerobic biodegradability of a wide range of commercial available materials used to manufacture plastic products. (Michel, Tr. 2904).

2916. One or two of the materials Dr. Michel tested in his study was the ECM additive. (Michel, Tr. 2904).

2917. In order to measure the anaerobic biodegradation of plastics infused with the ECM additive, Dr. Michel's study tested those materials based on a protocol similar to that described in ASTM D5511-02. (Michel, Tr. 2904–05).

2918. At the hearing, Dr. Michel testified that he used the protocol similar to ASTM D5511 only because that protocol mimicked really anaerobic digestion conditions. (Michel, Tr. 2905).

2919. However, Dr. Michel's study states that he chose the protocol similar to ASTM D5511 because "[t]hese conditions resemble those found in high-solids AD digesters and in **biologically active landfills**." (Michel, Tr. 2905–06; CCX 880)) (emphasis added).

2920. Dr. Michel further testified at the hearing that he did use the protocol similar to ASTM D5511 to test the anaerobic biodegradability of ECM amended plastics at least in part because that protocol resembles the environment in a biologically active landfill. (Michel, Tr. 2906).

2921. In testing for anaerobic biodegradation of ECM amended plastics in his peer-reviewed study, Dr. Michel used no C-14 radiolabeling testing. (Michel, Tr. 2906; CCX 880).

2922. In fact, Dr. Michel has never tested any polymer using 14C radiolabeling testing. (Michel, Tr. 2906).

2923. In testing for anaerobic biodegradation of ECM amended plastics in his peer-reviewed study, Dr. Michel used no in situ testing. (Michel, Tr. 2906–07; CCX 880).

2924. In testing for anaerobic biodegradation of ECM amended plastics in his peer-reviewed study, Dr. Michel used no lysimeter testing. (Michel, Tr. 2906–07; CCX 880).

2925. According to Dr. Michel and Dr. Michel's study, respirometric testing, like the D5511 tests, are generally recognized in the field as competent and reliable evidence to show biodegradation. (Michel, Tr. 2907; CCX 880).

2926. In his study, Dr. Michel defines "biodegradation" as "the mineralization of materials as a result of naturally-occurring microorganisms such as bacteria and fungi." (Michel, Tr. 2907–08; CCX 880).

2927. In the definition of biodegradation that Dr. Michel writes in his study, there is no statement of rate of biodegradation or time for biodegradation. (Michel, Tr. 2908; CCX 880).

2928. In fact, Dr. Michel has never defined biodegradation as having to result in a complete breakdown of material into elements found in nature within one year after customary disposal in any of his peer-reviewed articles. (Michel, Tr. 2908).

2929. Furthermore, Dr. Michel has never stated in any of his peer reviewed article that biodegradation has to occur within any specific time period. (Michel, Tr. 2908).

2930. However, in his rebuttal report, Dr. Michel conveniently states that:

> Biodegradation in the context of disposable consumer products must mean something different. It means that a material will biodegrade to natural products over a time frame used for municipal waste management via composting, anaerobic digestion and/or landfilling. It also implies that materials will biodegrade rapidly if they end up in natural environment and will not accumulate.

(Michel, Tr. 2909–10; CCX 895).

2931. At his deposition, Dr. Michel defined "rapidly," in the context of the definition of biodegradation he stated in his rebuttal report, as:

> [D]uring the process of those waste management technologies, so during the composting process, which would be a period of 30 to 60 days in anaerobic environment, which could include landfills or anaerobic digesters, it would be the course of 30 to 60 days. Or in a natural environment to the extent of maybe 60 to 90 days that material is broken down.

(Michel, Tr. 2912; RX 970 (Michel, Dep. at 18)).

2932. So, despite never defining biodegradation to include any rate or time frame in any of his peer reviewed articles, Dr. Michel defined biodegradation for purposes of this litigation as requiring material to break down within 90 days in any natural environment. (Michel, Tr. 2908–12; RX 970 (Michel, Dep. at 18)).

2933. According to Dr. Michel, if a plastic product completely breaks down into elements found in nature one year after being disposed of in a landfill, that plastic product is not biodegradable. (Michel, Tr. 2912–13).

2934. According to Dr. Michel, if a plastic product completely breaks down into elements found in nature 6 months after being disposed of in a landfill, then that plastic product is not biodegradable. (Michel, Tr. 2915–16).

2935. According to Dr. Michel, if a plastic product completely breaks down into elements found in nature 3 months after being disposed of in a landfill, then that plastic product is not biodegradable. (Michel, Tr. 2916–17).

2936. However, Dr. Michel is not aware of any plastic product that would always biodegrade within 90 in an anaerobic landfill. (Michel, Tr. 2923).

2937. Dr. Michel is a paid consultant for multiple companies in the composting industry, such as DuPont, Indian Summer Composting, AllTreat Organics Composting, Amylex, and International Paper, and Myers Company. (Michel, Tr 2919–22).

2938. Dr. Michel has also consulted for the Federal Trade Commission on two or three cases. (Michel, Tr. 2922–23).

2939. In Dr. Michel's study, Myers Company prepared the two sample materials purportedly containing the ECM additive. (Michel, Tr. 2925; CCX 880).

2940. Dr. Michel readily admits that he is not an expert on the types of plastic processing that Myers used to prepare the samples allegedly blended with the ECM additive. (Michel, Tr. 2925).

2941. Other than simply stating that the samples containing the ECM additive were produced by injection molding, Dr. Michel's article does not indicate the conditions for the injection molding. (Michel, Tr. 2926; CCX 880).

2942. There is nothing in Dr. Michel's article that identifies anything regarding the particular processing conditions that were in the injection molding of the blends containing the ECM additive. (Michel, Tr. 2927; CCX 880).

2943. There is nothing in Dr. Michel's rebuttal report that discusses anything about the particular manufacturing methods and conditions that were used in the injection molding of the blends containing the ECM additive. (Michel, Tr. 2927; CCX 895 (Michel, Rebuttal Rep.)).

2944. Nothing in Dr. Michel's study or Dr. Michel rebuttal report provides the molding conditions for the negative control employed in Dr. Michel's study. (Michel, Tr. 2927–28).

2945. Myers Industries first paid Dr. Michel to conduct a study around 2008 or 2009. (Michel, Tr. 2928).

2946. Myers Industries has paid around 40 or 50 thousand dollars for the work done by Dr. Michel. (Michel, Tr. 2929).

2947. Myers' financial support of 40 or 50 thousand dollars to Dr. Michel and his employer culminated in Dr. Michel's article. (Michel, Tr. 2929).

2948. Dr. Michel is aware, and has been aware since he first started doing work for Myers, that Myers sells pots made out of natural fibers, which means that Myers markets those pots as compostable or biodegradable without incorporating the ECM additive. (Michel, Tr. 2931–32).

2949. Myers Industries provided Dr. Michel and his co-author Eddie Gomez with the products that were purportedly infused with the ECM additive that were the subject of Dr. Michel's article. (Michel, Tr. 2932–33).

2950. Dr. Michel does not have any certificate of ingredients regarding the samples provided to him by Myers Industries which purportedly contain the ECM additive. (Michel, Tr. 2933).

2951. Dr. Michel never contacted ECM directly to ensure that Myers Industries properly manufactured the plastics purportedly containing the ECM additive. (Michel, Tr. 2935).

2952. Dr. Michel did no testing to ensure that the plastics Myers Industries told him contained the ECM additive actually contained the ECM additive. (Michel, Tr. 2935–36).

2953. Dr. Michel did no testing to ensure that the plastics Myers Industries told him contained the ECM additive was manufactured in strict accordance with the instructions for doing so given by ECM. (Michel, Tr. 2936).

2954. Dr. Michel did no testing to determine whether the ECM additive had been scorched by Myers during the manufacturing process of the plastic products purportedly amended with the ECM additive. (Michel, Tr. 2936).

2955. Dr. Michel did no testing of the test environment in his study to ensure that the inoculum contained microbes know to biodegrade plastics. (Michel, Tr. 2936).

2956. Dr. Michel performed no tests on the samples purporting to contain the ECM additive to determine whether any ingredient in the plastic had an adverse effect on microbial life forms in the environment. (Michel, Tr. 2938).

2957. Dr. Michel is not aware of whether or not Compost Science & Utilization Journal, which he edits, has a conflict of interest policy. (Michel, Tr. 2937).

2958. Dr. Michel is aware of the ethical standards that apply to peer-reviewed journal publications in his field. (Michel, Tr. 2939).

2959. Dr. Michel submitted his article to Elsevier for peer review publication. (Michel, Tr. 2940).

2960. When Dr. Michel submitted his study for publication, he submitted only the article itself and no other documentation such as the underlying data that the study was based on. (Michel, Tr. 2940).

2961. Elsevier based their decision to publish Dr. Michel's article solely on the text of the article and no underlying data. (Michel, Tr. 2940).

2962. The data underlying Dr. Michel's study was not the subject of peer review. (Michel, Tr. 2940).

2963. Myers Industries funded Dr. Michel's article. (Michel, Tr. 2941).

2964. Dr. Michel did not disclose to Elsevier that Myers funded his article. (Michel, Tr. 2942).

2965. Dr. Michel's article does not disclose the fact that Myers Industries funded the article. (Michel, Tr. 2942; CCX 880).

2966. Dr. Michel did not disclose the fact that Eddie Gomez, a co-author of Dr. Michel's article, was financially supported mostly by Myers' contributions to Ohio State University. (Michel, Tr. 2942).

2967. Dr. Michel's article does not disclose the fact that Myers' Industries supported Eddie Gomez, one of the co-authors of that article. (Michel, Tr. 2942; CCX 880).

2968. Under an agreement between Dr. Michel, Eddie Gomez, and Myers Industries, Dr. Michel could disseminate data obtained and used in the article only after revision by Myers Industries. (Michel, Tr. 2943–44; RX 223, at 15).

2969. Dr. Michel did not disclose to Elsevier the fact that dissemination of the data, which was funded by Myers Industries, could only occur after revision by Myers Industries. (Michel, Tr. 2944).

2970. At the hearing, Dr. Michel testified that Myers Industries did not approve his article before he sent it to Elsevier. (Michel, Tr. 2945–46).

2971. However, Eddie Gomez sent Dr. Michel's article directly to Myers Industries for approval before sending the article to Elsevier. (Michel, Tr. 2946–47; RX 244).

2972. Dr. Michel did not send his article to Elsevier until after Myers Industries approved the article. (Michel, Tr. 2947).

2973. Dr. Michel did not disclose the fact that Myers Industries approved the article before submitting it for peer review to either Elsevier or in the article itself. (Michel, Tr. 2947).

2974. Mr. Tarang Shah was an employee for Myers Industries at the time Dr. Michel conducted his studies for his article. (Michel, Tr. 2946–48).

2975. Eddie Gomez asked Tarang Shah whether he had any suggestions for conducting the research for Dr. Michel's article. (Michel, Tr. 2948).

2976. Dr. Michel failed to disclose the fact that Eddie Gomez asked a Myers Industries employee for suggestions regarding the article either to Elsevier or in the article itself. (Michel, Tr. 2948).

2977. Dr. Michel failed to disclose the fact that a Myers Industries employee worked with Mr. Gomez and Dr. Michel on the article to either Elsevier or in the article itself. (Michel, Tr. 2948).

2978. Elsevier probably directed Dr. Michel to review the terms and conditions for authoring articles in its publications. (Michel, Tr. 2949).

2979. Dr. Michel would expect that Elsevier, like most, if not all, reputable peer review publishers to have a conflict of interest policy. (Michel, Tr. 2949).

2980. According to Dr. Michel, if Elsevier did not have a conflicts of interest policy, that fact would call into question Elsevier's status as a reputable academic journal. (Michel, Tr. 2950).

2981. Dr. Michel is aware that reputable peer review publishers, like Elsevier, require disclosures of conflicts of interest. (Michel, Tr. 2950).

2982. Elsevier's conflicts of interest policy requires that all funding sources be declared. (Michel, Tr. 2951–52).

2983. Dr. Michel violated Elsevier's conflict of interest policy by failing to disclose the fact that Myers Industries provided funding for Dr. Michel's article. (Michel, Tr. 2941, 2951–52).

2984. It was so important to Dr. Michel that he and Eddie Gomez finish the report for Myers Industries on time that Dr. Michel actually told Eddie Gomez that he should drop a course he was taking so that he could complete the report in a timely manner. (Michel, Tr. 2953).

2985. Dr. Michel considers cellulose to be fully biodegradable. (Michel, Tr. 2954).

2986. In his article, Dr. Michel did not stop his biodegradation test at 365 days. (Michel, Tr. 2954–55).

2987. In his article, cellulose degraded roughly 74% in approximately 400 days. (Michel, Tr. 2955).

2988. According to Dr. Michel, if a positive control in a biodegradation test does not biodegrade, it indicates that the test environment failed. (Michel, Tr. 2959).

2989. According to Dr. Michel, a material that biodegrades only 44 percent to elements found in nature is biodegradable:

> Q. So then a material that only biodegrades 44 percent to elements found in nature is biodegradable; right?
>
> Dr. Michel: Yes.

(Michel, Tr. 2961).

2990. According to Dr. Michel, the fact that cellulose plateaued at 44 percent biodegradation in a test does not mean that the cellulose itself is not biodegrade. (Michel, Tr. 2961).

2991. Dr. Michel conducted no investigation of the inoculum used in his article to determine if the inoculum remained viable halfway through the test. (Michel, Tr. 2961–62).

2992. Dr. Michel conducted no investigation to determine why the cellulose in his test stopped degrading at roughly 74 percent. (Michel, Tr. 2962).

2993. Neither Dr. Michel's article nor rebuttal report informs the reader as to the molecular weight of the polypropylene employed in the article. (Michel, Tr. 2962; CCX 880; CCX 895 (Michel, Rebuttal Rep.)).

2994. Neither Dr. Michel's article nor rebuttal report informs the reader as to the molecular weight of the polystyrene employed in the article. (Michel, Tr. 2962; CCX 880; CCX 895 (Michel, Rebuttal Rep.)).

2995. Neither Dr. Michel's article nor rebuttal report informs the reader as to the level of crystallinity of the polypropylene or polystyrene that Dr. Michel employed in his article. (Michel, Tr. 2963; CCX 880; CCX 895 (Michel, Rebuttal Rep.)).

2996. Dr. Michel's article reveals no investigation to determine which kinds of bacteria were alive within the test environment at the conclusion of the test. (Michel, Tr. 2963).

2997. The only test of ECM amended plastic that Dr. Michel mentioned in his rebuttal report, besides the test he himself conducted, was an Environ BioPVC report. (Michel, Tr. 2965–66; CCX 895 (Michel, Rebuttal Rep.)).

2998. The Environ BioPVC report is not a gas evolution test. (Michel, Tr. 2965).

2999. Dr. Michel's rebuttal report does not contain any statistical analysis of any tests at issue in this case. (Michel, Tr. 2966; CCX 895 (Michel, Rebuttal Rep.).

3000. During his direct examination, Dr. Michel discussed polyethylene succinate. (Michel, Tr. 2968).

3001. In his rebuttal report, Dr. Michel does not mention polyethylene succinate. (Michel, Tr. 2968; CCX 895 (Michel, Rebuttal Rep.)).

3002. Dr. Michel provided no documentation other than a one page estimate that he himself drafted regarding the possibility of, and costs associated, with conducting C-14 radiolabeling testing on plastic polymers. (Michel, Tr. 2968–69; CCX 895 (Michel, Rebuttal Rep. at Appx. 2).

3003. While Dr. Michel testified that its possible to conduct radiolabeled testing on polymers, Dr. Michel never testified that the scientific community requires radiolabeled testing to conclude that polymers are biodegradable. (Michel, Tr. 2829–2998).

3004. The Court accepted ECM's offer of proof of Dr. Steven Grossman's testimony as RX 970, however RX 970 is a different exhibit; Dr. Grossman's proffer should be marked as RX 971. (Tr. 2821; JX-1-A).

RESPONDENT'S ECM BIOFILMS' PROPOSED CONCLUSIONS OF LAW

OVERVIEW OF APPLICABLE LAW

1. The FTC's authority to regulate false or misleading claims derives from the Federal Trade Commission Act ("FTC Act"). Section 5 of the FTC Act prohibits "unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45.

2. Complaint Counsel bears the burden of proving jurisdiction and liability by a preponderance of evidence. *In the Matter of POM Wonderful LLC*, 2012 WL 2340406, at *257 (F.T.C. May 17, 2012).

COMPLAINT COUNSEL HAVE FAILED TO SATISFY THEIR BURDEN OF PROVING THAT ECM VIOLATED THE FTC ACT

3. The parties' burdens in this proceeding are governed by Federal Trade Commission Rule 3.43(a), Section 556(d) of the APA, and case law.

Complaint Counsel Have Failed To Satisfy Their Burden Of Production

4. "The general provision regarding the burden of proof in administrative hearings is found in the Administrative Procedure Act (APA), 5 U.S.C. § 556(d): 'Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof.'" *State of Me. V. U.S. Dep't of Labor*, 669 F.2d 827, 829 (1st Cir. 1982) (*quoting* 5 U.S.C. § 556(d)).

5. The Court has clarified that the burden of proof in the APA context refers to both the burden of persuasion and burden of production. *San Miguel Hosp. v. N.L.R.B.*, 697 F.3d 1181, 1186 (D.C. Cir. 2012) (*citing Dir., Office of Workers' Compensation Programs, Dep't of Labor v. Greenwich Collieries*, 512 U.S. 267, 276 (1994)). "The burden of production is the obligation to come forward with evidence of a litigant's necessary

propositions of fact." *Chicago Bridge & Iron Co. N.V. v. F.T.C.*, 534 F.3d 410, 425 (D.C. Cir. 2008) (quotation omitted).

6. At a minimum, that burden requires the calling of fact witnesses sufficient to state a prima facie case of deceptive advertising under Section 5 of the FTC Act. *See, e.g.*, *Cooper v. Salazar*, 196 F.3d 809, 815 (7th Cir. 1999) (holding that an effective opportunity for cross-examination is required by the Due Process Clause where the ultimate decision necessarily requires important credibility determinations).

7. In FTC administrative proceedings wherein Complaint Counsel is the proponent of a proposed order, such as here, Complaint Counsel must first present sufficient evidence to support a finding in favor of Complaint Counsel. *See Creswell Trading Co. Inc. v. U.S.*, 15 F.3d 1054, 1060 (Fed. Cir. 1994) (noting that the "burden of production is initially upon the party who bears the ultimate burden of proof and generally requires that a party produce sufficient evidence to support a finding in favor of that party").

8. In this case, Complaint Counsel failed to satisfy its burden of production because, among other reasons, Complaint Counsel failed to present any evidence whatsoever that any consumer relied on any claim made by ECM when making a purchasing decision. In fact, Complaint Counsel has not provided any evidence that any consumer actually purchased any plastic containing the ECM additive. Complaint Counsel has further failed to provide any evidence showing that any consumer or entity was harmed as a result of any claim made by ECM.

ECM has Conducted no Advertising Material to a Purchase; Therefore, ECM has Made no Claims that are Actionable

9. The FTC defines advertisement "to mean a notice or announcement that is publicly published and is paid-for." *In the Matter of R.J. Reynolds Co., Inc.*, FTC Dkt. No. 9206, 1988 WL 490114, at *2 (Mar. 4 1988).

10. "Advertising is a form of promotion to anonymous recipients, as distinguished from face-to-face communication. In normal usage, an advertisement read by millions (or even thousands in a trade magazine) is advertising, while a person-to-person pitch by an account executive is not." *First Health Grp. Corp. v. BCE Emergis Corp.*, 269 F.3d 800, 803–04 (7th Cir. 2001).[1] Therefore, an in person statement by a company's sales team is not "advertising." *Zurich Ins. Co. v. Amcor Sunclipse N. Am.*, 241 F.3d 605, 607 (7th Cir. 2001). Likewise, statements by a company's executive made in person to other executives cannot be called "commercial advertising or promotion." *First Health*, 269 F.3d at 804. Similarly, in order to constitute "promotion," materials must be "disseminated sufficiently." *Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 735 (9th Cir. 1999); *Seven-Up Co. v. Coca-Cola Co.*, 86 F.3d 1379, 1384 (5th Cir. 1996) (same).

11. Under the legal definition of advertising, the material basis for sale of the ECM additive does not depend on advertising.

Complaint Counsel Have Failed To Satisfy Their Burden Of Proof

12. Pursuant to Commission Rule 3.43(a), "Counsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to

[1] Black's law definition defines an "advertisement" as "notice given in a manner designed to attract public attention."

sustain the burden of proof with respect thereto." 16 C.F.R. § 3.43(a); *see also* 5 U.S.C. § 556(d) (explaining that "the proponent of a rule or order has the burden of proof").

13. Regardless of the level of substantiation required, the FTC will bear the burden of proving advertising claims are false or misleading. *See Sterling Drug, Inc. v. F.T.C.*, 741 F.2d 1146, 1150 (9th Cir. 1984); *Porter & Dietsch, Inc. v. F.T.C.*, 605 F.2d 294, 305 (7th Cir. 1979); *F.T.C. v.* Garvey, 383 F.3d 891, 900 (9th Cir. 2004) ("we put the burden of proving falsity or deception on the FTC").

14. To prove that an advertisement is false or misleading, the FTC must show (1) the existence of a "representation, omission, or practice," that is (2) "likely to mislead consumers acting reasonably under the circumstances," and that 3) "the representation, omission, or practice is material." *F.T.C. v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 124 (D. Conn. 2008) (citation omitted).

15. The determination of whether challenged claims are false or misleading, begins with ascertainment of the level of substantiation Respondents are required to have for their advertising claims. Respondents have the burden of establishing what substantiation they relied on for their product claims. Complaint Counsel has the burden of proving that Respondents' purported substantiation is inadequate. *In the Matter of POM Wonderful LLC*, 2012 WL 2340406, at *259 (F.T.C. May 17, 2012).

16. An advertisement is deceptive under the FTC Act only if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect. *In the Matter of POM Wonderful LLC*, 2012 WL 2340406, at *258 (F.T.C. May 17, 2012).

17. "The Commission shall have no authority under this section or section 57a of this title to declare unlawful an act or practice on the grounds that such act or practice is unfair

unless the act or practice causes or is likely to cause substantial injury to ***consumers*** which is not reasonably avoidable by consumers themselves and **not outweighed by countervailing benefits to consumers or to competition**. In determining whether an act or practice is unfair, the Commission may consider established public policies as evidence to be considered with all other evidence. Such public policy considerations may not serve as a primary basis for such determination." 15 U.S.C. § 45 (emphasis added).

18. A consumer is defined as "an individual" or a "natural person." 15 U.S.C. §§ 1681a, 1693a, 6603, 1679a. In order to be considered a "consumer," the individual or natural person must "obtain, through a transaction, products or services which are used primarily for personal, family, or household purposes." 15 U.S.C. § 7006; 52 U.S.C. § 3501. In other words, "consumer" means "a buyer (other than for purposes of resale) of any consumer product, any person to whom such product is transferred during the duration of an implied or written warranty (or service contract) applicable to the product, and any other person who is entitled by the terms of such warranty (or service contract) or under applicable State law to enforce against the warrantor (or service contractor) the obligations of the warranty (or service contract)." 15 U.S.C. § 2301. Similarly, a consumer means a natural person who uses products for personal rather than business purposes. 40 C.F.R. § 721.8100; 15 C.F.R. § 16.3. A retailer buying consumer products for resale from the manufacturer is not within the definition of "consumer." *Black v. Don Schmid Motor, Inc.*, Kan.1983, 657 P.2d 517, 232 (Kan. 1983). Consumer cannot include any person "operating as a manufacturer, distributor, wholesaler, or retailer…" 15 U.S.C. § 375. A consumer product

19. "Two theories have been used to prove that an advertisement is deceptive or misleading: (1) the 'falsity' theory or (2) the 'reasonable basis' theory." *In the Matter of Pom Wonderful LLC*, 9344, 2012 WL 2340406 (F.T.C. May 17, 2012) (at 234) (citing *Pantron I*, 33 F.3d at 1096).

20. Where the "issue of whether Respondents' claims were deceptive turns on the nature and quality of Respondents' substantiation … the falsity and reasonable basis theories collapse into the same inquiry: did [Respondents] possess adequate substantiation to make such a claim?" *Id.* (quoting *FTC v. QT, Inc.*, 448 F.Supp. 2d 908, 966 (N.D. Ill. 2006)).

21. Proof of deception requires an analysis of the evidence as follows:

> [T]he Court must first determine what level of substantiation Defendants were required to have for their advertising claims, and this determination is a question of fact. Then, the Court must determine whether the Defendants possessed that level of substantiation … Defendants have the burden of establishing what substantiation they relied on for their product claims. The FTC has the burden of proving that the Defendants' purported substantiation is inadequate…

22. *FTC v. QT, Inc.*, 448 F. Supp. 2d at 959 (citations omitted). For efficacy claims, the Commission must determine the level of substantiation by applying the *Pfizer* factors. *In re Pfizer, Inc.*, 81 F.T.C. 23 (July 11, 1972).

23. Complaint Counsel must prove each element of its case by a preponderance of the evidence. *See, e.g.*, *In re Adventist Health Sys./West*, 117 F.T.C. 224, 297 (Apr. 1, 1994) (explaining that "[e]ach element of the case must be established by a preponderance of the evidence"); *see also In the Matter of POM Wonderful, LLC*, 2012 WL 2340406, at *171 (F.T.C. May 17, 2012) (noting that "Complaint Counsel has the burden of proving each of the foregoing factual issues by a preponderance of credible evidence").

24. "The burden of showing something by a 'preponderance of the evidence' … requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before he may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Concrete Pipe & Prods., Inc. v. Construction Laborers Pension Trust*, 508 U.S. 602, 622 (1993) (internal quotations and citations omitted).

25. Complaint Counsel has the burden of proving by a preponderance of credible evidence that ECM made the alleged claims in the challenged advertising and did not have a reasonable basis for such claims. *In the Matter of Bristol-Myers Co.*, 102 F.T.C. 21, 1983 FTC LEXIS 64, at *143 (requiring proof by "preponderance of credible evidence"); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 959 (N.D. Ill. 2006) (holding that to prevail on a reasonable basis theory, the FTC must prove that the advertiser lacked a reasonable basis for asserting the challenged claim, that the advertiser has the burden of establishing the substantiation it relied on for its claim, and that the FTC has the burden of proving the advertiser's substantiation is inadequate), *aff'd* 512 F.3d 858 (7th Cir. 2008).

Complaint Counsel Failed to Satisfy Their Burden that ECM Made an Implied Claim that Plastic Containing the ECM Additive Will Decompose Into Elements Found in Nature Within One Year of Customary Disposal

26. An advertisement is deemed to convey a claim if a significant minority of reasonable consumers would find the advertisement to contain that message. Whether an advertisement conveys a claim is a question of fact. *In the Matter of POM Wonderful LLC*, 2012 WL 2340406, at *257 (F.T.C. May 17, 2012).

27. To determine whether an advertisement conveys an alleged claim, the first step is to examine the advertisement itself (a "facial analysis"). A proper facial analysis requires an evaluation of such factors as the entire document, the juxtaposition of various phrases in

the document, the nature of the claim, and the nature of the transaction. *In the Matter of POM Wonderful LLC*, 2012 WL 2340406, at *257 (F.T.C. May 17, 2012).

28. "[I]n determining what claims are conveyed by a challenged advertisement, the Commission relies on two sources of information: its own viewing of the ad and extrinsic evidence. Its practice is to view the ad first and, if it is unable on its own to determine with confidence what claims are conveyed in a challenged ad, to turn to extrinsic evidence." *Kraft, Inc. v. F.T.C.*, 970 F.2d 311, 318 (7th Cir. 1992).

29. If, after viewing the advertisement as a whole, examining the interaction of all the different elements in the advertisement, it can be concluded with confidence that an advertisement can reasonably be read to contain a particular claim, a facial analysis is a sufficient basis to conclude that the advertisement conveys the claim. However, an implied claim must be reasonably clear or conspicuous from the face of the advertisement. *In the Matter of POM Wonderful LLC*, 2012 WL 2340406, at *257 (F.T.C. May 17, 2012).

30. If, after a facial analysis, it cannot be concluded with confidence that a particular advertisement can reasonably be read to contain a particular implied message, the advertisement will not be deemed to have made the alleged claim unless extrinsic evidence supports the conclusion that such a reading of the advertisement is reasonable. *In the Matter of POM Wonderful LLC*, 2012 WL 2340406, at *257 (F.T.C. May 17, 2012).

31. The FTC must use extrinsic evidence to determine what the claim implies when the claim is not "reasonably clear from the face of the advertisement." *F.T.C. v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 126 (D. Conn. 2008). And as another case clarified, "if the

language or graphic is susceptible to more than one reasonable interpretation . . . the district court must look to consumer data to determine what the person to whom the advertisement is addressed finds to be the message." *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007).

32. A facial analysis of the claim "biodegradable" does not reasonably lead to the conclusion that the term "biodegradable" implies decomposition into elements found in nature within one year after customary disposal.

33. Complaint Counsel does not contend that ECM made any express claim that plastic containing the ECM additive will decompose into elements found in nature within one year after customary disposal. Furthermore, it is not "conspicuous and 'reasonably clear from the face of the advertisements[2]'" that the naked claim of "biodegradable" on a product implies that the product will decompose into elements found in nature within one year of customary disposal. *See F.T.C. v. QT, Inc.*, 448 F. Supp. 2d 908, 958 (N.D. Ill. 2006) (*quoting Kraft, Inc. v. F.T.C.*, 970 F.2d 311, 320 (7th Cir. 1992)). Therefore, Complaint Counsel must present extrinsic evidence that provides proof by a preponderance of the evidence that a significant minority of consumers, *Kraft*, 114 F.T.C. at 60, understand the term "biodegradable" on a plastic product to mean that the product will decompose into elements found in nature within one year after customary disposal. *F.T.C. v. Bronson Partners, LLC*, 564 F, Supp. 2d 119, 127 (D. Conn. 2008) (*citing In the Matter of Thompson Med. Co., Inc.*, 104 F.T.C. 648 (1984) (explaining that, under *Kraft* and its progeny, the FTC requires extrinsic evidence "if its initial review of evidence from the advertisement itself does not allow the FTC to conclude with

[2] Assuming *arguendo* that ECM has made any "advertisement."

confidence that it is reasonable to read an advertisement as containing a particular implied message").

The Extrinsic Evidence Disproves the Notion that Consumers Interpret the Word "Biodegradable" to Mean Decompose into Elements Found in Nature Within One Year of Customary Disposal

34. Express claims unequivocally state the representation at issue. No further proof about the meaning of an express claim is necessary because the express claim itself is explicitly stated. *See* FTC Deception Policy Statement, appended to *Cliffdale Assocs., Inc.*, 103 F.T.C. at 176; *Thompson Medical Co.*, 104 F.T.C. at 788.

35. Implied claims are any claims that are not express. *See In the Matter of Kraft, Inc.*, 114 F.T.C. 40, 120 (1991). Because implied claims are not stated explicitly, Complaint Counsel must prove that they are conveyed to a significant minority of reasonable consumers. *Id.*

36. When an implied claim is at issue, "[t]he Commission will carefully consider any extrinsic evidence that is introduced, taking into account the quality and reliability of the evidence." *In re Stouffer Foods Corp.*, 118 F.T.C. 746, 799 (Sept. 26, 1994). Such extrinsic evidence includes "reliable results from **methodologically sound consumer surveys.**" *Id.* (emphasis added). In weighing survey evidence, the Commission "looks to whether such evidence is reasonably reliable and probative. Flaws in the methodology may affect the weight that is given to the results of the copy test or other consumer survey." *Id.* (citation omitted).

37. Extrinsic evidence includes survey results and other evidence governing how consumers may have perceived certain claims. *Kraft*, 114 F.T.C. at 121. The Commission can look at:

> evidence not specifically showing how consumers understood the advertisements at issue before us, but showing how consumers might ordinarily be expected to perceive or understand representations like those contained in the ads we are reviewing. For example, we might look at the dictionary definition of a word to identify the word's common usages. Or we might look at principles derived from market research, as expressed by marketing experts, which show that consumers generally respond in a certain manner to ads that are presented in a particular way, and presume that consumer reactions to a particular ad before us would be consistent with the general response pattern. Where we apply such marketing principles, we will derive them from research presented in references generally accepted as reliable in the field of marketing. Such references may be cited by marketing experts called to testify in the proceeding.

In the Matter of Thompson Med. Co., Inc., 104 F.T.C. 648 (1984).

38. Implied claims may only be found where it is determined with confidence, after examining all of the constituent elements of the advertising, that the challenged claims are conspicuous, self-evident, or reasonably clear on the face of the ad. *Stouffer*, 118 F.T.C. at 777 (citing *Kraft*, 970 F.2d at 318); *Thompson Medical*, 104 F.T.C. at 320.

This Court Must Interpret ECM's Claims, Both Implied and Express, through the Perspective of the Target Audience for Those Claims—Sophisticated Plastic Manufacturers

39. "Target audiences," for purposes of interpreting advertising, refer to special audiences who as a group have a greater or lesser capability to recognize deceptive advertising than ordinary members of the adult population or have a distinctive reaction to particular advertising claims. *In the Matter of POM Wonderful LLC*, 2012 WL 2340406, at *259 (F.T.C. May 17, 2012).

40. "In reviewing allegedly false and misleading statements, courts are to read the statements in their entirety and in context to determine whether they are actionable." *Schering-*

Plough Healthcare Prods., Inc. v. Schwartz Pharma, Inc., 547 F. Supp. 2d 939, 943 (E.D. Wisc. 2008) (citing *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir 1997) ("[w]hen evaluating whether an advertising claim is literally false, the claim must always be analyzed in its full context")); *Castrol, Inc. v. Pennzoil Co.*, 987 F.2d 939, 946 (3d Cir. 1993) ("in assessing whether an advertisement is literally false, a court must analyze the message conveyed in full context"); *Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc.*, 388 F.Supp.2d 967, 976 (E.D. Wis. 2005) ("To determine whether a particular representation is literally false, it must be analyzed with its full context")). "In addition, the specific audience is part of the context that must be considered in deciding whether a statement is literally false." *Id.*

41. "Context can often be important in discerning the message conveyed and **this is particularly true where, as here, the target of the advertising is not the consuming public but a more well informed and sophisticated audience.**" *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 229 (3d Cir. 1990) (emphasis added) (citation and internal quotation marks omitted); *see also DeSena v. Beekley Corp.*, 729 F. Supp. 2d 375, 393 (D. Me. 2010) ("A target audience's special knowledge of a class of products is highly relevant to any claim that it was misled by an advertisement for such a product").

42. Similarly, "[w]hen the practice [at issue] is targeted to a sophisticated purchaser, the question of whether it is misleading to the public will be viewed from the vantage point of members of the targeted group, not others to whom it is not primarily directed." *Ariz. Cartridge Remanufacturers Assoc., Inc. v. Lexmark Int'l, Inc.*, 290 F. Supp. 2d 1034, 1041 (N.D. Cal. 2003).

ECM's Claims Could Not Have Misled Because ECM's Customers Are Sophisticated Plastic Manufacturers Who Evaluated the ECM Product Before Purchase

43. In business transactions, when the selling company provides the purchasing company with specifications or data, such transactions are "classified as sophisticated." *John Crane Prod. Solutions, Inc. v. R2R and D, LLC*, 861 F. Supp. 2d 792, 799 (N.D. Tex. 2012).

44. Even if "a company's engineers may be distinct from the employees who purchased the [product] . . . [s]uch business transactions are at least as complex as transactions that other courts have classified as sophisticated." *John Crane Prod. Solutions, Inc. v. R2R and D, LLC*, 861 F. Supp. 2d 792, 799 (N.D. Tex. 2012).

45. There is less likelihood of confusion when the parties to a business transaction "have a close working relationship." *Id.* at 801. In fact, "[c]ourts have found that the sophistication of the potential purchasers alone is enough to find that there is no likelihood of confusion even when all of the other digits [in the trademark context] weigh in favor of such a finding. *See, e.g., Perini Corp. v. Perini Constr.*, 915 F.2d 121, 128 (4th Cir.1990) (reversing summary judgment because district court did not consider how sophistication of purchasers of construction services affected analysis, even though all other digits weighed in favor of finding likelihood of confusion)." *Id.* at n. 16.

46. Courts have classified transactions and purchasers as sophisticated in a number of contexts. *See, e.g., Checkpoint Sys., Inc. v. Check Point Software Tech.*, 269 F.3d 270, 285 (3d Cir.2001) (holding that purchasers of retail store security equipment and computer security software were sophisticated); *Rust Env't & Infrastructure, Inc. v. Teunissen*, 131 F.3d 1210, 1217 (7th Cir. 1997) (holding that purchasers of services from engineering consulting firms were sophisticated); *Oreck v. U.S. Floor Sys., Inc.*, 803 F.2d

166, 173 (5th Cir. 1986) ("because these persons are buying [vacuums and extraction machines] for professional and institutional purposes at a cost in the thousands of dollars, they are virtually certain to be informed, deliberative buyers"); *Armstrong Cork Co. v. World Carpets, Inc.*, 597 F.2d 496, 504 n. 10 (5th Cir. 1979) ("a person buying a 'big ticket' item such as carpeting would ordinarily be expected to be a more careful buyer than the impulse purchaser or the purchaser of a relatively inexpensive item").

47. In order to succeed in a fraud action, a challenger must establish that he or she reasonably relied on the alleged material representation. *Terra Sec. Asa Konkursbo v. Citigroup, Inc.*, 740 F. Supp. 441, 448 (S.D.N.Y. 2010). "In assessing the reasonableness of a plaintiff's alleged reliance, [courts] consider the entire context of the transaction, including factors such as its complexity and magnitude, the sophistication of the parties, and the content of any agreements between them." *Emergent Capital Inv. Mgmt., LLC v. Stonepath Grp., Inc.*, 343 F.3d 189, 195 (2d Cir. 2003). For example, [s]ophisticated investors must investigate the information available to them with the care and prudence expected from people with full access to information." *Terra*, 740 F. Supp. 2d at 448 (citing *Hirsch v. du Pont*, 553 F.2d 750, 763 (2d Cir. 1977)); *see also Banque Franco–Hellenique de Commerce Int'l., et Maritime, S.A. v. Christophides*, 106 F.3d 22, 27 (2d Cir. 1997) (finding that analysis of reasonable reliance in fraud cases "has taken account of the degree to which the truth was accessible to the defrauded person"). The rationale being that the informed or sophisticated entity has the wherewithal to determine whether claims are supported and, so, the need to protect those sophisticated "consumers" is lessened.

48. Other courts outside of the Second Circuit have similar requirements to determine whether sophisticated purchasers reasonably relied on misrepresentations. *See, e.g.*, *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 767–68 (7th Cir. 2010) (finding that the plaintiff's alleged reliance was unreasonable where "two sophisticated businesses negotiated an arms-length transaction of a period of several months"); *Tom Hughes Marine, Inc. v. Am. Honda Motor Co., Inc.*, 219 F.3d 321, 324 (4th Cir. 2000) (affirming decision that reasoned that the plaintiff was "a sophisticated businessman … and he [was] unable to establish that he had a right to rely on [the defendant's] representation or that he justifiably relied upon it"); *Gilchrist Timber Co. v. ITT Rayonier, Inc.*, 95 F.3d 1033, 1035 (11th Cir. 1996) (collecting cases supporting the proposition that a fraud claim is not actionable where "the parties are equally sophisticated, and have an equal opportunity to discover a defect"); *Cheney Bros., Inc. v Batesville Casket Co., Inc.*, 47 F.3d 111, 114 (4th Cir. 1995) (citation omitted) (holding that "there is no right to rely, as required to establish fraud, where there is no confidential or fiduciary relationship, and there is an arm's length transaction between mature, educated people"); *Kline v. First Western Gov't Sec., Inc.*, 24 F.3d 480, 497–98 (3d Cir. 1994) (holding that the "investor could not justifiably rely on representations" where the transaction "was on the cutting edge of strategic planning"); *Roberts v. United N. Mex. bank at Roswell*, 14 F.3d 1076, 1080 at n. 4 (5th Cir. 1994) (internal quotations and citations omitted) ("If an investor is sufficiently sophisticated and experienced, that may be evidence that he did not rely on the seller's representations but on his own expertise."); *Davidson v. Wilson*, 973 F.2d 1391, 1399 (8th Cir. 1992) (noting that the "sophisticated investors should have been on notice not to rely upon those representations"); *Skeen v. C.I.R.*, 864 F.2d 93, 95 (9th Cir.

1989) (explaining that where the plaintiffs "are all sophisticated businessmen," the court "simply do[es] not believe that they would enter into profit-motivated transactions with an unknown party and rely solely on the representations of such part with respect to the most crucial aspect affecting the viability of the proposed venture").

49. In the trademark context, courts find that there is a reduced likelihood that a sophisticated party, as opposed to an unsophisticated party, will be influenced by a similar mark in an advertisement. *See, e.g.*, *Mead Data Dent., Inc. v. Toyota Motor Sales, U.S.A., Inc.*, 875 F.2d 1026, 1031–32 (2d Cir. 1989). "The degree of consumer care and sophistication can be proven by survey evidence, expert testimony, or inference." *Marketquest Grp., Inc. v. BIC Corp.*, 2011 WL 5360899, at *12 (S.D. Cal. Nov. 7, 2011) (citation omitted) (finding that the buyers were likely to be sophisticated because they were institutional buyers placing bulk orders and because the marketing materials "appear to be aimed at institutional purchasers").

50. The issue in *Mead* was whether the use of the term "Lexus" used by Toyota Motors would dilute the profitability of the term "Lexis" as used by Mead. *Mead*, 875 F.2d at 1027. The Second Circuit explicitly made clear that "the recognized sophistication of attorneys, the principal users of [Lexis], has *substantial relevance*." *Id.* at 1031 (emphasis added). Given the fact that Lexis' users were principally sophisticated attorneys, the court concluded that there would not "be any significant amount of blurring between the LEXIS and LEXUS marks." *Id.* at 1032.

51. In *Mead*, the court did not evaluate each individual attorney's level of sophistication to ensure that each attorney was capable him or herself of differentiating between Lexus and Lexis. Rather, the court found that the mere fact that Mead's customers were attorneys

had substantial relevance. Likewise, need not evaluate each of ECM's customers to determine how sophisticated each is. Rather, the fact that the customers are plastic manufacturers has substantial relevance when determining whether any customer can possibly be misled when purchasing a product to be used for commercial purposes during the plastic manufacturing process.

52. Numerous additional courts likewise find that purchasers are less likely to be confused when they are sophisticated, technical, experienced, retailers, or otherwise involved in the industry or have any relevant knowledge. *See, e.g.*, *In re Synthroid Mktg. Litig.*, 264 F.3d 712, 717 (7th Cir. 2001) (noting that "[u]nlike members of the consumers class, [third party payors] are sophisticated purchasers"); *Interstellar Starship Servs., Ltd. v. Epix Inc.*, 184 F.3d 1107, 1110 (9th Cir. 1999) (citation omitted) (holding that confusion is less likely where the "customers are sophisticated industry and university researchers" and where the "goods cost in the range of several thousand to tens of thousands of dollars"); *Homeowners Grp., Inc. v. Home Mktg. Specialists, Inc.*, 931 F.2d 1100, 1111 (6th Cir. 1991) ("A sophisticated purchaser exercises a high degree of care and is less likely to be confused as to a product's origin."); *Pride Family Brands, Inc. v. Carl's Patio, Inc.*, 992 F. Supp. 2d 1214, 1222 (S.D. Fla. 2014) (noting that "[as] industry participants, retailers are a sophisticated customer base"); *Acxiom Corp. v. Axiom, Inc.*, 27 F. Supp. 2d 478, 497 (D. Del. 1998) (citations omitted) (explaining that "courts recognize that generally" when a seller "sell[s] relatively expensive products and services to sophisticated and knowledgeable purchasers that typically involve relatively long sales cycles . . . these factors indicate that great care, effort, and attention go into the purchase decision making which lessens likelihood of confusion."); *Giorgio Beverly Hills, Inc. v. Revlon Consumer*

Prods. Corp., 869 F. Supp. 176, 185 (S.D.N.Y. 1994) (citation omitted) (explaining that "[t]he more sophisticated the ordinary purchaser of a product is, the less likely it is that the use of similar marks or trade dress will lead to confusion" and holding that "women tend to be sophisticated purchasers of perfume"); *Marketquest*, 2011 WL5360899, at *11 (noting that "experienced industry distributors or agents [] are likely to be sophisticated consumers and investigate any potential confusion"); *In re Trans Union Corp. Privacy Litig.*, 2009 WL 4799954, at *11 (N.D. Ill. Dec. 9, 2009) (noting that insurance companies are sophisticated purchasers of legal services).

53. Like in the trademark context, parties are held to different levels of duty of disclosure when conducting business with sophisticated purchasers as opposed to the general public. For example, a purchaser is under no duty to disclose the financial conditions of its business when "the parties are represented by sophisticated businessmen, who are active and experienced in the area, and are dealing at arm's length without any fiduciary or confidential relationships or expectations." *Nationwide Book Indus., LLC v. A & S Booksellers, Inc.*, 950 F. Supp. 2d 264, 267 (D. Mass. 2013) (citations and quotations omitted).

54. Similarly, in the securities context, securities issuers must disclose significantly more information when making public offering as opposed to selling the securities only to sophisticated qualified institutional buyers. *Gustafson v. Alloyd Co.*, 513 U.S. 561, 569 (1995) (citing 15 U.S.C. §§ 77b(11), 77d, 77e) ("By and large, only public offerings by an issuer of a security, or by controlling shareholders of an issuer, require the preparation and filing of registration statements."). This is because the sophisticated purchaser, capable of fending for itself and determining the benefits and costs of entering a business

transaction, are held liable for their own decisions. *See, e.g.*, *Miller v. Berman*, 289 F. Supp. 2d 1327, 1334 (M.D. Fla. 2003) ("Surely, as a sophisticated boat and sail maker, Mr. Miller relied on his own expertise in deciding to enter into a contract for the purchase of a highly customized catamaran boat with Cougar Marine").

55. ECM representations are targeted to plastic manufacturers. The plastic manufacturers, unlike consumers, are sophisticated buyers who technically evaluated samples of the ECM additive with the aid of scientists, engineers, lawyers, and marketers before purchasing it for infusion into their plastics and spent six months to two years performing an assessment. Based on that sophistication, they may be presumed impervious to deception related to the characteristics of biodegradability of the ECM plastic. *Perini Corp.*, 915 F.2d at 128; *Checkpoint Sys.*, 269 F.3d at 285; *Oreck*, 803 F.2d at 173; *Armstrong Cork*, 597 F.2d at 504 n. 10; *Metavante Corp.*, 619 F.3d at 767–68; *Tom Hughes*, 219 F.3d at 324; *Gilchrist Timber*, 95 F.3d at 1035; *Cheney Bros.*, 47 F.3d at 114; *Roberts*, 14 F.3d at 1080 n. 4; *Davidson*, 973 F.2d at 1399; *Skeen*, 864 F.2d at 95; *Mead*, 875 F.2d at 1031–32; *Synthroid Mktg.*, 264 F.3d at 717; *Interstellar Starship*, 184 F.3d at 1110; *Homeowners Grp.*, 931 F.2d at 1111; *Pride Family*, 992 F. Supp. 2d at 1222; *Acxiom Corp.*, 27 F. Supp. 2d at 497; *Giorgio Beverly Hills*, 869 F. Supp. at 185; *Miller*, 289 F. Supp. 2d at 1334; *Marketquest*, 2011 WL 5360899, at *12; *In re Trans Union*, 2009 WL 4799954, at *11.

56. A manufacturer's duty to warn of dangers in the products liability context is "precluded in situations where the purchaser has particular knowledge of or experience with the inherent dangers in the use of a product or in instances when the purchaser has designed and requested a product for a particular application." *Byrd v. Hunt Tool Shipyards*, 650

F.2d 44, 47 at n. 1 (5th Cir. 1981); *see also O'Neal v. Celanese Corp.*, 10 F.3d 249, 252 (4th Cir. 1993) ("The [sophisticated purchaser] defense is available not only when the supplier actually warned the intermediary, but also when the supplier shows that it was reasonable to believe that a warning was unnecessary because the intermediary was already well aware of the danger"); *Goodbar v. Whitehead Bros*., 591 F. Supp. 552, 561 (W.D. Va. 1984) ("Stated another way, when the supplier has reason to believe that the purchaser of the product will recognize the dangers associated with the product, no warnings are mandated"). This rule of law is known as the "sophisticated purchaser defense" which is "based upon the principles set forth in the Restatement (Second) of Torts." *Akin v. Ashland Chem. Co.*, 156 F.3d 1030, 1037 (10th Cir. 1998). "This exception absolves suppliers of the duty to warn purchasers who are already aware or should be aware of the potential dangers." *Id.* (citing *O'Neal*, 10 F.3d 249, 251–52 (4th Cir. 1993); *Davis v. Avondale Indus.*, 975 F.2d 169, 171 (5th Cir. 1992)).

57. Indeed, in certain situations, a "manufacturer [may] reasonably [] rely on an intermediary purchaser to warn ultimate users of dangers associated with the use of a product." *Baker v. Monsanto Co.*, 962 F. Supp. 1143, 1151 (S.D. Ind. 1997). Such a situation arises where "it would be impossible for a manufacturer to access all ultimate users of a product because it had no control over the site of usage." *Id.*

58. Because ECM's customers were aware of the dangers associated with selling a "biodegradable" product, ECM had no duty to the end use consumer. *Akin*, 156 F.3d at 1037; *O'Neal*, 10 F.3d at 251–52; *Davis* 975 F.2d at 171. This is particularly true where, as here, ECM's customer audience was free and able to test the products themselves,

consult with legal counsel, and where ECM does not have access to all ultimate users of a product and has no control over the usage of its product. *Baker*, 962 F. Supp. at 1151.

Complaint Counsel Did Not Satisfy their Burden that ECM's Claims Regarding Rate of Biodegradation, Whether Express or Implied (if made at all), were Material to Either ECM's Customers or to Consumers

59. The FTC must also establish materiality of a misleading claim in order to prevail. "A 'material' misrepresentation is one that involves information that is important to consumers, and is therefore likely to affect a consumer's choice of or conduct regarding a product." *F.T.C. v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 135 (D. Conn. 2008) (quoting *In Re Kraft, Inc.*, 114 F.T.C. 40 (1991)); *see also FTC Policy Statement on Deception*, Federal Trade Commission (1983)).

60. In order to determine whether an advertisement is material, "[t]he basic question is whether the act or practice is likely to affect the consumer's conduct or decision with regard to a product or service." *Cliffdale Assocs., Inc.*, 103 F.T.C. 110, at 45 (1984)). "In other words, [information that is material] is information that is important to consumers." *Id*. at 49. "A claim is considered material if it involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding a product." *Kraft, Inc. v. F.T.C.*, 970 F.2d 311, 322 (7th Cir. 1992) (internal quotations and citations omitted); *see also F.T.C. v. Colgate-Palmolive Co.*, 380 U.S. 374, 391 (1965) (citing *F.T.C. v. Raladam Co.*, 316 U.S. 149, 152 (1942)) ("when the Commission finds deception it is also authorized, within the bounds of reason, to infer that the deception will constitute a material factor in a purchaser's decision to buy").

61. The FTC applies a presumption of materiality to "(1) express claims; (2) implied claims where there is evidence that the seller intended to make the claim; and (3) claims that

significantly involve health, safety, or other areas with which reasonable consumers would be concerned." *Id.* The first situation applies "[w]here the seller knew, or should have known, that an ordinary consumer would need omitted information to evaluate the product or service, or that the claim was false," and, in such a circumstance, "materiality will be presumed because the manufacturer intended the information or omission to have an effect." *Cliffdale*, 103 F.T.C. 110, *49. The second situation applies "when evidence exists that a seller intended to make an implied, the commission will infer materiality." *Id.* The third situation can apply when the advertisement concerns information that "pertain[s] to the central characteristics of the product or service." *Id.*

62. "A representation is material if likely relied upon by a reasonable prospective purchaser." *F.T.C. v. Wash Data Ress.*, 856 F. Supp. 2d 1247, 1272 (M.D. Fla. 2010). Importantly, "[r]ather than an isolated word, phrase, or sentence, the representations net impression controls." *Id.* at 1272 (citations omitted). "What is important in determining whether a statement is misleading is the over-all impression it tends to create on the public." *Country Tweeds, Inc. v. F.T.C.*, 326 F.2d 144, 148 (2d Cir. 1964) (citing *Murray Space Shoe Corp. v. F.T.C.*, 304 F.2d 270 (2d Cir. 1956)).

63. A respondent can counter a presumption of materiality with extrinsic evidence. *See In the Matter of Pom Wonderful LLC*, 2012 WL 2340406 (F.T.C. May 17, 2012). As explained in *POM Wonderful* and *Novartis*:

> Respondent can present evidence that tends to disprove the predicate fact from which the presumption springs (*e.g.*, that the claim did *not* involve a health issue) or evidence directly contradicting the initial presumption of materiality. This is not a high hurdle. Unless the rebuttal evidence is so strong that the fact finder could not reasonably find materiality, the fact finder next proceeds to weigh all of the evidence presented by the parties on the issue. *See id.* at 516 (noting that after the presumption drops

> out, "the inquiry ... turns from the few generalized factors that establish [the presumption] to the specific proofs and rebuttals ... the parties have introduced").

Id. at *235.

64. "Materiality turns upon whether those consumers who have drawn the claim from the advertisement and have been misled by it are also **likely to have their conduct affected by the misrepresentation**." *In re Novartis Corp.*, 127 F.T.C. 580, 691 (1999) (emphasis added).

The *Pfizer* Factors Demonstrate That Biodegradable Claims Need Not Meet a High Standard of Competent and Reliable Evidence

65. The FTC has the burden of showing that a particular claim was made without a reasonable basis. *See FTC v. Braswell*, 2005 WL 4227194 (C.D. Cal. Sept. 27, 2005); *F.T.C. v. Medlab, Inc.*, 615 F. Supp. 2d 1068, 1079 (N.D. Cal. 2009); *FTC v. Pantron I Corp*., 33 F.3d 1088, 1096 (9th Cir.1994). In order to have a reasonable basis to make the claim at issue, an advertiser must possess "competent and reliable scientific evidence" to substantiate that claim. *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 1156–57 (9th Cir.1984).

66. The FTC has not defined what constitutes "competent and reliable scientific evidence" in the context of biodegradable advertising. The FTC is using this litigation to define what competent and reliable scientific evidence is in the context of biodegradable advertising. Consistent with precedent, FTC may not set a high reasonable basis standard comparable to that applied in the drug context in the absence of evidence that the claim affects human health. *Thompson*, 104 F.T.C. 648, at ¶¶ 71–72; *see also POM*, 2013 WL 268926, at *48 (noting that the respondents "made claims regarding serious diseases"); *In the Matter of Removatron Int'l Corp.*, 111 F.T.C. 206, at *14 n. 20 (Nov. 4, 1988) (noting that a drug

or product that directly affects human safety requires more substantiation). Rather, the FTC must look to what the industry accepts as a reasonable basis of proof in support of the claim. *F.T.C. v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1190 (N.D. Ga. 2008) (quotation omitted) ("the FTC has defined competent and reliable scientific evidence as tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures **generally accepted in the profession** to yield accurate and reliable results") (emphasis added).

67. Fully protected speech of a technical or scientific nature may not be subjected to cease and desist orders or limitations on the prospective right to communicate unless the FTC possesses a compelling state interest, a means that is narrowly tailored to achieve the interest, and proof that its chosen means is the least restrictive alternative. *See, e.g.*, *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310, 340 (2010); *Am. Civil Liberties Union v. Reno*, 31 F. Supp. 2d 473, 493 (E.D. Pa. 1999). On this record, the FTC goal of eliminating consumer deception is not served through imposition of a cease and desist order that has the effect of burdening the right of ECM or the ability of ECM to communicate that its additive is biodegradable. *C.f. Am. Civil Liberties Union v. Mukasey*, 534 F.3d 181, 204 (3d Cir. 2008) (holding that the Child Online Protection Act (COPA), which criminalized transmission over the Internet, for commercial purposes, of material "harmful to minors," was not least restrictive alternative to advance government's compelling interest in protecting minors from exposure to sexually explicit material because available filtering technology, which Congress could promote and

support in place of COPA, was more effective at blocking sexually explicit material, and unlike COPA, did not chill speech).

68. Commercial speech is speech involving an offer for sale of a product. *United States v. United Foods, Inc.*, 533 U.S. 405, 409 (2001); *Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 473–74 (1989); *Hunt v. City of L.A.*, 638 F.3d 703, 715 (9th Cir. 2011).

69. "The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading, or that proposes an illegal transaction. Commercial speech that is not false or deceptive and does not concern unlawful activities, however, may be restricted only in the service of a substantial governmental interest, and only through means that directly advance that interest." *Zauderer v. Office of Disciplinary Counsel of Supreme Ct. of Ohio*, 471 U.S. 626, 637 (1985) (citing *Central Hudson*, 447 U.S. at 566) (other internal citations omitted).

70. "[C]ommercial speech is . . . constitutionally protected so long as it concerns lawful activity and is not misleading. . ." *Kiser v. Reitz*, 13-3956, 2014 WL 4211193 (6th Cir. Aug. 27, 2014).

71. The government may not prospectively impose limitations or burdens on the right to communicate speech by requiring excessively high levels of supporting scientific evidence, and a claim may not be barred "simply because the scientific literature is inconclusive." *Pearson v. Thompson*, 141 F. Supp. 2d 105, 110 (D.D.C. 2001). In addition, even if some studies show efficacy, the fact that other studies produce no such result does not justify suppression of that information. *See Whitaker v. Thompson*, 248 F. Supp. 2d 1, 13 (D.D.C. 2002) (where only one-third of the studies showed benefit and

were criticized as procedurally flawed, the court held that suppression of information was improper and where the court stated that because there was "some" evidence of efficacy, "a complete ban of the [c]laim cannot be justified").

72. Even assuming the information exchanged by ECM is commercial speech, because the speech at issue is, at worst, only potentially (and not inherently) misleading, it may not be burdened, prospectively limited, or constrained absent satisfaction of the intermediate scrutiny test stated in *Central Hudson*, 447 U.S. 557 (1980), and its progeny. *Zauderer v. Office of Disciplinary Counsel of Supreme Ct. of Ohio*, 471 U.S. 626, 638 (1985) (citations omitted) ("There is no longer any room to doubt that what has come to be known as "commercial speech" is entitled to the protection of the First Amendment, albeit to protection somewhat less extensive than that afforded "noncommercial speech.").

73. Under that test, FTC must have a substantial state interest, there must be a reasonable fit between the means chosen and the ends, the chosen regulation must directly and materially advance the chosen ends, and there must not be obvious less speech restrictive alternatives. *Id.* In this case, there is not a reasonable fit between a cease and desist order or fencing in provisions and advancement of the FTC's interest in avoiding deceptive advertising, nor do such means directly and materially advance that interest, because imposition of proof requirements beyond the credible evidence already supporting ECM's biodegradation claim impairs communication between ECM and its customers about the primary characteristic of the ECM additive in a manner indistinguishable from a prior restraint. Moreover, there are obvious, less speech restrictive alternatives that directly advance the FTC's interest, such as a claim

qualification that rates of biodegradation vary based on environmental conditions at the location where the plastic is disposed. *See Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 632 (1995) (*quoting Cincinnati v. Disc. Network, Inc.*, 507 U.S. 410, 417 n. 13 (1993)) (noting that "the existence of 'numerous and obvious less-burdensome alternatives to the restriction on commercial speech ... is certainly a relevant consideration in determining whether the 'fit' between ends and means is reasonable'").

74. Lesser constitutional protection is warranted for statements "made only in the context of commercial transactions," because businesses "enjoy the full panoply of First Amendment protections for their direct comments on public issues." *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557, 562 n. 5 (1980); *Bolger v. Youngs Drug Products Corp*., 463 U.S. 60, 68(1983); *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 637-38 n. 7 (1985).

75. Based on the *Pfizer* factors outlined below, the standard to be applied in this case must be lower than standards applied in other FTC proceedings considering advertisements related to medical or health claims. For example, in the medical context, advertising claims must be substantiated by double-blind, randomized, placebo-controlled clinical trials. *Thompson Med. Co., Inc. v. Fed. Trade Comm'n*, 791 F.2d 189 (D.C.Cir.1986); *Bristol-Myers Co. v. Fed. Trade Comm'n*, 738 F.2d 554 (2d Cir.1984).

76. Similarly, the standard to apply in this case must necessarily be lower than the standard for advertising claims related to food products which purport to have health benefits—"one well designed, randomized, and double-blind, placebo-controlled clinical trial

involving an appropriate sample population and endpoint." *POM*, 2013 WL 268926, at *43.

77. While those standards obviously cannot apply to biodegradability, they are important benchmarks to demonstrate that ECM's "competent and reliable scientific evidence" need not be as high as that mandated in *Thompson*, *Bristol-Myers*, and *POM*. *See Statement of Commissioner Ohlhausen*, 2014 WL 587857, at *1 (F.T.C. Jan. 7, 2014) ("[T]he burden for substantiation for health- or disease-related claims about a safe product . . . should be lower than the burdens imposed on drugs and biologics because consumers face lower risks when consuming the safe product."). Of course, the burden for substantiation for biodegradation related claim should be lower than the burdens imposed on health and disease related because consumers face no risk when deciding to obtain a product labeled as biodegradable.

78. To help determine what constitutes "competent and reliable scientific evidence," the FTC has recognized two types of claims: establishment and non-establishment claims. *See Thompson Med. Co., Inc. v. F.T.C.*, 791 F.2d 189, 194 (D.C. Cir. 1986). Establishment claims contain express or implied representations about the level of support for a particular claim (i.e., the claim states that a product has been found to be superior by scientific tests). *Id.* For such claims, the advertiser must possess the level of proof claimed in the ad. *Id.*

79. By contrast, a non-establishment claim is a simple claim of efficacy. *Id.* A simple claim that a product is "biodegradable" is a claim of efficacy and therefore a non-establishment claim.

80. For such non-establishment claims, "the reasonable basis inquiry has been defined more flexibly." *Id.* This standard is a "flexible standard" that calls for an evaluation of a variety of factors suited to the particular case at hand. *Direct Mktg. Concepts, Inc. v. F.T.C.*, 581 F. Supp. 2d 115, 118 (D. Mass. 2008). Therefore, the Commission's "reasonable basis cases have identified several factors that [the Commission] will weigh in determining the appropriate level of substantiation for objective advertising claims." *In the Matter of Thompson Med. Co., Inc.*, 104 F.T.C. 648, at ¶ 70 (Nov. 23, 1984).

81. The relevant factors are: "(1) the product involved; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and 6) the amount of substantiation experts in the field would agree is reasonable." *Id.* These factors are used to weigh the benefits and costs of developing substantiation for the claim. *In the Matter of POM Wonderful LLC*, 2013 WL 268926, at *30 (F.T.C. Jan. 16, 2013).[3] The level of proof required to meet the *Pfizer* test in this case is significantly reduced because all of the *Pfizer* factors favor a more relaxed standard.

The Nature of the Product Involved

82. Regarding the first factor, the product involved, the Commission has made clear that products like drugs—which improve physical welfare—as opposed to products that do not purport to improve physical welfare, "require[] a relatively high level of substantiation." *Thompson*, 104 F.T.C. 648, at ¶¶ 71–72; *see also POM*, 2013 WL

[3] ECM has not made any "establishment" claims to end-consumers. To ECM's sophisticated manufacturing customers, it has disclosed the types of tests shown to have resulted in biodegradation. To the extent ECM's disclosure of its test data and names of test standards is an establishment claim, the claim is truthful and non-misleading. ECM does possess the tests its claims to have, and those tests do show that ECM's technology creates a biodegradable plastic.

268926, at *48 (noting that the respondents "made claims regarding serious diseases"); *In the Matter of Removatron Int'l Corp.*, 111 F.T.C. 206, at *14 at n. 20 (Nov. 4, 1988) (noting that a drug or product that directly affects human safety requires more substantiation).

83. ECM does not market products like drugs, foods, medical devices, or dietary supplements that improve physical welfare. ECM has not made claims concerning serious diseases or health conditions. Moreover, significantly, ECM has never sold product to end-consumers. ECM sells a plastic additive to plastics manufacturers that, when manufactured correctly, will help render the finished plastic biodegradable in a landfill over time.

84. The first *Pfizer* factor weighs in favor of a finding that ECM has presented sufficient substantiation for its biodegradable claims.

The Type of Claims Made

85. The second factor is the type of claim being made. One type of claim that requires a high a level of substantiation "is a claim that refers to specific facts or figures, rather than making generalized descriptions of the product's capabilities." *Thompson,* 104 F.T.C. 648, at ¶ 72.

86. Therefore, a generalized claim, such as "biodegradable," would require a lower level of substantiation than a more specific claim.

87. The Second *Pfizer* factor weighs in favor of a finding that ECM has presented sufficient substantiation for its biodegradable claims.

The Benefits of a Truthful Claim and Ease of Developing Substantiation for the Claims

88. The third and fourth factors are often considered "in conjunction with each other." *Id.* at ¶ 74. The Commission's "concern in analyzing these factors is to ensure that the level of substantiation [the Commission] require[s] is not likely to prevent consumers from being told potentially valuable information about product characteristics." *Id.*; *see also Removatron*, 111 F.T.C. 206 at n. 20 ("These two factors together seek to ensure that the level of substantiation we require is not likely to deter product development or prevent consumers from being told potentially valuable information about product characteristics").

89. Consumers can be prevented from being told potentially valuable information about product characteristics when the cost of developing substantiation for these claims would be high in comparison to the amount of sales the product can earn. *Id.* at ¶¶ 74–75. So, the Commission will not require substantiation that, because of its prohibitive costs, will become non-feasible. *POM*, 2013 WL 268926, at *49.

90. The third and fourth *Pfizer* factors weigh in favor of a finding that ECM has presented sufficient substantiation for its biodegradable claims.

The Consequences of a False Claim

91. Under the fifth factor, the consequences of a false claim can be divided into either health or economic consequences. *See Thompson*, 104 F.T.C. 648, at ¶¶75–76 (noting that false claims can be "injurious to health and economically harmful").

92. In order to be economically harmful, the economic harm suffered by consumers must be "material" and "substantial." *See POM*, 2013 WL 268926, at *50, n. 31 (noting that a

one year supply of the POM Juice costs at least $780); *Removatron*, 111 F.T.C. 206 at n. 20 (noting that the device at issue cost approximately $4,000, and required treatments that cost $35 per hour over a period of years).

93. The fifth *Pfizer* factor weighs in favor of a finding that ECM has presented sufficient substantiation for its biodegradable claims.

The Amount of Substantiation Experts in the Field Agree Is Reasonable

94. The final factor is the amount of substantiation experts in the field agree is reasonable. This factor "must be examined in relation to each field being evaluated." *POM*, 2012 WL 2340406, at *206.

95. The sixth *Pfizer* factor weighs in favor of a finding that ECM has presented sufficient substantiation for its biodegradable claims.

COMPLAINT COUNSEL'S DEFINITION OF BIODEGRADATION IS ARBITRARY AND CAPRICOUS

96. A court should "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706.

97. An agency's decision is arbitrary and capricious when the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983).

98. Review of agency action is "not merely perfunctory," the review should be a 'searching and careful' inquiry.'" *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795

(D.C. Cir. 1983); *Specialty Equip. Mkt. Ass'n v. Ruckelshaus*, 720 F.2d 124, 132 (D.C. Cir. 1983) ("when reviewing agency's determinations under "arbitrary and capricious" standard, "we must make a substantial and searching inquiry to ensure that the agency's decisions are the product of reasoned thought and based upon a consideration of relevant factors"); *Dickinson v. Zurko*, 527 U.S. 150, 155 (1999) ("[t]he APA requires meaningful review; and its enactment meant stricter judicial review of agency fact finding than Congress believed some courts had previously conducted").

99. As applied to the ECM plastic here in issue, the One-Year Rule is arbitrary and capricious and lacking in any reasonable factual basis. Reliance upon it as a rule of decision would therefore be an abuse of agency discretion. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Ins. Co.*, 463 U.S. 29, 43 (1983) (explaining that an agency abuses its discretion when its explanation runs counter to the evidence before the agency).

COMPLAINT COUNSEL'S PRIMARY SCIENTIFIC EXPERT WITNESS HAS A DIRECT FINANCIAL INTEREST IN THE OUTCOME OF THIS LITIGATION AND HAS TAKEN INCONSISTENT POSITIONS THROUGHOUT THIS CASE; HIS OPINION SHOULD THEREFORE BE GIVEN NO WEIGHT.

100. Expert witness testimony can be rebutted by evidence of the expert's direct financial interest in the outcome of the litigation or by inconsistencies in the expert's testimony. *Mims v. U.S.*, 375 F.2d 135, 134–35 (5th Cir. 1967) (noting that [i]t has been recognized that expert opinion evidence may be rebutted by … the interest or bias of the expert [] or inconsistences in his testimony as to material matters")

101. Where an expert witness has a direct financial interest in the outcome of the litigation, that expert witness's opinion should be given no weight. *Western Assur. Co. Inc. v.*

Connors, 101 F. Supp. 2d 1111, 1116 (S.D. Ind. 1999) (giving no weight to expert opinion where expert had financial incentive in the outcome of the case).

102. In FTC proceedings, credibility is always in issue. Chappell, Tr. 1526, 1706. It is for the judge to make character findings in instances where testimony, particularly of experts, is evasive, false, misleading, or perjurious. *Cota v. Tucson Police Dep't*, 783 F. Supp. 458, 464 (D. Ariz. 1992) ("When sitting as a finder of fact, a trial judge necessarily determines the credibility of expert witnesses.").

103. "[T]he nature and extent of a witness's motives and his interest in the outcome of the case bear importantly upon an evaluation of the witness's objectivity, his bias, and the weight to be accorded his testimony." *United States v. IBM Corp.*, 66 F.R.D. 215, 219 (S.D.N.Y. 1974); *Nemir v. Mitsubishi Motors Corp.*, 200 F.Supp.2d 770, 774 (E.D. MI 2002) ("The more subjective and controversial the expert's inquiry, the more likely the testimony should be excluded as unreliable.").

A SURVEY MUST MEET STANDARDS IN ORDER TO BE CONSIDERED BY THE FTC OR ANY OTHER COURT OF LAW

104. "[A] party seeking to admit survey evidence must show that the survey was conducted according to accepted principles." *Clicks Billiards, Inc. v. Sixshooters Inc.*, 251 F.3d 1252, 1262 (9th Cir. 2001).

105. Factors the FTC takes into account when determining whether to afford a survey any weight include whether the survey was performed in the usual manner for surveys of that type, whether the survey employed controls and validation procedures, whether the samples were reasonably representative, whether the respondents to the survey actually understood the questions being asked, and whether the respondent has sufficient experience with the product involved in the survey. *In re Littelton Indus., Inc.*, 97 F.T.C.

1, at ¶¶ 69–73 (Jan. 5, 1981); *In the Matter of Bristol-Myers*, 85 F.T.C. 688 at n. 14 (Apr. 22, 1975).

COMPLAINT COUNSEL'S ENFORCMENT ACTION AGAINST ECM IS NOT IN THE PUBLIC INTEREST

106. As a prerequisite to enforcement action, the Commission must determine whether there is a reason to believe that an unfair method of competition is being used, that the proceeding would be in the public interest, and that such interest is specific and substantial. *See Federal Trade Commission v. Raladam Co.*, 283 U.S. 643 (1931).

107. A proceeding by the Commission to prevent the use of unfair methods or unfair or deceptive acts or practices must appear to be in the interest of the public. *Thomas v. FTC*, 116 F.2d 347, 349 (10th Cir. 1940).

108. In fact, the "commission is authorized to act only in the public interest, and to justify it in filing a complaint that public interest must be specific and substantial." *Arnold Stone Co. v. FTC*, 49 F.2d 1017, 1019 (5th Cir. 1931).

109. The "mere misrepresentation and confusion or deception of purchasers" is insufficient for FTC action. *FTC v. Royal Milling Co.*, 288 U.S. 212, 216 (1933).

110. FTC precedent establishes that where a sophisticated entity, and not a consumer, makes the decision whether to purchase the product at issue from a respondent, the respondent's claims regarding that product cannot have any influence on the consumers, and therefore the public interest is not served by requiring corrective action. *In the Matter of Charles F. Harad*, 50 F.T.C. 300, 315–316 (1953).

111. In *Harad*, the respondent claimed in a trade magazine that its product will be beneficial following patient surgeries or after specific medical treatment. *Id.* at 315. The experts in that case disagreed over whether or not the product was actually beneficial. *Id.*

112. However, the hearing examiner found "it unnecessary to resolve th[at] difference of opinion." *Id.* The court first noted that because it was the physician's decision whether or not to purchase the device, the respondent's claim could not have "any significant influence on the[] patients." *Id.*

113. In recommending dismissal of the complaint, the court then went on to state:

> In any event, since the representation made with respect to the … use of the device was concededly made in a publication intended for circulation among physicians only, who, it can be assumed, will not be misled by anything respondents might say regarding their product, and since there is no substantial evidence that the general consuming public would be misled thereby, it is the opinion of the undersigned that the public interest does not require the taking of any corrective action based on the alleged falsity of any representation that respondents' device may be used post-operation or post-injection.

Id. at 315–16 (*contrasting Irwin v. F.T.C.*, 143 F.2d 316 (8th Cir. 1944)) (where the respondent made claims regarding its product in "periodicals and by booklets, pamphlets, circulars, letters, and other advertising material").

114. Just like in *Harod*, it is undisputed that ECM did not market its product directly to consumers. Rather, ECM, like the respondent in *Harod*, made claims to entities interested in purchasing the product for commercial and not personal use, namely plastic manufactures. Whether or not to purchase the ECM additive is a decision left entirely to the plastic manufacturers that actually purchases the ECM additive. Like physicians determining whether or not to purchase a controversial medical device, plastic manufacturers cannot be misled by any marketing claims regarding additives used in the manufacture of plastics, which is their specific profession and area of expertise.

115. Therefore, "the public interest does not require the taking of any corrective action based on the alleged falsity of any representation that" that ECM made only to plastic manufacturers. *Harad*, 50 F.T.C. at 316.

116. The public interest is not served by having the Federal Trade Commission wade into areas of unsettled and complex science where the debate within industry and academia has yet to be resolved. *See Koch v. FTC*, 206 F.2d 311 (6th Cir. 1953). ("A principal test as to whether a particular case affects the public interest is whether the misleading or deception of the public is shown"). Here, there is no evidence that the public have been misled.

117. In *Arnold Stone*, the Court held that action was not in the public interest or misleading because the FTC had failed to produce any evidence showing that a stone company's use of the word "stone" deceived any of their sophisticated customers, even though the "stone" products sold were actually made of composite materials like concrete. *Arnold Stone*, 49 F.2d at 1018-19.

118. Significant to this case, the Court explained that "none of the words employed by the petitioner to describe any of its manufactured products or materials had the effect of misleading or deceiving architects, contractors, or builders who were the only classes of persons to whom petitioner sold or offered to sell any such products or materials." *Id.* The Court continued, "[t]he sum and substance of all the evidence was that the words 'cast stone' were understood by petitioner's prospective customers and by its competitors to mean just such a product as petitioner manufactured and sold." *Id.*

119. In addition, "there must be a showing that the acts and practices sought to be proscribed are detrimental to the public interest in order to satisfy the statutory requirement that the

proceeding be in the public interest." *S. Buchsbaum & Co. v. FTC*, 160 F. 2d 121, 123-24 (7th Cir. 1947).

120. That fact was dispositive in the *Buchsbaum* case, as the Court explained:

> [T]he Commission made no finding that the deception, if any, had ever resulted in or had any tendency to result in detriment to the purchasing public. We find nothing in the findings to support the conclusion that the acts and practices are all to the prejudice and injury of the public.

Id. at 123-24.

121. This ECM case is similar to *Buchsbaum*, where the FTC challenged a company making shatterproof "glass" products because, according to the FTC, the "glass" was actually made out of plastic. *Id.* at 123. The Court observed that, just like in this case where ECM can undercut the prices of the more expensive bioplastics:

> It is quite evident that [the] proceeding was actuated by the manufacturers of [competing] glass as contained in window panes, tumblers and the like. The trouble arises in trying to compete with petition in the sale of the same articles made of 'Elasti-Grass' by petition. Thus far, it appears from the record, the competition has not been successful for such manufacturers, because of the cheaper prices of petitioner's products.

Id. at 124.

122. The ECM case is not materially different from *Buchsbaum*. Complaint Counsel alleges that the word "biodegradable" has a specific meaning (just like "glass" had a meaning in *Buchsbaum*), and that customers will be misled into thinking the "biodegradable" plastic is of a specific kind, to wit, a kind that rapidly degrades. In *Buchsbaum* the court rejected this very type of case for the same reason the Administrative Law Judge should deny Complaint Counsel its requested relief: "We find in this record no evidence of any injury to any dissatisfied customer, indeed, there are no dissatisfied customers so far as this

record discloses." *Id.* at 123. The Court also wisely acknowledged that any theorized injury could be alleviated through a more proactive consumer:

> It is intimated that the injury will occur to those who have been 'long accustomed to the worth and use of glass.' If this class of customers would consult their lexicons and inform the merchants as to the kind of glass they desire they will never be misled. Certainly they cannot be misled or injured by petitioner's advertisements.

Id. at 123.

123. As the precedent makes clear, Complaint Counsel is obliged to identify some tangible or palpable injury in the market in order to establish that this case is in the public interest. They have not done so, and they cannot do so on this record.

COMPLAINT COUNSEL'S CENSORSHIP OF "BIODEGRADABLE" CLAIMS VIOLATES THE FIRST AMENDMENT

124. First Amendment protections directly apply to FTC orders and limit the expansion of FTC advertising regulation. *See, e.g., Standard Oil C. of California v. F.T.C.*, 577 F.2d 653, 662 (9th Cir. 1978) ("First Amendment considerations dictate that the Commission exercise restraint in formulating remedial orders which may amount to a prior restraint on protected commercial speech"); *Sears, Roebuck and Co. v. F.T.C.*, 76 F2d 385, 399 n.31 (9th Cir. 1982); *Beneficial Corp*, 542 F.2d at 611; *F.T.C. v. Simeon Management Corp.*, 532 F.2d 708, 713 (1976) ("[a]lthough commercial advertising may be subject to regulation serving an important public interest, it is not beyond the protection of the First Amendment").

125. The Constitution prohibits restriction of potentially misleading speech when there are obvious, less speech restrictive alternatives to imposing prospective speech burdens. *See, Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

126. A burden on speech need not be a complete prior restraint in order to compel constitutional assessment under the commercial speech standard. *See, e.g., Alliance for Natural Health U.S. v. Sebelius*, 786 F. Supp. 2d 1, 24 (D.D.C. 2011) ("the FDA cannot require a disclaimer that simply swallows the claim . . .").

127. A cease and desist order that either prohibited use of the term "biodegradable" unless more than the credible evidence in this record was prospectively produced or unless confined to the impossible (such as a set rate within one year, despite the impossibility of reliably achieving same, or such as a demand for 100% break down of the plastic into elements in nature, despite the fact that science proves biodegradation of plastics inevitably leaves residues that still contain elements of plastic) would violate both the "reasonable fit" prong of the commercial speech test and the "obvious, less speech restrictive alternative" prong. *See, e.g., City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 (1993) (holding that ban on news racks containing "commercial handbills," which did not apply to news racks containing "newspapers" was not a "reasonable fit" between city's legitimate interest in safety and esthetics and means chosen to serve interest); *Western States Medical Center*, 535 U.S. 357, 371 (2002) (explaining that the Court has "in previous cases addressing this final prong of the *Central Hudson* test, . . . made clear that if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so").

128. In particular, a cease and desist order that prohibits commercial speech that is backed by credible evidence on the demand that more evidence exist before government will allow the claim is a burden on speech already held unconstitutional by our Court of Appeals in

Pearson v. Shalala and its progeny (and that, in a public health context). *See, e.g., ANH*, 786 F. Supp. 2d at 24 ("Where the evidence supporting a [health] claim is inconclusive, the First Amendment permits the claim to be made . . .").

129. In *Pearson I*, the D.C. Circuit held that perceived deficiencies in the scientific record must be proven incapable of being rendered non-misleading by resort to reasonable claim qualifications before the government may burden speech with a prospective speech ban. *See Pearson I*, 164 F.3d at 658 (holding that "[i]t is clear … that when government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness—government disregards a 'far less restrictive' means"); *see also Whitaker v. Thompson*, 248 F.Supp. 2d 1 (D.D.C. 2002); *Alliance for Natural Health U.S. v. Sebelius*, 714 F.Supp. 2d 48, 53 (D.D.C. 2010) ("*ANH I*"); *Alliance for Natural Health U.S. v. Sebelius*, 786 F.Supp. 2d 1, 8 (D.D.C. 2011) ("*ANH II*"). The same law and logic applies to FTC orders that restrain future speech through cease and desist and fencing in orders or other burdens.

130. A government mandated claim qualification is constitutional only if it is reasonable. *See, e.g. Whitaker v. Thompson*, 248 F. Supp. 2d 1, 2 (D.D.C. 2002) (enjoining FDA from taking any action that would prevent the use of the antioxidant vitamin health claim at issue as proffered or with reasonable disclaimers).

131. Although the government may have an interest in protecting consumers from misleading claims, that interest cannot overcome the First Amendment's preference for disclosure (compelled or voluntary) over suppression when claim qualification is a suitable, less speech-restrictive alternative. *See Whitaker*, 248 F. Supp. 2d at 10. As in this case, when "credible evidence supports a claim, that claim may not be absolutely prohibited." *See*

id. (citing *Pearson I*, 164 F.3d at 659). Moreover, significantly, "[t]he mere absence of significant affirmative evidence in support of a particular claim … does not translate into negative evidence against it." *Pearson v. Shalala*, 130 F.Supp. 2d 105, 115 (D.D.C. 2001) ("*Pearson II*"); *Edenfield v. Fane*, 507 U.S. 761, 770 (1993) ("[I]t is well established that the party seeking to uphold a restriction on commercial speech carries the burden of justifying it").

132. Moreover, significantly, "[t]he mere absence of significant affirmative evidence in support of a particular claim … does not translate into negative evidence against it." *Pearson v. Shalala*, 130 F.Supp. 2d 105, 115 (D.D.C. 2001) ("*Pearson II*"); *Edenfield v. Fane*, 507 U.S. 761, 770 (1993) ("[I]t is well established that the party seeking to uphold a restriction on commercial speech carries the burden of justifying it").

133. A limitation on the use of a broad, but scientifically accepted, definition of "biodegradable" must comply with the First Amendment commercial speech doctrine as articulated in *Pearson I.*

THE FTC'S PROSECUTION OF ECM IS ULTRA VIRES BECAUSE FTC IS ASSUMING REGULATORY POWER VESTED BY CONGRESS IN THE EPA

134. Government action is *ultra vires* if the agency or other government entity "is not doing the business which the sovereign has empowered him to do or he is doing it in a way which the sovereign has forbidden." *Ancient Coin Collectors Guild v. U.S. Customs & Border Prot., Dep't of Homeland Sec.*, 698 F.3d 171, 179 (4th Cir. 2012) (quoting *Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682, 689 (1949)).

135. Courts review *ultra vires* agency action when an agency "patently misconstrues a statute, disregards a specific and unambiguous statutory directive, or violates a specific command of a statute." *Hunter v. F.E.R.C.*, 569 F. Supp. 12, 16–17 (D.D.C. 2008). Put differently,

"[a]n *ultra vires* act is one performed without any authority to act…" *Sahaviriya Steel Indus. Public Co. Ltd. v. U.S.*, 601 F. Supp. 2d 1355, 1366 (C.I.T. 2009). The APA further contemplates that agency action is void if found to be "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." *See* 5 U.S.C. § 706 (2)(C).

136. The U.S. EPA has primary responsibility for enforcing the environmental statutes and regulations of the United States. Under the federal Resource Conservation and Recovery Act (RCRA), Congress delegated to the EPA the task of managing solid waste disposal. *See, e.g.,* 42 U.S.C. § 6901. Congress passed the RCRA, in part, to address the "ever-mounting increase … of the mass material discarded by the purchaser of … products." 42 U.S.C. § 6901(a)(1). Moreover, with respect to energy, Congress explained that "solid waste represents a potential source of solid fuel, oil, or gas that can be converted into energy." 42 U.S.C. § 6901(d)(1).

137. Complaints Counsel's definition of "biodegradable," which limits the naked term to products that degrade completely into elements found in nature within one year after customary disposal, is patently arbitrary and capricious and in conflict with environmental policies set by the federal Environmental Protection Agency.

THE "ONE-YEAR" RULE IS AN INDUSTRY-WIDE TRADE REGULATION UNLAWFULLY PROMULGATED

138. The "One-Year" Rule promulgated in the 2012 revision of the Green Guides is not an interpretative, non-binding statement of policy, but an industry-wide rule that redefines the kind and scope of products that can be marketed. 16 C.F.R.§ 260(V). The rule inherently favors short-term degradable products to the prejudice of those products that

would biodegrade slowly in a landfill, but still within a reasonably short period of time compared to conventional plastics. 16 CFR §§ 260.7–260.8.

139. Furthermore, because Complaint Counsel has explained through this proceeding that no test can accurately substantiate the time for disposal in an MSW landfill, and the rule expressly states that it is "deceptive to make an unqualified degradable claim for items entering the solid waste stream if the items do not completely decompose within one year after customary disposal," the Green Guides prohibit technologies that do not, in fact, disappear in landfills within one year. *See* 16 C.F.R. § 260.8(c). In other words, the Commission has condemned the use of *landfill-able* technologies *in toto*. That is an environmental policy that declares landfill-able products undesirable—not a position with respect to consumer deception. The FTC has thus enacted a new industry-wide rule without complying with the requirements of 15 U.S.C. § 57.

140. 15 U.S.C. § 57 requires that FTC proceed through Magnuson-Moss rulemaking when promulgating rules defining practices which are unfair or deceptive. *See* 15 U.S.C. § 57a (requiring heightened procedural safeguards in FTC rulemaking proceedings); *see also* 5 U.S.C. § 553 (requiring federal agencies, with limited exceptions, to follow notice-and-comment rulemaking procedures when promulgating a new rule, regulation, or interpretation of a regulation). Because the Commission has not complied with all of the requirements of Section 57a (in particular, provide an informal hearing under 15 U.S.C. § 57a(c), and submit notice to the Committee on Commerce, Science, and Transportation of the Senate and to the Committee on Energy and Commerce of the House of

Representatives under 15 U.S.C. § 57a(b)(B)), the trade regulation rule implemented and now enforced against ECM is invalid and should be given no weight in this proceeding.[4]

141. The FTC has thus enacted a new industry-wide rule equivalent to the FDA's prior restraint the United States Court of Appeals condemned as unconstitutional in *Pearson I*. *See Pearson I*, 164 F.3d at 655–60.

THIS FTC PROCEEDING VIOLATES THE SEPARATION OF FUNCTIONS DOCTRINE

142. Due Process is required in administrative proceedings. See *Withrow v. Larkin*, 421 U.S. 35, 46 (1975); *Utica Packing Co. v. Block*, 781 F.2d 71, 76 (6th Cir. 1986).

143. Under 5 U.S.C. § 556 of the Administrative Procedures Act, Congress requires administrative agencies to conduct hearings mandatory under §§ 553 and 554 "in an impartial manner." 5 U.S.C. § 556. "A fair trial in a fair tribunal is a basic requirement of due process. Fairness of course requires an absence of actual bias in the trial of cases. But our system of law has always endeavored to prevent even the probability of unfairness." *In re Murchison*, 349 U.S. 133 (1955). As the D.C. Circuit has stated: "With regard to judicial decision making, whether by court or agency, the appearance of bias or pressure may be no less objectionable than the reality." *D.C. Federation of Civic Ass'ns v. Volpe*, 459 F.2d 1231, 1246–47 (D.C. Cir. 1971), *cert. denied*, 405 U.S. 1030 (1972).

144. "When governmental agencies adjudicate or make binding determinations which directly affect the legal rights of individuals, it is imperative that those agencies use the

[4] For example, because the FTC did not properly characterize the industry rule as a Trade Regulation Rule under Section 57a, the Commission did not apparently notify and seek input from the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Energy and Commerce of the House of Representatives. *See* 15 U.S.C. § 57a(2).

procedures which have traditionally been associated with the judicial process." *Utica Packing*, 781 F.2d at 78.

145. In administrative proceedings, "the requirement of a fair trial before a fair tribunal has not been eliminated. This concept requires the appearance of fairness and the absence of a probability of outside influences on the adjudicator; it does not require proof of actual partiality." *Id.* at 76 (*citing Withrow*, 421 U.S. at 35).

146. In order to enforce separation of functions and impartiality in administrative hearings, Congress included 5 U.S.C. § 554(d) in the APA. That statute restricts the investigator/prosecutor from being involved in the decision making process. "The clear purpose of [5 U.S.C. § 554(d)] is to separate the investigative and prosecutorial functions from the adjudicative function" in administrative hearings. *Utica Packing*, 781 F.2d at 76 (*citing Wong Yang Sung v. McGrath*, 339 U.S. 33, 41 (1950)). 5 U.S.C. § 556(d) cannot be read narrowly. *Id.*

147. While the Commission is obligated to acknowledge the ALJ's findings, there is no requirement that the Commission credit those findings or give them any weight. The Commission brought the allegations against ECM and will be the ultimate adjudicator against ECM. Thus, the Commission necessarily has an interest in the outcome sufficient to violate the doctrine of separation of functions. *See Leer Elec., Inc. v. Penn. Dep't of Labor and Indus.*, 597 F. Supp. 2d 470, 481 (M.D. Pa. 2009) (noting that the officials' multiple roles as investigators, prosecutors, and adjudicators were sufficient to present a risk of actual bias).

148. Due process affords parties the right to introduce certain evidence. *See Chambers v. Mississippi*, 410 U.S. 284 (1973); *Epstein v. MCA , Inc.*, 54 F.3d 1422 (9th Cir. 1995)

(the federal rules ordinarily contemplate a "broad right of discovery"); *Berger v. United States*, 295 U.S. 78, 88 (1935) ("[The Government] is the representative *not* of an ordinary party … but of a sovereignty … whose interest is not that it shall win cases, but that justice be done") (emphasis original).

149. Where information from persons not present at hearing concerns an important issue in dispute, a due process objection may well be valid. *See, e.g., Prebble v. Brodrick*, 535 F.2d 605, 616 (10th Cir. 1976).

150. Fair rebuttal testimony is only "that which is precisely directed to rebutting *new matter or new theories* presented by the defendant's case-in-chief." *Bowman v. Gen. Motros Co.*, 427 F.Supp. 234, 240 (E.D. Pa. 1977) (emphasis added).

Respectfully submitted,

/s/ Jonathan W. Emord
Jonathan W. Emord
Peter A. Arhangelsky
Bethany R. Kennedy
Eric J. Awerbuch
EMORD & ASSOCIATES, P.C.
Telephone: 202-466-6937
Fax: 202-466-6938
Email: jemord@emord.com

DATED: September 25, 2014

CERTIFICATE OF SERVICE

I hereby certify that on September 25, 2014, I caused a true and correct copy of the foregoing to be served as follows:

One electronic copy to the **Office of the Secretary** through the e-filing system:

Donald S. Clark, Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Room H-113
Washington, DC 20580
Email: secretary@ftc.gov

One electronic courtesy copy to the **Office of the Administrative Law Judge**:

The Honorable D. Michael Chappell
Administrative Law Judge
600 Pennsylvania Ave., NW, Room H-110
Washington, DC 20580

One electronic copy to **Counsel for Complainant**:

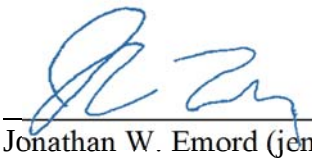
Katherine Johnson
Division of Enforcement
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
Mail stop M-8102B
Washington, D.C. 20580
Email: kjohnson3@ftc.gov

Arturo Decastro
Division of Enfoncement
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
Mail stop M-8102B
Washington, D.C. 20580
Email: adecastro@ftc.gov

Jonathan Cohen
Division of Enforcement
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
Mail stop M-8102B
Washington, D.C. 20580
Email: jcohen2@ftc.gov

I certify that I retain a paper copy of the signed original of the foregoing document that is available for review by the parties and adjudicator consistent with the Commission's Rules.

Respectfully submitted,



Jonathan W. Emord (jemord@emord.com)
EMORD & ASSOCIATES, P.C.
11808 Wolf Run Lane
Clifton, VA 20124
Telephone: 202-466-6937
Facsimile: 202-466-6938

DATED: September 25, 2014

Respondent's RX Exhibit Index

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-00	AMPAC Advertisement	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-01	AMPAC Living Green	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-02	SENTRY Green Advertisement	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-03	Buckeye/Beauty.com Advertisement	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-04	Covidien e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-06	Document with OWS	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-08	Covidien e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-09	Command Packaging promotional materials	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-10	Letter from SNR Denton	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-11	Muthu Article	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-12	Live Report	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-13	Geneva Watch Group e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-15	Island Plastic Bags Flier	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-17	Plastic bag	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-18	Lancelot Compendium of References	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-19	TJ's biodegradable bag	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-20	GOMMUS E-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-21	7/20 Environ internal e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-22	Umbra advertisement	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-23	ECM letter to Poly-America	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-24	Umbra e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-25	Umbra Catalog	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-26	Eaton Flier	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-27	Enviroware label	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-28	Sansei bag	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-31	Eaton e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-32	Flexible Plastics Inc.: Logo	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-33	FP International website screen capture	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-34	FP International press release	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-35	e-mail to Aladina	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-36	e-mail to American Plastics	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-37	e-mail to Americo Mfg	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-38	e-mail to Bodyglovemobile	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-39	e-mail to Brooks Sports	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-40	e-mail to Clark Container	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-41	e-mail to Contempo Card	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-42	e-mail to Dole and Bailey	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-43	e-mail to Down to Earth	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-44	e-mail to Eaton	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-45	e-mail to Eco Golf	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-46	e-mail to Ecorite Imaging	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-47	e-mail to Epsilon Plastics	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-48	e-mail to E-Z Products	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-49	e-mail to Gilman Bros	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-50	e-mail to Global Garden Friends	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-51	e-mail to Global Resource International	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-52	e-mail to Gommus	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-53	e-mail to Green Packaging	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-54	e-mail to Howard Packaging	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-55	e-mail to Hunter Amenities	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-56	e-mail to Island Plastic Bags	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-57	e-mail to Italcom	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-58	e-mail to JL Clark	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-59	e-mail to Kleertech	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-60	e-mail to Ladycare Amenities	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-61	e-mail to Marietta Corp	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-62	e-mail to McNeil Engineering Corp.	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-63	e-mail to minigrip	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-64	e-mail to Odorno	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-65	e-mail One2Products	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-66	e-mail to Opiline	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-67	e-mail to PAC Worldwide	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-68	e-mail to PrimexPlastics	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-69	e-mail to Regal Lager	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-70	e-mail to Selan Bioscience	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-71	e-mail to Shell Packaging Corp	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-72	e-mail to Shields Bag	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-72	e-mail to Sigma Plastics	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-73	e-mail to SL Plastics	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-74	e-mail to Sondor	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-75	e-mail to Sunway Kordis	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-76	e-mail to TekPak Solutions	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-77	e-mail to Victory Plastic	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-78	1/22 3M e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-79	2/4 3M e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-80	6/4 3M e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-81	8/12 3M e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-82	8/16 3M e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-83	10/5 3M e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-84	10/28 3M e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-85	5/5 BER and customer e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-86	9/16 Dispozo e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-87	10/21 Dispozo e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-88	11/2 Dispozo e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-89	1/9 D&W Fine Pack e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-90	1/11 D&W Fine Pack e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-91	2/6 D&W Fine Pack e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-92	11/3 e-mail to D & W Fine Pack	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-93	11/16 e-mail to D & W Fine Pack	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-94	Dispozo Brochure	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-95	7/1 Eagle e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-96	6/27 Eagle e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-97	10/8 Eagle e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-98	4/23 Flexible Plastics e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-99	2/10 FP e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-100	2/12 FP e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-101	4/4 FP e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-102	9/18 FP e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-103	8/10 FP e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-104	11/3 FP e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-105	11/8 FP e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-106	11/22 FP e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-107	4/22 FP e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-108	8/2 FP e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-109	12/13 FP e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-110	4/10 FP e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-111	FP's The Science of Biodegradable Plastics	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-112	1/27 Island Plastic Bags e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-113	9/28 Island Plastic Bags e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-114	7/20 Island Plastic Bags e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-115	1/5 Island Plastic Bags e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-116	7/4 Island Plastic Bags e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-117	10/8 Island Plastic Bags e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-118	1/22 Island Plastic Bags e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-119	1/21 Island Plastic Bags e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-120	Barber letter to Kappus	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-121	3/22 Kappus e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-122	9/12 Kappus e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-123	10/22 Kappus e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-124	11/23 e-mail from Sigma Plastics	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-125	11/4 e-mail chain from Green Genius	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-126	Collection of e-mails from ECM customers inquiring about ECM's Masterbatch's ingredients	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-127	Collection of e-mails from ECM customers inquiring about whether ECM plastics biodegrade in water	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-128	Collection of e-mails from ECM customers inquiring on environmental friendliness of ECM products	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-129	Collection of e-mails from ECM customers inquiring on whether ECM Master is FDA approved and/or safe for food products	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-130	Collection of e-mails from ECM customers asking questions on manufacturing process or other practical questions	JX-1-A, dated Sept. 4, 2014; Tr. 521		Yes
RX-131	E-mail from Island Plastic Bag; customers want to know if foam products are biodegradable	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-132	Collection of e-mails from ECM customers asking ECM multiple questions not about rate of biodegradation	JX-1-A, dated Sept. 4, 2014; Tr. 521		Yes
RX-133	Collection of e-mails from ECM customers asking about shelf life of ECM products	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-134	Collection of e-mails from ECM customers asking if ECM products are biodegradable	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-135	Collection of e-mails wherein ECM qualifies or refuses to provide rate of	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-136	3/28 Geneva Watch Group e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-137	2/20 e-mail to Green Tech Partner Solutions	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-138	ECM Marketing Materials	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-139	10/27 e-mail chain with S. Patrick Morgan	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-140	12/28 e-mail chain with Pueri Elemental	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-141	Guide for RONA Suppliers	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-142	7/21 e-mail to Earth Cure	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-143	9/13 e-mail chain with Transilwrap	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-144	7/5 e-mail chain with Nu-Methods	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-145	1/2 e-mail chain with Begg & Co.	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-146	10/3 e-mail chain with Westchem	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-147	12/8 e-mail from BPI to Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-148	12/15 e-mail from BPI to Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-149	11/20 e-mail chain between Mojo and Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-150	Proposal to BPI	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-151	10/23 e-mail from Mojo to Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-153	9/6 e-mail from Michel to Wilshire	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-154	3/5 PPC e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-155	8/20 PPC e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-156	11/24 PPC e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-157	9/13 PPC e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-158	3/30 PPC e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-159	6/1 Pregis e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-160	Dispozo Enviroware Advertisement	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 20	
RX-161	Lagasse Sweet Advertisement	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-162	Ohio's Country Journal Article	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-163	Licking County Article	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-164	1/29 e-mail from Mojo to Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-165	11/13 e-mail chain between Mojo and Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-166	12/10 e-mail chain between Mojo and	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-167	6/25 e-mail chain between Michel and Malaree	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-168	4/18 e-mail chain between Mojo and Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-169	Who is the BPI	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-170	11/10 e-mail from Buzz to Mojo	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-171	BPI Comments on Marketing Guides	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-172	BPI comments on Green Guides	JX-1-A, dated Sept. 4, 2014; Tr. 521		
EX-173	Excerpt from Green Guides	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-174	2/27 BPI letter to FTC	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-175	Collection of e-mails between Mojo and Frankle	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-176	Collection of e-mails between Mojo and McCormick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-177	Collection of e-mails between Mojo and Koss	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-178	BPI presentation	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	Collection of e-mails between Mojo and	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-179	Davis			
RX-180	FTC Green Packaging Claims	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-181	2/7 letter from Mojo to FTC	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-182	7/10 letter from Mojo to FTC	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-183	3/30 letter from Mojo to FTC	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-184	Collection of e-mails between Narayan and Mojo	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-185	10/14 e-mail from Narayan to Mantri	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-186	4/30 e-mail from Narayan to Russo and Sheets	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-187	10/21 e-mail from Mojo to Stromberg	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-188	8/29 e-mail from Narayan to Fine	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-189	7/28 e-mail chain between Mojo and Vernon	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-190	BPI FAQ	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-191	7/17 Mojo e-mail to Cal Gov't	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-192	9/21 letter from Mojo to FTC	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-193	9/12 letter from Mojo to FTC	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-194	FTC goals and proposed agenda items	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-195	FTC: The Green Guides Statement of Basis and Purpose	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-204	Aguirre Article	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-207	Collection of McCarthy's patents	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-209	Umass-Lowell Press Release	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-211	6/26 e-mail from Igoe to FTC	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-213	11/15 e-mail from Wilshire to Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-214	11/18 e-mail chain between Shah and Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-215	2/2 Letter from Shah to Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-216	2/26 e-mail from Shah to Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-217	2/23 e-mail chain between Shah, Michel, and Thomas	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-218	Biodegradability and Life Cycle Analysis of Plastic and Bioresin Nursery Pots	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-219	8/18 e-mail chain between Shah and Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-220	Grant application	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-221	7/27 Shah and Michel e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-222	10/21 e-mail from Gomez to Shah	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-223	Gomez PHD Proposal	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2943	
RX-224	7/7 e-mail chain between Gomez and Shah	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-225	10/10 Gomez and Michel e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-226	2/26 e-mail chain between Michel and Shah	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-227	5/19 e-mail chain between Gomez and Shah	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-228	6/9 Gomez and Shah e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-229	6/14 e-mail chain between Gomez and Shah	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-230	7/28 e-mail chain between Gomez and Shah	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-231	8/6 e-mail chain between Gomez and Shah	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-231	8/8 e-mail chain between Gomez and Shah	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-232	8/16 e-mail chain between Gomez and Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-233	10/27 e-mail chain between Gomez and Shah	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-234	1/8 e-mail chain between Gomez and Shah	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-235	1/31 e-mail chain between Gomez and shah	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-236	2/1 Gomez e-mail to Shah	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-237	4/1 e-mail chain between Gomez and Shah	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-238	5/9 e-mail chain between Gomez and Shah	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-239	5/27 e-mail chain between Gomez and Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-240	12/28 e-mail chain between Gomez and Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-241	6/29 e-mail from Gomez to Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-242	4/25 e-mail from Shah to Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-243	Presentation by Michel and Gomez	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-244	1/31 e-mail chain between Gomez and Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2946	
RX-245	Gomez Dissertation Draft	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-246	Draft report for Myers	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-247	Draft article by Gomez and Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-248	Eden 9/25 test to FP	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1475, 1491-92, 1500, 1503-04, 1507, 1538, 1543-45	
RX-249	120 day test analysis	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-250	ATSDR Chapter 2: Landfill Gas Basics	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-251	Eden Manual	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1455, 1464, 1471	

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-252	Eden Inoculum manual	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1456, 1461	
RX-253	Article by Yagi et al produced by Eden	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-254	Environ report for BIOPVC	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1911, 2049	
RX-255	Letter from Environ to Kappus 3/11	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-256	Bodycote Test cert	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-257	Bodycote Test cert	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-258	Memo for Warner to Advent Environ	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-259	Letter from Environ to Kappus 8/12	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-261	OWS protocol for study PFR-4	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-262	OWS Protocol for study PFR-3/1	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-264	OWS final Report; Composting test, followed by ecotoxicity tests	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2014	
RX-265	OWS Final Report; High solids Anaerobic Digestion (HSAD) Test	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2015, 2071	
RX-267	OWS Final Report Infrared Analysis	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	ChemRisk Ecological Assessment of	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-269	ECM Plastic			
RX-270	UNM 12/12 test	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-271	UNM 3/6 test	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-272	SSCCP Italcom test	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-272A	SSCCP Italcom test translated	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-273	Ecologia Report	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-274	Biofoam Degradation Test	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-275	Environ Letter to FP 3/2	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2030, 2045, 2113-16, 2152	
RX-276	Ecologia Test to 180 days	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-277	Intertek Isoe Printpack	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-278	SEM Examination of ECM Plastic	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-279	12/3 Letter from ECM to 3M	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	BPI's Background Biodegradable	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-280	Additives to 3M			

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-281	3M internal notes and e-mails	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-282	1/27 e-mail from Joseph to Baker	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-283	BER Plastic's faxes	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-284	The Truth About Biodegradable Plastics	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-285	Dispoz-o Press Release	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-286	Enviroware Premier Contract PP-DI-427	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-287	Enviroware Stages of Degradation	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-288	dispoz-o products enviroware	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-289	Questions you may concerning enviroware	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-290	Enviroware FAQ	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-291	enviroware leading the Drive to "Green"	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-292	Enviroware answering FAQ and other	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-293	Enviroware slideshow	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-294	NACUFS newsletter	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-295	5/23 e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-296	10/13 e-mail chain between Swiger and green issues	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-297	4/26 e-mail from Leiti to Ellsworth	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-298	2/23 D&W internal e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-299	8/4 e-mail chain between Leiti and Swiger	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-300	8/19 e-mail from Leiti to Hartman	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-301	5/10 e-mail from Glymph to Beecroft	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	7/11 e-mail chain between Schultz, Leiti,	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-302	and Staton			
RX-303	3/20 internal D&W e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-304	Enviroware facts	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-305	Reprint of a letter to an Interested Party	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-306	5/19 Letter to Councilman Molina	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-307	1/19 Letter to Yoshimoto	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-308	5/25 e-mail chain between Sinclair and Santana	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-309	4/23 e-mails from Collins to Mathias	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-310	4/23 e-mail from Collins to Mathias	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-311	6/23 e-mail chain from Eagle	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-312	4/16 e-mail chain from Eagle	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-314	1/23 Letter from Flexible Plastic to Customer	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-315	Flexible Plastic Advertisement	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-316	10/18 e-mail from Hong to Ohana Sales and Marketing	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-317	3/14 e-mail from Hong to Flynn	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-318	3/20 e-mail from Hong to Sumira	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-320	3/5 e-mail from Hong to bby	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-321	9/29 e-mail chain between Blood and Ghosh e-mail chain between NE Labs and	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-322	Dansko e-mail chain between NE Labs and	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-323	NE Labs and Masternet Email chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-324	Masternet 9/5 e-mail chain between NE Labs and Sweettape	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-325	6/23 e-mail from NE Labs to ECM			
RX-326	ECM Pricing Sheets	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-327	ECM Material Safety Data Sheet	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-330	ECM 6.0701 pricing sheet	JX-1-A, dated Sept. 4, 2014; Tr. 521		Yes
RX-331	ECM 6.0404 pricing sheet	JX-1-A, dated Sept. 4, 2014; Tr. 521		Yes
RX-332	ECM web capture	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-333	About ECM web capture	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-334	Green Impact web capture	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-335	ECM Comparison web capture	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-336	Barber Biography	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-337	Barber C.V.	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2142-43	
RX-338	9/3 e-mail from Nealis	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-340	Standard Mutual Confidentiality Agreement	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-341	9/23 e-mail chain between Sinclair and Tyrone	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-342	Schwarzenegger veto	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-343	Interoffice Memorandum	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-344	9/29 e-mail from Tim to Nealis	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-345	Levis and Barlaz article	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-346	Barlaz declaration	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-347	Green Guides Green Guide's statement of basis and	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-348	Green Guide's statement of basis and purpose	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-349	Article by Gattin et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-350	Environ letter to Albert	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-351	12/20 e-mail from Barber to Langen	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-352	ETC Report	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-353	Article by Shen and Bartha	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-354	Article by Albertsson et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-355	Article by Albertsson et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-356	Designation: D5511-12	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-357	Designation: D5511-12	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-358	Designation: D5526-12	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-359	Designation: D5526-12	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-360	Article by Tokiwa et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-361	Article by Iwamoto & Tokiwa	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-362	199 Patent	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-363	Article by Fontaine et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-364	Sahu white paper	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-365	Article by Tilstra and Johnsonbaugh	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-366	10/16 Hall and Barber e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-367	Standard test method for determining mass loss from plastics exposed to activated aerobic and anaerobic compost and landfill environments	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-369	7/19 e-mail chain Alire and Barber	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-371	Report by Sinclair	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-372	11/20 Environ internal e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-373	11/17 Environ internal e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-374	7/23 Barber and Kappus e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-375	3/1 e-mails from Kappus and Pennington	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-376	6/5 e-mails from Kappus and Barber	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-377	3/1 Kappus e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-378	Environ terms and conditions	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-379	US Greenhouse Gas Emissions	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-380	Chapter IX to Monitored Natural Attenuation	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-382	FP Web Capture	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-383	FP Web Capture	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-384	Plastics & Packaging News	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-386	4/21 e-mail chain between Young and Barber	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-387	Eden response to Subpoena	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-388	Clemson Test Results Phase I	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-389	Clemson Test Protocol	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-390	Clemson Test Conclusion	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-391	Clemson Test Results	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-392	NE Labs Report # 1048036	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-394	NE Labs Report # 1150851	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-395	NE Labs Report # 1150851	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-396	NE Labs Report # 1048819	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-397	NE Labs Report #N0946510-02	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-398	NE Labs Report #N0946510-01	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-399	NE Labs Report #N0843980	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-400	Eden Labs ASTMD5511-12	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-401	Eden Test to Smithers Oasis	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-402	Eden test to FP	JX-1-A, dated Sept. 4, 2014; Tr. 521	1537	
RX-403	Eden test to Fellows	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-404	Eden test to Shields	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1534-35	
RX-405	NE Labs Report # 1048742-01	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-406	10/21 letter and test results from Environ	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-407	6/2 Letter and test from Environ to Kizer	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-408	OWS test for Shields	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-410	Environ Dispozo test data	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-412	OWS report for Funsam	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-413	11/3 Letter from Environ to FP	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-414	P.C. Richardson advertisement	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-416	Article by Ruiz	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-417	FP Super 8 Loosefill	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-418	FP Cell-O Air cushions	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-419	FP Speed Feeder	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-420	FP Pillow Pack	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-421	Biodegradable Plastic Packaging	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-422	Material by Alire	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-423	Earth Aware Promotional Materials	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-424	Anderson Die & Mfg Article	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-426	12/17 e-mail from Barber to Sulano	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2056	

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-427	10/3 e-mail chain between Barber and Ranyi	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2061	
RX-428	9/25 e-mail chain between Barber and Ranyi	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-429	10/16 Barber and Shahar e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-430	12/8 Barber and Walters e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2064	
RX-431	7/20 e-mail from Alire to Barber	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-432	2000 article by ECM	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-434	Barber Affidavit	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-435	10/17 Environ internal e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-436	2/17 Barber e-mail to Porter	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-437	Dansko and Ecologic Gas Production	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-438	Dansko and Ecologic Gas Totals	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	Minigrip, Ecologic, Lather, Polimernet	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-439	Gas Totals			
RX-440	Minigrip Continued Gas Totals	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-441	Minigrip Data	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	Minigrip, Ecologic, Lather, Polimernet	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-442	Gas Production			
RX-443	PP Chart	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-444	PPC Gas Totals	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-445	PPC Gas Totals Continued 545 + Days	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-446	PPC Sheets	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-447	PPC-Ecologic-Transil Gas Production	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-448	PPC-ECO-TRAN Gas Totals	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-449	ppc-transil-eco 108 day totals	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-450	Tycoplas and Sweettape Gas Production	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-451	Tycoplas Gas totals	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-452	Narayan's Summary	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	3/14 e-mail chain between Katherine	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-453	Johnson and Dana Rosenfeld	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-454	EPA Facts and Figures for 2008	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-455	Initial prehearing Conference excerpt	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-456	Green Guides Excerpt	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-457	Statement of Basis and Purpose excerpt	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-460	Methane Generation in Landfills	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-462	Environ Dispozo Test Results	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-463	Environ Dispozo Test Results II	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-465	SSCCP Test Report 75/2	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-466	SSCCP Test Report 9	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-469	SSCCP Test Report 10	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	Translation certificate from Day	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-470	Translations			
RX-471	Orders by customer	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-472	Summary of Testing Data	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2251-52, 2264, 2331, 2334-35, 2342	
RX-473	e-mail from Barlaz to Poth on 5/13	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-474	e-mail chain between Barlaz and Alire	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-475	e-mail chain between Barlaz and Alire	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-475A	attachment to Barlaz 8-17 e-mail to Alire	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-476	e-mail chain between Barlaz and Alire	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-477	e-mail chain between Barlaz and Alire	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-478	Letter from Barlaz to Poth	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-479	BMP FP International data	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-480	Letter from Barlaz to Khalil	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-481	FP International Data Summary	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-482	Letter from Barlaz to Alire	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-483	Letter from Barlaz to Alire	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-484	e-mail chain between Barlaz and Alire	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-485	Letter from Barlaz to Pech	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-486	Baldwin et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-487	Bareither et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	Performance of N. Am. Bioreactors	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-488	Landfills II			
	Forest products decomposition in municipal solid waste landfills	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-489				
RX-490	Methane production from municipal refuse: A review of enhancement techniques and microbial dynamics	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-491	Bacterial Population Development and Chemical Characteristics of Refuse Decomposition in a Simulated Sanitary Landfill	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-492	Levis and Barlaz	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-493	Deipser and Stegmann	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-494	De La Cruz and Barlaz	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-495	Vermont Waste Composition Study	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-496	Eleazer et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-497	Finlay and Fenchel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-498	Hanson et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-499	Hilger and Barlaz	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-500	Solid Waste Disposal	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-501	Kjeldsen et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-502	LandGEM Version 3.02	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-503	Levis and Barlaz	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-504	Levis and Barlaz	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-505	Levis and Barlaz	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-506	Mormile et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-507	Pohland and Gould	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-508	Ress et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	Wake County Waste Characterization	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-509	Study			
RX-510	Shelton and Tiedje	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-511	EPA Facts and Figures for 2011	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
	Inventory of US Greenhouse Gas	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-512	Emissions and Sinks 1990-2010			
	Inventory of US Greenhouse Gas	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-513	Emissions and Sinks 1990-2011			
RX-514	Wang et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-515	Wang et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-516	Wang et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-517	Yesiller et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-518	Ecology of Methane Formation	JX-1-A, dated Sept. 4, 2014; Tr. 521		
		JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-519	Physiological Ecology of Methanogens			
	ECM article entitled Biodegradable	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-520	Plastic products			
	ECM technology for the biodegradation of plastic products	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-521				
	Life expectancy of Products manufactured with ECM	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-522				
RX-523	Environ BioPVC Final Summary	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-524	Letter from Barber to Kappus	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-525	Letter from Barber to Kappus	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-526	Letter from Barber to Kappus	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-527	Half life calculations	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-529	e-mail from Scott Hall	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-530	e-mail from Scott Hall	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-531	e-mail from Kappus to Barber	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-532	e-mail from Hall to Barber	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-533	e-mail from Hall to Barber	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-534	e-mail between Kappus and Barber	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-535	e-mail between Barber and Kappus	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-536	e-mail chain between Kuykindall, Barber, and Hall	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-537	Barber and Kappus e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2069	
RX-538	Barber and Kappus e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-539	Letter from Barber to Kizer	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-540	e-mail chain between Kizer and Barber	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-541	e-mail chain between Barber and Hall	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-542	e-mail chain between Barber and Hall	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-543	Ramirez, Barber, and Grove e-mails	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	e-mail chain between Barber and	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-544	Ramirez			
RX-545	e-mail chain between Lichtle and Barber	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	e-mail chain between Hall, Sutton, and	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-546	Moore			
RX-547	Image of Aerobic Condition	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-548	Image of Anaerobic Condition	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-549	Standard Test Method document	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-550	e-mail from Scott Hall	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-551	OWS Final Report PFR-3	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-552	PC Analysis	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-553	Heterephobic Plate Count Summary	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-554	e-mail chain between Barber and Hall	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-555	Barber e-mails	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-556	Dolco test data	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-558	Letter from Barber to Alire	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-559	NAD Finding on Masternet	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-561	e-mail chain between Barber and Zhu	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2060, 2080	
RX-562	e-mail chain between Barber and Green	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-563	e-mail from Harty to Barber	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-564	e-mail chain between Clayton and Barber	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-565	e-mail chain between Curren and Barber	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-566	e-mail chain between Curren and Barber	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-567	e-mail chain between Barber and Zhu	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-568	e-mail chain between Barber and Albert	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-569	e-mail chain between Barber and Zhu	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2060	
RX-570	e-mail chain between Barber and McGregor	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	e-mail chain between Barber and	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-571	McGregor			
RX-572	e-mail chain between Sulano and Barber	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-573	e-mail chain between Barber and Langen	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2066	
RX-574	e-mail chain between Barber and Albert	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-575	Additives in Plastics	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-576	Demir et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-577	EM 200 1 10	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-578	EPA G8 Final	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-579	Ling et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-580	Pramila and Ramesh	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-581	Shah et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	Intro to Polymer Additives and	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-583	Stabilization			
RX-584	Chap. 11 by van der Zee	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-586	Arutchelvi et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-587	Bhardwaj et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-588	EPA web capture	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-589	Plastipedia web capture	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-590	Tilstra and Johnsonbaugh	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	e-mail chain between Johnson and	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-591	Rosenfeld			
	e-mail chain between Johnson and	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-592	Rosenfeld			

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-593	e-mail from Johnson to Rosenfeld	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-594	Letter from Narayan to Mojo	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-595	E-mail from Narayan to Monica	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-596	APCO Study	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-597	APCO questions	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2511	
RX-598	APCO data	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-599	APCO survey	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-600	Survey responses	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-601	Appendix A to Stewart Report	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2494	
RX-602	Appendix B to Stewart report	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2568-69, 2573, 2576	
RX-603	Appendix C1 to Stewart Report	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-604	Appendix C2 to Stewart Report	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-605	Appendix D to Stewart Report	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2571-72	
RX-606	Appendix E to Stewart Report	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-607	Appendix F1 to Stewart Report	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-608	Appendix F2 to Stewart Report	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-609	Data for survey	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-610	Codes	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-611	Manufacturers Survey	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-612	Verbatim answers	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-613	Environment Questionnaire	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-614	Environment Tabs	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-615	Read et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-616	Frederick and Mochon	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-617	Mochon and Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1030	
RX-618	Automated Choice Heuristics	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-619	Lee et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-620	Frederick and Shafir	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	Cognitive Reflection and Decision	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-621	Making			

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-622	Frederick and Loewenstein	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-623	Read et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-624	Read et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-625	Frederick et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-626	Simmons et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-627	Kahneman and Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-628	Frederick et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	Valuing future life and future lives: A	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-629	framework for understanding discounting			
		JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-630	Persuasive Power of Opportunity Costs			
RX-631	Hedonic Adaptation	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-632	Hedonic Treadmill	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-633	Frederick et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-634	Mochon and Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-635	Frederick et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-636	Fischoff et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	Measuring Intergenerational Time	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-637	Preference			
RX-638	Kahneman and Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-639	Frederick et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-640	Soman et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-641	Kahneman and Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-642	Frederick and Read	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-643	Frederick et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-644	Loewenstein and Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-645	Songer et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-646	Weaver and Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-647	Frederick et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-648	Frederick and Fischoff	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-649	Kahneman and Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-650	Time Preference & Personal Identity	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-651	Redden and Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-652	Frederick and Peterman	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	Overestimating Others' Willingness to	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-653	Pay			
RX-654	Of Frogs and men	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-655	ACC survey	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-657	Lead Customer Contacts	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-658	Ecologic Sustainability Study Data	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-659	Ecologic Sustainability Study Data	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-670	Ecologic Sustainability Study Data	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	Saeed, Meyer and Frederick e-mail chain	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-671				
RX-671A	attachment 1	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-671B	attachment 2	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-673	Synovate study	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	E-mails and documents considered by	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-674	Stewart			
RX-675	Reduced customer list	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-676	Reprint of a Letter to an Interested Party	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-678	ECM Marketing Materials	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-679	ECM Sample Claims	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-680	ECM web capture	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-681	ECM web capture	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-682	ECM web capture	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-683	ECM Technical Sheet	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-684	Coding	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-685	Coding	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-686	Gelman article	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-687	Morgan Article	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-688	Busby Article	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-690	Kahan article	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-691	Kahan article II	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-692	Partial manufacturing data	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-693	Wilshire to Michel e-mail	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-694	Pessalano and Merenda e-mails	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-695	e-mail from Michel to Wilshire	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-696	e-mail from Wilshire to Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-697	e-mail from Thompson to Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-698	e-mail from Michel to FTCPayment	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-699	e-mail from Wilshire to Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-700	e-mail from Michel Thompson and Wilshire	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-701	e-mail from Pessalano to Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-702	e-mail chain between Wilshire and Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-703	e-mail chain between Michel and Wilshire	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-704	e-mail chain between Wilshire and Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2991	
RX-705	e-mail chain between Wilshire and Michel	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-706	OSU Compost Research group	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-708	Article by Knebusch	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-709	Umass Lowell Faculty and Staff	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	Center for biodegradable Polymer	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-710	Research			
RX-711	Center for Sustainable Research	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-712	Center for Sustainable Research	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-713	Center for Green Chemistry excerpt	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-714	OWS biogas plants	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-715	OWS Household Waste	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-716	US Patent 5883199 A	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-717	Certain Docs considered by Volokh	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-718	e-mail from Mojo to Davis	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-719	e-mail from Mojo to Davis	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-720	e-mail from Mojo to Koss	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-721	e-mail from Mojo to Frankle	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-722	e-mail chain between Frankle to Mojo	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-723	e-mail chain between Koss and Mojo	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-724	e-mail chain between Frankle and Mojo	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-725	e-mail chain between Frankle and Mojo	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-726	e-mail chain between Frankle and Mojo	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-727	e-mail chain between Frankle and Mojo	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-728	e-mail chain between Frankle and Mojo	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-729	e-mail chain between Frankle and Mojo	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-730	e-mail chain between Frankle and Mojo	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-731	Letter from FTC to Mojo	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-732	e-mail chain between Koss and Mojo	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-733	e-mail chain between Frankle and Mojo	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-734	Article by Aguirre	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-735	Submission # 00334	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-736	Song et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	E-mail chain between De Wilde and	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-737	Mojo			
RX-738	OWS Comments	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-740	Aliphatic-aromatic copolyester	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-741	e-mail chain between Johnson and Narayan	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-742	e-mail chain between Johnson and Brookover	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-743	e-mail from Narayan to Johnson	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-744	Letter from Mojo to Frankle	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-745	e-mail from Mojo to FTC	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-746	e-mail from Mojo to Koss	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-747	e-mails from Johnson	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-748	FTC Green guides for BioPlastics	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	e-mail chain between Johnson and	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-749	Narayan			
RX-750	Compilation of McCarthy Patents	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-751	Luckachan and Pillai	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-752	Considerations affecting biodegradability of PVC	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-753	McCarthy declaration	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-754	Response to Action	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-756	Patent Number 5,883,199	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1892	
RX-757	Metabolix steps up for UML	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-758	EASTER BIO news release	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-759	Center for biodegradable Polymer	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	Research 05			
RX-760	BPI and Metabolix web capture	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-761	Metabolix affiliations	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-762	Solutia becomes Eastman	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-763	Warner Lambert and BPI	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-764	Zheng et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-765	Iwamoto and Tokiwa	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-766	Roy et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-767	Shin et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-768	Linos et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-769	Russell et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-770	Vandevivere et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-771	McCarthy et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-772	Tutorial on Biodegradable Plastics	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-773	Gu et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-774	Gross and Gu	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-775	McCarthy et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-776	Farrell et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-777	Sheth et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-778	Gu et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-779	McCarthy et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-780	Kemnitzer et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-781	Wang et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-782	Koroskenyi and McCarthy	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-783	Shaked et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-784	Bhalakia et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-785	Parandoosh et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-786	Li and McCarthy	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-787	Biodegradable Polymers	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-788	Koroskenyi and McCarthy	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-789	Dave et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-790	Gross et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-791	Smith et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-792	Rios et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	e-mail chain between Meyer and	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-793	Frederick			
RX-794	Pew Research report	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-795	e-mail from APCO to FTC	JX-1-A, dated Sept. 4, 2014; Tr. 521		
	e-mail chain between Meyer and	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-796	Frederick			
RX-797	5/12/14 survey results	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-798	2/14/14 survey results	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-799	3/23/14 survey results	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-800	5/12/14 survey results	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-801	3/23/14 survey results	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-802	5/15/14 survey results	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-803	Ecologic Comments	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-804	e-mail chain between Meyer and Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-805	e-mail chain between Meyer and Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-806	e-mail from Saeed to Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-807	e-mail chain between Meyer and Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-808	Compilation of e-mails between Frederick, Meyer, and Saeed	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-809	e-mail chain between Meyer and Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-810	e-mail chain between Meyer and Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-811	e-mail from FTC to APCO	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-812	5/12/14 survey results	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-813	Google Consumer Surveys overview	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-814	e-mail from Klein to Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1287	
RX-815	e-mail chain between Meyer and Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-816	e-mail chain between Meyer and Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-817	5/15/2014 survey results	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-818	Chapman and Johnson	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-819	Tversky and Kahneman	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-820	Jacowitz and Kahneman	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-821	Englich et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-822	How the Questions Shape the Answers	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-823	Compilation of articles Critiquing Google Surveys	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-824	Tolaymat notes	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-825	Tolaymat notes	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-826	Tolaymat notes	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-827	ISO 14855-1	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-828	Tolaymat et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-829	Tolaymat et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-831	Barlaz et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-832	Musson et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-833	EPA Presentation	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-834	Tolaymat et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-835	Final Report for 3M test	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-836	NE Labs Report # N1048340	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1587-88, 1591	
RX-837	Colplast test	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-838	NE Labs Report # 1149980	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1571	
RX-839	Eden report to Shields	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1534-35	
RX-840	Deposition transcript of Ryan Burnette	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-0841	Deposition Transcript of Dr. McCarthy	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-0842	Deposition Transcript of Dr. Sahu	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-0843	Deposition Transcript of Dr. Stewart	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-0844	Survey Data	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2748, 2757, 2800	
RX-0844A	Subset of Survey Data RX-844	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2748	
RX-0845	Progress Report CSRS #32240 Environmental Study to D. Stewart from Y. Linares	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2698, 2703, 2719, 2724	
RX-0846	Table of Contents	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1086, 1088, 2718, 2724, 2771-72, 2779, 2795, 2801, 2810-11	
RX-0847	Environment Study Screenshot CSRS #32240	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1412, 2694, 2737, 2758, 2775, 2795	

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-0848	Manufacturers' Survey Screenshot CSRS #32241	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-0849	Data from Manufacturers' Survey	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-0850	Progress Report CSRS #32241 Environmental Study to D. Stewart from Y. Linares	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2815	
RX-0851	Deposition Transcript of Dr. Tolaymat	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 242	
RX-0852	Exhibit 4 to Frederick Deposition - Table of Survey Characteristics	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-0853	Expert Report of Dr. Morton Barlaz	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2170, 2175, 2194, 2196, 2294, 2299	
RX-0854	Expert Report of Dr. Ryan Burnette	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2370	
RX-0855	Expert Report of Dr. Ranajit (Ron) Sahu	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1737	
RX-0856	Expert Report of Dr. David Stewart	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1080, 2493, 2548, 2555, 2571, 2649-50, 2684, 2686	
RX-0857	Expert Report of Dr. Alexander Volokh	JX-1-A, dated Sept. 4, 2014; Tr. 521-**---Withdrawn from evidence**	Tr. 2475	
RX-0858	Deposition Transcript of Dr. Shane Frederick	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1189	
RX-859	Eden Report to FP	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-860	Eden Report to FP	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-861	Eden Report to MicroTek	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-862	Eden Report to EcoLab	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-863	NE Labs Report to Dansko	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-865	E-mail chain between Katherine Johnson and Mark Leen	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-866	Article by Brown and Marlar	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-867	US Census Bureau page	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-868	Article by Hamilton	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-869	Report by Keeter, et al	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-877	Feature or Bug? Google Consumer Surveys pre-fills in the Answer for You	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1105-06	
RX-878	4 mos after launch, pitiful Google Consumer Surveys struggles to find its footing	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-879	Google fixes 5 problems	JX-1-A, dated Sept. 4, 2014; Tr. 521		

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-880	Cure for Color Blindness Being Explored on Google Consumer Surveys	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-881	Google Consumer Surveys Begins to Hit Stride Locating Low-Incidence Populations	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-882	BBB Latest Group to Throw Away Money on Google Consumer Surveys	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-883	If we Deliver the Garnet Hill Catalog to you in Microfiche, would you think less of us then?	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-884	Obsession with Junk Clicks Continues to	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1370-01, 1373, 1376	
RX-885	Throw away all of these questions and start over…	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-886	Google Consumer Surveys Hidden Revenue Stream	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-887	Intuit Labs using Google Consumer	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-888	Google Consumer Surveys allows DIY Researchers to confuse check one and check all that apply	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-889	If at first you don't succeed with google consumer surveys, fail fail again	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1109	
RX-890	Harris Poll using Interns to analyze Google Consumer Surveys	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-891	Jobs? Did someone say job?	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-892	How many GCS are being taken by Google	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-893	All things being equal…	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-894	What part of Yes don't you understand?	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-895	The essence of DIY Google Consumer Surveys	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-899	Tolaymat Depo 4A	JX-1-A, dated Sept. 4, 2014; Tr. 521*	Tr. 337	
RX-900	Tolaymat Depo 4B	JX-1-A, dated Sept. 4, 2014; Tr. 521*	Tr. 337	
RX-901	Tolaymat Depo 4C	JX-1-A, dated Sept. 4, 2014; Tr. 521*	Tr. 337	
RX-902	Tolaymat Depo Exhibit 5	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-904	Tolaymat Depo Exhbit 7	JX-1-A, dated Sept. 4, 2014; Tr. 521*	Tr. 304	
RX-905	Tolaymat Depo Exhibit 8	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 267	
RX 906	Tolaymat Depo Exhibit 9	JX-1-A, dated Sept. 4, 2014; Tr. 521*	Tr. 240	
RX-908	Tolaymat Depo Exhibit 11	JX-1-A, dated Sept. 4, 2014; Tr. 521*	Tr. 291, 293	
RX-909	Tolaymat Depo Exhibit 12	JX-1-A, dated Sept. 4, 2014; Tr. 521*	Tr. 291	
RX-911	Tolaymat Depo Exhibit 14	JX-1-A, dated Sept. 4, 2014; Tr. 521*	Tr. 311	

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-918	Tolaymat Depo Exhibit 21	JX-1-A, dated Sept. 4, 2014; Tr. 521*	Tr. 325	
RX-919	Tolaymat Depo Exhibit 22	JX-1-A, dated Sept. 4, 2014; Tr. 521*	Tr. 324-25	
RX-920	Tolaymat Depo Exhibit 23	JX-1-A, dated Sept. 4, 2014; Tr. 521*	Tr. 327	
RX-921	Tolaymat Depo Exhibit 24	JX-1-A, dated Sept. 4, 2014; Tr. 521*	Tr. 330	
RX-923	McCarthy Depo Exhibit 1	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 636, 1772	
RX-924	McCarthy Depo Exhibit 2	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 488, 494, 514, 570-71,	
RX-925	McCarthy Depo Exhibit 3	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 511, 527, 643, 646, 667, 1873, 1875	
RX-926	McCarthy Depo Exhibit 4	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-927	McCarthy Depo Exhibit 5	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-928	McCarthy Depo Exhibit 6	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 535, 598, 649	
RX-929	McCarthy Depo Exhibit 7	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-930	McCarthy Depo Exhibit 8	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-931	McCarthy Depo Exhibit 9	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-932	McCarthy Depo Exhibit 10	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-933	McCarthy Depo Exhibit 11	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-934	McCarthy Depo Exhibit 12	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-935	McCarthy Depo Exhibit 13	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-936	McCarthy Depo Exhibit 14	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-937	McCarthy Depo Exhibit 15	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-938	McCarthy Depo Exhibit 16	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-939	McCarthy Depo Exhibit 17	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-940	McCarthy Depo Exhibit 18	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 578, 581	
RX-941	McCarthy Depo Exhibit 19	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 583	
RX-942	McCarthy Depo Exhibit 20	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 585	
RX-943	McCarthy Depo Exhibit 21	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-944	McCarthy Depo Exhibit 22	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-945	McCarthy Depo Exhibit 23	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 586	
RX-946	McCarthy Depo Exhibit 24	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 587	
RX-947	McCarthy Depo Exhibit 25	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-948	McCarthy Depo Exhibit 26	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 589	

RX	Description	Where Admitted	Tr. Pages Where Discussed	In Camera
RX-949	Frederick Depo Exhibit 1	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1192, 1269	
RX-950	Frederick Depo Exhibit 2	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1255	
RX-951	Frederick Depo Exhibit 3	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 1300-02	
RX-952	Frederick Depo Exhibit 4	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-953	Frederick Depo Exhibit 5	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-954	Frederick Depo Exhibit 6	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-955	Frederick Depo Exhibit 7	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-956	Frederick Depo Exhibit 8	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-957	Frederick Depo Exhibit 9	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-958	Frederick Depo Exhibit 10	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-959	Frederick Depo Exhibit 11	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-960	Frederick Depo Exhibit 12	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-961	Metabolix 2006 – Fee for Service Agreement	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 595	
RX-962	Metabolix 2008 – License Agreement	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 599	
RX-963	Metabolix 2012 - Letter	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 602	
RX-964	Metabolix 2014 - Letter	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 606	
RX-965	Umass-Metabolix License execution	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 599, 609	
RX-966	Metabolix e-mails	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 607	
RX-967	EPA web page	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 341	
RX-968	The attached excel sheet (can call ECM Anaerobic Degradability Analysis Summary Data)	JX-1-A, dated Sept. 4, 2014; Tr. 521		
RX-969	The Influence of Injection Molding Conditions on Biodegradable Polymers	Tr. 644-45	Tr. 643-45	
RX-970	Michel Deposition Transcript	JX-1-A, dated Sept. 4, 2014; Tr. 521	Tr. 2821	

*Referenced at hearing as RX document, but on JX-1-A as CCX document

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF THE ADMINISTRATIVE LAW JUDGES
Washington, D.C.

In the Matter of **ECM BioFilms, Inc.,** **a corporation, also d/b/a** **Enviroplastics International,** **Respondent.**	**Docket No. 9358** **PUBLIC**

RESPONDENT ECM BIOFILMS' POST-TRIAL BRIEF

Jonathan W. Emord, Esq.
Emord & Associates, P.C.
11808 Wolf Run Lane
Clifton, VA 20124
Ph: 202-466-6937
Fx: 202-466-6938
Em: jemord@emord.com

Peter A. Arhangelsky, Esq.
Eric J. Awerbuch, Esq.
Bethany R. Kennedy, Esq.
Joshua Furman
Emord & Associates, P.C.
3210 S. Gilbert Road, Ste 4
Chandler, AZ 85286
Ph: 202-466-6937
Fx: 602-393-4361
Em: parhangelsky@emord.com, eawerbuch@emord.com,
bkennedy@emord.com

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Rules

Regulations

8

I. SUMMARY OF THE CASE

As the charging party for the agency, Complaint Counsel bears the burden of production. *Chicago Bridge & Iron Co. N.V. v. F.T.C.*, 534 F.3d 410, 425 (D.C. Cir. 2008) (quotation omitted) ("The burden of production is the obligation to come forward with evidence of a litigant's necessary propositions of fact"). At a minimum, that burden requires the calling of fact witnesses sufficient to state a prima facie case of deceptive advertising under Section 5 of the FTC Act. *See, e.g., Cooper v. Salazar*, 196 F.3d 809, 815 (7th Cir. 1999) (holding that an effective opportunity for cross-examination is required by the Due Process Clause where the ultimate decision necessarily requires important credibility determinations). Complaint Counsel has failed to satisfy that fundamental burden. Despite deposing over 19 fact witnesses in the pre-hearing phase, Complaint Counsel called not a single one at hearing, resting their case exclusively on the testimony of four expert witnesses. That decision has proven fatal because the resulting record is devoid of foundational facts necessary for Complaint Counsel to meet the elements of their case. Having not pled facts sufficient to meet the elements of their case, Complaint Counsel must undergird their legal argument with speculation, thus failing to meet their burden of proof. 16 C.F.R. § 3.43(a) ("Counsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto."); *see also* 5 U.S.C. § 556(d) (explaining that "the proponent of a rule or order has the burden of proof"); *In re ECM Biofilms*, Order on Post-Trial Briefs, Dkt. 9358 (Sep. 3, 2014), at 3 (The parties were instructed to "not cite to expert testimony to support factual propositions that should be established by fact witnesses or documents").

The following facts had to be adduced from testimony at the hearing to meet Complaint Counsel's burden of production, but were not: (1) facts sufficient to show that at least a

significant minority of those who purchased the ECM additive did so in reliance on a rate claim (the now defunct claim that plastics infused with the additive would biodegrade within 9 months to 5 years or the claim that plastics so diffused would biodegrade in some period greater than a year); (2) facts sufficient to show that at least a significant minority of those who purchased the ECM additive did so with the expectation that it would cause plastics so infused to biodegrade completely within one year after customary disposal, meaning that it would cause 100% of the plastic to be broken down into elements in nature within that time period; (3) facts sufficient to show that at least a significant minority of those who purchased the ECM additive considered the rate of biodegradation material to their purchase; (4) facts sufficient to show that at least a significant minority of those who purchased the ECM additive considered material to their purchase a complete break down of the ECM additive infused plastic into elements found in nature; and (5) facts sufficient to show that ECM lacked a reasonable basis for the claim that the ECM additive causes plastics to biodegrade faster than plastics not containing the additive. On those five essential elements of factual proof Complaint Counsel has not a shred of credible evidence in the record. Accordingly, based solely on a failed burden of production, the Complaint should be denied because in light of that failure Complaint Counsel cannot satisfy their burden of proof and any cease and desist order and any fencing in provision would therefore be arbitrary and capricious, an abuse of agency discretion, and a violation of the free speech rights of the respondent on this record.

Complaint Counsel's case collapses in the end because Complaint Counsel never did prove at all, let alone by the requisite preponderance of the evidence, that ECM's actual customers, or a significant minority of them, were recipients of a deceptive advertising message material to their purchasing decisions. Not one shred of reliable evidence exists that actual

customers considered any claim made by ECM material to a purchase, other than the general claim of biodegradability. *See* Respondent ECM's Proposed Finding of Facts at ¶¶ 1–3003 (hereinafter "RPFF"). Not even a significant minority of ECM customers has been shown to have made a purchasing decision on the basis of anything other than an understanding that plastics infused with the ECM additive are more biodegradable than plastics not so infused, which the scientific record reveals to be demonstrably true (i.e., to be supported by at least a reasonable basis). (RPFF ¶¶ 296–725). Not even a significant minority of end use consumers has been shown to purchase ECM infused plastics, as opposed to obtain them for free, and to be aware of ECM, its claims, or the fact that any of the plastics they have obtained and used are those of ECM. Of those who obtain plastics at retail, there is no evidence that even a significant minority have any common understanding of the term biodegradable or any common conception of a set rate for biodegradation of plastics. (RPFF ¶¶ 1105–1344).

The record confirms that ECM spends only about $12,000 per year on advertising, the vast majority of which goes to pay to maintain the ECM web site. (RPFF ¶ 300). The web site is designed for its plastic manufacturer customers; ECM does not sell to end use consumers and its product is not available for purchase to them in any online venue, including, e.g., Amazon.com. (Sullivan, Tr. 765–66). The record confirms that ECM's customers are not lay consumers but are sophisticated plastics manufacturers who themselves have downstream business or retail customers, often two or three levels removed from end use consumers. (Sullivan, Tr. 904; RPFF ¶¶ 296–432). The record confirms that these customers test the ECM additive and engage in a period of assessment in reliance on their own scientists, engineers, lawyers, and marketing people that spans a period of six months to several years before ever purchasing and including the ECM additive in their plastic products. (RPFF ¶ 355). The record

confirms that in almost every, if not in every, case those customers predicate their purchasing decisions not on what ECM tells them but on their own assessment of the ECM product. (RPFF ¶¶ 355–367). Given their sophistication and the fact that they base their purchase on their own evaluation, including testing, this case is fundamentally one in which advertising material to a purchase is not in issue. Indeed, because the record reveals the purchase to be made based on a sophisticated independent assessment and not a paid for advertising message, the content here in issue does not even meet the definition of "advertising" and, even if it did, the facts do not support a conclusion that the "advertising" was material to a purchase (which materiality hinges instead on these sophisticated purchasers own, lengthy evaluations of actual samples of the product). (RPFF ¶¶ 296–739).

There is scant evidence that any claim made by ECM to its actual customers ever reaches end use consumers when they receive a plastic product containing the ECM additive, and there is no evidence that end use consumers purchase the finished plastic products here in issue or, if they do, purchase ones that bear overt labeling that associates the products with ECM or any claim. (RPFF ¶¶ 296–725). Complaint Counsel came up with several rare exceptions at hearing, but those examples represent a very small fraction of ECM products in the market, those products were given away and not "sold" to any consumer, and there is no evidence of any kind in the record that, in those limited situations, customers considered those claims material to any purchasing decision.

Most, if not all, of the ultimate retail customers of ECM's plastic manufacturer customers distribute the ECM infused plastic products, such as plastic bags, to end use consumers free of charge. (Sinclair, Tr. 765–67). The record fails to show that even a significant minority of ECM's customers who manufacture plastics or those manufacturer's ultimate wholesale and

retail customers include on plastics any identification of ECM and any claim whatsoever, including any claim of biodegradation or rate of biodegradation. (RPFF ¶¶ 296–725). Complaint Counsel offered no evidence of the frequency or amount of ECM rate claims and logos that appear in the market, except to offer several rare examples. Certainly Complaint Counsel offered no proof to establish that even a significant minority of end use consumers has any knowledge of ECM or any claim made by ECM and, indeed, the only survey evidence on that point, from ECM survey expert Dr. David Stewart, confirms that they lacked that familiarity. (RPFF ¶¶ 1105–1344).

To be sure, based on the Stewart survey evidence, those end use consumers do not have any common understanding of the meaning of the term biodegradation or any common understanding that plastics labeled biodegradable will biodegrade within any specific time frame. (RPFF ¶¶ 1105–1344).

The uncontroverted record establishes that ECM's actual plastic manufacturer customers are indeed sophisticated, having their own engineers, scientists, lawyers, and marketing departments. (RPFF ¶¶ 356, 417–18). They take between 6 months to several years to evaluate the ECM additive before making a decision to purchase the ECM product. (Sullivan, Tr. 703–04). ECM's customers test the ECM product themselves before infusing it into the plastics they sell. (Sinclair, Tr. 761–63; Sullivan, Tr. 704–05). The record confirms that ECM engages in extensive communication with its customers, encouraging them to test the product to determine its biodegradability, transparently supplying them with the scientific evidence ECM possesses, explaining that biodegradation of any particular piece of plastic infused with the ECM additive will occur over time and that no set rate or time can be predicted for any given piece of ECM additive infused plastic (that being dependent upon where the plastic ends up in the environment

and the ambient temperature, moisture, and other biodegrading matter conditions at that location). (*See e.g.*, RPFF ¶¶ 419–426). Nearly all of the 30+ of the positive ASTM D5511 tests concerning biodegradation that are in evidence, (RPFF ¶¶ 2129–2706), are not ones ECM ordered but are independent, critical evaluations of ECM additive infused plastics by ECM customers that wished to determine before purchase if the additive would cause their plastics to biodegrade. Note well that not a single one of those tests endeavored to determine an actual rate of biodegradation rather than intrinsic biodegradability, evincing vital secondary, confirmatory proof that ECM's customers purchased the product based on concern for the fact of biodegradation, not the rate of biodegradation. (RPFF ¶¶ 2129–2706).

When it comes to the meaning of biodegradation, the record is likewise very clear. The meaning ECM conveyed to its customers in association with that term is spelled out, quite literally, in the certificate of biodegradability ECM issued to every one of its customers after they confirmed manufacture of their plastics in strict accord with ECM's manufacturing instructions. (RPFF ¶ 320; CCX 1). That definition given to ECM's customers reads as follows:

> A Degradable Plastic is defined (ASTM 1991) as a plastic that is designed to undergo a significant change in its chemical structure under specific environmental conditions resulting in a loss of some properties that may vary as measured by standard test methods appropriate to the plastic and the application in a period of time that determines its classification. A Biodegradable Plastic is defined as a degradable plastic in which the degradation results from the action of naturally occurring microorganisms such as bacteria, fungi and algae.

(*See, e.g.,* CCX 1 (ECM Certificate of Biodegradability)).

That definition does not mirror the one adopted by the Commission in the Green Guides at 16 C.F.R. § 260.8(c), which reads: "Unqualified claims for items that are customarily disposed in landfills, incinerators, and recycling facilities are deceptive because these locations do not present conditions in which complete decomposition will occur within one year." 16 C.F.R. §

260.8(c); *In re ECM Biofilms*, Complaint, Dkt. No. 9358, at 12 ¶ 4(A)–(B). It is that Green Guides' definition that Complaint Counsel insists must be adopted by the Administrative Law Judge in this case, despite the fact that no ECM customer was ever told by ECM that the Green Guides' definition applied to the ECM product and despite the fact that competent survey evidence refutes the notion that either consumers or ECM's own customers shared any common expectation that the term biodegradable connotes complete break down of the plastic into elements in nature within one year after customary disposal.

Rather, the only definition given to each customer by ECM is the one contained in ECM's Certificate of Biodegradability. (CCX 1; *see also* RX 35–77 (example emails sent by ECM to customers explaining the regulatory landscape following revisions to the Green Guides)). That definition, which is the present ASTM definition for the term and comports with the definitions contained in the scientific literature in this case (RPFF ¶¶ 767–817), sets no time limit on the process of biodegradation and does not require 100% break down of the plastic into elements found in nature.[1]

This Court need not adopt the definition in the Green Guides if, indeed, it is understood not to be a Commission rule but, rather, a guidance, as the Green Guides itself proclaims: "The guides … do not confer any rights on any person and do not operate to bind the FTC or the public." 16 C.F.R. § 260.1(a). That is because the given definition of ECM is, itself, a qualification revealing no rate limit and no assurance of 100% break down.

[1] *Compare* RPFF ¶¶ 767–817 (citing broad definitions of "biodegradable" accepted by the scientific community), *and* Tolaymat, Tr. 130 (citing broad definition of "biodegradable"), *and* Michel, Tr. 2907–08 (broad definition of "biodegradable"), *and* Sahu, Tr. 1760 (broad definition of "biodegradable"), *and* Barlaz, Tr. 2281 (same), *and* Burnette, Tr. 2376 (same), *and* Barber, Tr. 2069 (same), *with* (RX 841 (McCarthy, Dep. at 20)) (McCarthy and Complaint Counsel's narrow definition of "bioedegradable").

Were the Administrative Law Judge to hold, as Complaint Counsel insists, that the Green Guides' definition is despite its Green Guides' label, an actual rule of decision and to apply it in this case (hereinafter we refer to it as the "One Year Rule"), then the Administrative Law Judge must of necessity must evaluate that rule under the rulemaking requirements of Magnusson Moss, *see* 15 U.S.C. § 57a, and under the Administrative Procedure Act. *See* 5 U.S.C. § 553. Under the rulemaking requirements, the adoption of the One Year Rule by guidance and not through the process specified in 15 U.S.C. § 57a violates the law and, thus, the One Year Rule still cannot serve as a rule of decision.[2] Even if it were deemed to satisfy the rulemaking requirements, the One Year Rule is nevertheless arbitrary and capricious as applied in this case, because the record reveals that it results in absurd distinctions and is grossly inconsistent with not one, not most, but all of the peer-reviewed scientific definitions of biodegradable plastics in the record. (RPFF ¶¶ 460–510). Indeed, adherence to the One Year Rule results in absurd conclusions that bananas, banana peels, orange peels, tree trunks, and paper are not biodegradable when generally accepted scientific evidence is to the contrary. (McCarthy, Tr. 506–509). Adherence to the One Year Rule results in the draconian and irrational rule of decision that a plastic which biodegrades to 95% on the 365th day after customary disposal is not biodegradable even if biodegradation of that same plastic reaches 100% on the 366th day. (McCarthy, Tr. 495–96, 525–26; RX 841 (McCarthy, Dep. at 28)). Indeed, the record evidence reveals that virtually no substance, and certainly no plastic, can reliably break down into elements found in nature within one year after customary disposal, thus exposing the rule to be indistinguishable with an actual ban on every biodegradable plastics claim (and by dint thereof

[2] For example, because the FTC did not properly characterize the industry rule as a Trade Regulation Rule under Section 57a, the Commission did not apparently notify and seek input from the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Energy and Commerce of the House of Representatives. *See* 15 U.S.C. § 57a(2).

every biodegradable plastic product) for the record reveals no evidence that any plastic can reliably biodegrade to the extent of breaking down completely into elements found in nature within one year.[3] The record reveals no evidence that when biodegradable plastics (or compostable products for that matter) break down in nature they do so to the point of causing every molecule of plastic to be converted into an element found in nature, rather than for some of the plastic to remain as a residue (a residue that is in nearly every respect indistinguishable from common dirt). (Michel, Tr. 2960–62). What public interest is served by the FTC banning the term biodegradable from products that effect biodegradation of plastics in 2 years, 3 years, 4 years, a decade, or even 100 years, when conventional plastics not treated may remain in the environment for hundreds or thousands of years? (Sahu, Tr. 1758–59; CCX 891 at ¶ 17). What public interest is served by the FTC banning the term biodegradable from products that effect biodegradation of plastics to the extent of eliminating most or nearly all of them but not 100% of them?

Moreover, the agency's own experts are hopelessly conflicted in their efforts to defend the One Year Rule. That effort to defend the One Year Rule against the prevailing science to the contrary revealed FTC's lead scientific expert McCarthy to be a biased and unreliable witness. At trial McCarthy was impeached repeatedly when he testified in conflict with his deposition testimony that certain obviously natural and biodegradable substances are not "biodegradable." (McCarthy, Tr. 503, 506, 508–09, RX 841 (McCarthy, Dep. at 187)). Following testimony revealing that he could not cite a single peer-reviewed scientific article in which scientists defined biodegradation as FTC had in the Green Guides (or as he himself did in Footnote 1 to his Expert Report)—that despite the false affirmative avowal in his Expert Report at footnote 1 that

[3] *See, e.g.*, Tolaymat, Tr. 247–48 (explaining that even "rapidly degrading" waste is expected to take no less than ten years to biodegrade in a landfill).

Complaint Counsel's One Year Rule and the scientific definition of the term biodegradable were "interchangeable," (McCarthy, Tr. 486)—Dr. McCarthy asked if it was too late to change his definition of the penultimate term in issue "biodegradable." (McCarthy, Tr. 496). Even in McCarthy's own professional writings, he never once defined biodegradation as the FTC has in the Green Guides (and as Complaint Counsel did in footnote 1 to McCarthy's Expert Report). (RPFF ¶¶ 1362–1369). Moreover, no other scientist at hearing or in this field defined the term as FTC has. (RFPP ¶¶ 460–510).

There is no evidence that a significant minority of ECM customers ever considered material to a purchasing decision any claim here in issue other than the one that plastics infused with the ECM additive would biodegrade. (RFPP ¶¶ 798–1037). Indeed, the evidence overwhelmingly confirms that ECM's actual customers did not consider rate of biodegradation material to their decision to purchase and did not rely on any claims of rate in making a purchase. (RFPP ¶¶ 1038–1328). The purchase was predicated on their view, informed most commonly by their own critical testing of plastics infused with the ECM additive, that the ECM additive causes plastics to biodegrade faster than untreated plastics. (RFPP ¶¶ 1038–1328). They were not concerned with the rate of biodegradation, and with good reason. Rapid biodegradation within one year of customary disposal (to the level of breaking down the plastic into elements in nature) increases greenhouse gases, adversely affecting the environment. (RFPP ¶¶ 1592–1603).

Consequently, Complaint Counsel is obliged to construct their case based on assumptions and inferences which are neither factually nor legally competent. They recite the following sets of claims they say ECM made to its customers:

- ECM Plastics are biodegradable, *i.e.*, will completely break down and decompose into elements found in nature within a reasonably short period of time after customary disposal;

- ECM Plastics are biodegradable in a landfill;

- ECM Plastics are biodegradable in a stated qualified timeframe; and

- ECM Plastics have been shown to be biodegradable, biodegradable in a landfill, or biodegradable in a stated qualified timeframe under various scientific tests including, but not limited to, ASTM D5511.

See In re ECM Biofilms, Complaint, at 8, Dkt. 9358.

They presume the claims were all material to a purchasing decision by those customers but, despite ECM survey evidence confirming no materiality, they never rebut that proof. By contrast, multiple forms of evidence from direct customer testimony to Dr. Stewart's surveys of ECM customers and consumers prove that claims of rate of biodegradation were neither relevant nor material to even a significant minority of either.

Complaint Counsel presume that a subset of inconclusive test results involving plastics infused with the ECM additive is the same as affirmative proof that the ECM additive does not cause plastics to biodegrade, but they never competently investigated the inconclusiveness in any of those tests, including that of their own consultant, Dr. Frederick Michel. They never undertook any scientific evaluations to determine the actual cause of the inconclusive results to rule out the commonly expected failings arising from: death of the microbes in the inoculum, mis-manufacture of the plastic, or the presence in the test plastic of other additives or fillers that may contain anti-microbial agents, to name a few. They condemn all 30+ independent tests of the ECM additive that show biodegradation of the plastic infused with the additive without scientific foundation and without any analysis of the data derived from the tests.

Having failed to prove that the product does not biodegrade, they nevertheless presume that at least a significant minority of ECM customers purchased the ECM additive on the assumption that it would cause the plastics to biodegrade within one year after customary disposal or, if not that, within 9 months to 5 years after customary disposal, and yet even their own depositions of ECM customers fail to support that conclusion with deponent after deponent denying that rate claims were either material or relevant to their purchase of the ECM additive. (RPFF ¶¶ 1038–1350).

Having failed to prove that plastics infused with the ECM additive do not biodegrade and having failed to prove that ECM's actual customers depend on rate claims as a basis for their purchase of the additive, Complaint Counsel presume that at least a significant minority of those to whom ECM does not sell its product, i.e., end use consumers, harbor an understanding that plastics containing the ECM additive biodegrade within one year after customary disposal. Fundamentally, however, Complaint Counsel has not presented factual evidence, let alone proven, that at least a significant minority of end use consumers even understand whether plastics they have obtained (most commonly not by purchase) are ECM plastics or are biodegradable. Complaint Counsel's survey expert, Dr. Shane Frederick, asked no screening questions in his single question Google Consumer Surveys and, thus, did not qualify his survey respondents in a way that would reveal whether any of them were aware of whether any of the plastic products with which they have come into contact are biodegradable or contain ECM's additive or bear an ECM claim. (Frederick, Tr. 1224–25; RPFF ¶ 602).

In that regard, there is no record evidence revealing what quantity of plastics in the market are ones infused with the ECM additive and, of those, which ones contain any logo or claim by ECM. ECM itself is not aware of that information because its customers are ordinarily

too far removed from retail.[4] There is no record evidence establishing whether a significant minority of consumers has ever seen an ECM claim on a plastic infused with an ECM additive or has ever visited the ECM web site and associated an ECM claim there with a plastic product in the market that they have obtained (the web site presents no such information in any event). (RX -82) (ECM website captures)).

Although Dr. Shane Frederick performed Google Consumer Surveys and represents that a significant minority of consumers understand the term biodegradable to mean that products will biodegrade in one year or less, (CCX 890 (Frederick, Rep. at 1)), he is biased and his surveys are unreliable (as explained more fully below), failing to satisfy any of the principles required for competent survey research. (RPFF ¶¶ 572–798). The only competent survey research in this case, that of Dr. Stewart whose surveys and opinions the FTC and Administrative Law Judges within the FTC have repeatedly credited, reveals that consumers do not by a significant minority share any common definition of biodegradation or any common view of the rate at which plastics biodegrade. (RPFF ¶¶ 799–1038). In the end, however, the critical basic element of evidence, that a significant minority of consumers have even seen, let alone acquired, a plastic bearing an ECM logo or claim in the market is lacking.

In the end, Complaint Counsel has failed to prove by a preponderance of the evidence that a significant minority of ECM customers or consumers were deceived by any claim made by ECM. The only claim made to ECM's actual customers, and not proven to be associated in the market by even a significant minority of consumers who have obtained plastics containing the ECM additive, is that the ECM additive causes plastics infused with it to be more biodegradable than plastics without it, which claim is demonstrably true based on the testimony of three experts

[4] *See, e.g.*, Sinclair, Tr. 703–04, 707, 759; Sullivan, Tr. 696; RPFF ¶¶ 386–392.

(an environmental scientist, a plastics engineer, and a biochemist) and over 30+ independent tests showing biodegradation. The evidence concerning product efficacy points decidedly in favor of the Respondent, establishing its claim of biodegradation to have more than a reasonable basis sufficient to support the biodegradation claim. The totality of the scientific evidence establishes more than a reasonable basis, and at least competent and reliable scientific evidence, that plastics infused with the ECM additive (in accordance with ECM manufacturing instructions and at a 1% load rate) will biodegrade within a reasonably short period of time under conditions of customary disposal, particularly when compared with conventional, untreated plastics. (RPFF ¶¶ 1964–2009, 2129–2885). The totality of the scientific evidence, including generally accepted science on microbiological mechanisms that degrade plastics and on biodegradation in landfills as well as at least dozens of separate biodegradation tests and assessments of the ECM additive by the plastics industry, establish more than a reasonable basis, and at least competent and reliable scientific evidence, that ECM's additive causes biodegradation of the most widely used plastic resins in the external environment, including in landfills.

II. PRESENTATION OF EVIDENCE

The hearing convened in Docket Number 9358 on August 5, 2014. (RPFF ¶ 33). The evidentiary hearing was completed on August 29, 2014, and the record closed on September 4, 2014. (RPFF ¶ 36–7). Complaint Counsel chose to call no fact witnesses in support of its case. (RPFF ¶ 256). Although having taken 29 depositions, and having designated all of those witnesses in its final witness list, Complaint Counsel never called a single one to testify. (RPFF ¶¶ 31, 256). In many instances, because of the massive cost involved with the over-burdensome deposition schedule, ECM was not financially able to have its counsel appear at deposition, or had to limit its counsel's appearance to telephone. (RPFF ¶ 32). Although that was ECM's

choice, it was borne of economic necessity and Complaint Counsel sought to exploit that fact by leaving fact witnesses out of the courtroom, thus preventing ECM from having an effective opportunity to cross examine those witnesses at hearing. Regardless, as explained in more detail below, those deposition transcripts must be devalued because the FTC has made no showing that the witnesses were unavailable to appear at hearing, the Administrative Law Judge has been denied an opportunity to adjudge in person their testimony (essential for credibility findings), and opposing counsel has been denied a full and fair opportunity to adduce additional material facts through cross-examination at hearing necessary to determine the relative weight of testimony given. Nevertheless, in the vast majority of cases, the deposition transcripts actually cut against Complaint Counsel and support ECM's case in that witness after witness stated that his or her company had no concern for the rate of biodegradation. (RPFF ¶¶ 360, 1114–17, 1219–22, 1226–27, 1239–42, 1248, 1250–53, 1259–63, 1279–82, 1284, 1295–1301).

A. Respondent's Experts

ECM called four expert witnesses to testify in its defense. (RPFF ¶¶ 151, 182, 201, 217). Dr. Ranaji Sahu, an environmental, mechanical, and chemical engineer, testified concerning the mechanisms of action involved in plastics biodegradation and the totality of the scientific evidence concerning biodegradation of plastics in general and biodegradation of ECM additive infused plastics in particular, concluding that competent and reliable scientific evidence in the form of 30+ biodegradation tests of plastics containing the ECM additive confirm that the additive causes plastics to biodegrade faster than they would without the additive. (RPFF ¶¶ 152, 1631–32, 1722). Dr. Morton Barlaz, a civil and chemical engineer considered an authority on landfills and biodegradation of plastics in landfills, testified that landfills are not dry tombs but are biologically active and hospitable environments where biodegradation of plastics can and

does occur; that statistical analysis of the tests of biodegradation of plastic containing the ECM additive proves that the plastics themselves (and not simply the ECM additive) biodegraded by statistically significant amounts; and that the so-called "priming effect" (wherein only the additive is said to biodegrade) is not applicable in the anaerobic context and, in any event, is refuted by the evidence of plastic biodegradation in the 30+ tests of the ECM containing plastics that he reviewed. (RPFF ¶¶ 187–8, 1810, 1855–56, 2021, 2025–27).

Dr. Barlaz also testified to direct familiarity with the testing labs that performed tests on ECM additive containing plastics, Eden Labs and Northeast Labs, confirmed the propriety of their testing methods, and explained that the D5511 tests performed there are appropriate tests to determine whether the ECM additive predictably causes biodegradation of plastics in landfills. (RPFF ¶¶ 2211–16, 2430–31). Dr. Ryan Burnette, a biochemist, explained the mechanism of action by which microbial life attracted by the ECM additive to plastics biodegrade those plastics, identifying in detail the precise species of microbial life that are in landfills which produce enzymes known to biodegrade plastics and the precise role played by the ECM additive in attracting that life (bacteria and fungi), enabling them to affix themselves to the plastic, facilitating their formation of colonies, and resulting in the production by those life forms in those colonies of specifically identified enzymes scientifically documented to break down the carbon chains of plastics and result in the dissolution of them (biodegradation). (RPFF ¶¶ 202, 204, 2040, 2050, 2071, 2087-91, 2117, 2120).

Dr. David Stewart, a survey expert, testified concerning the telephone surveys with live interviews he caused to be conducted of 400 randomly selected and age-adjusted respondents concerning the extent to which the public (and, in a second survey, plastic company purchasers of the ECM additive), was aware of the ECM claims, had a common understanding of the term

biodegradation, and had a common view of the time plastics take to biodegrade in nature, (RPFF ¶¶ 217–55, 980–81, 997). He concluded that there was no common awareness or common definition among even a significant minority of respondents. Dr. Stewart also evaluated the Google Consumer Surveys performed by Dr. Shane Frederick for Complaint Counsel, concluding those surveys to be incompetent for failure to satisfy the seven accepted principles of survey research. (RPFF ¶¶ 217, 611). Dr. Stewart additionally testified about the APCO and Synovate surveys referenced as a basis for the One Year Rule specified in the FTC's Green Guides, deeming both incompetent. (RPFF ¶ 805).

ECM moved this Court for leave to call a surrebuttal expert, Dr. Grossman, a colleague of Complaint Counsel expert Dr. Stephen McCarthy, who teaches in the same department at UMass Lowell as Dr. McCarthy and is a professor of plastics engineering and a patent attorney. This Court ruled that Dr. Grossman not be permitted to testify in surrebuttal.[5] Had he testified, Dr. Grossman would have refuted key sections of Dr. McCarthy's scientifically erroneous testimony and revealed additional key inconsistencies in his testimony as compared to the patent he swore to be true and complete to the United States Patent and Trademark Office. An offer of proof for the reviewing authority was made, consisting of the report and affidavit of Dr. Grossman, which contains the substance of what he would have testified. (Tr. 2821).

1. Dr. Ranajit Sahu

Dr. Ranajit "Ron" Sahu, Ph.D. has more than twenty years of experience in environmental, mechanical, and chemical engineering. (RPFF ¶ 164). Dr. Sahu obtained his M.S. and Ph.D. in Mechanical Engineering from Caltech in Pasadena, CA. (RPFF ¶¶ 152, 155).

[5] *See In re ECM Biofilms*, Order on Respondent's Combined Motion for Sanctions, To Exclude Expert Witness, and for Leave, Dkt. No. 9358 (July 23, 3014).

Dr. Sahu studied polymer chemistry as part of his undergraduate and graduate coursework in material sciences (requisite to his degrees in mechanical engineering). (RPFF ¶¶ 153–54, 156). As a consultant and researcher, Dr. Sahu has been involved in, *inter alia*, landfill containment and remediation, emissions studies, and plastic polymer degradation with a focus on containment. (RPFF ¶¶ 168–72). He has worked for multinational engineering and technical firms like Parsons Corporation. (RPFF ¶¶ 161–63, 166). He has held various adjunct teaching positions at several California Universities including UCLA, UC Riverside, Loyola Marymount University, USC, Cal State Fullerton, and Caltech. (RPFF ¶ 174).

Dr. Sahu consults for private and government clients, including the U.S. EPA, the U.S. Department of Justice, and the states of New York, New Jersey, Connecticut, Pennsylvania, and New Mexico, among others. (RPFF ¶ 173). Concerning polymer science, Dr. Sahu has performed numerous projects over the past sixteen years involving aspects of polymer behavior in the environment. (RPFF ¶¶ 165–67). Some of those projects included plastics compatibility with fuels, safety issues related to plastics and fire, and environmental containment issues like permeation. (Sahu, Tr. 1740). Those projects required a well-developed knowledge of plastics chemistry, morphology, and function. (Sahu, Tr. 1740–41).

Dr. Sahu supported his opinion in this case not only with his knowledge of chemistry and material science but also with peer reviewed literature, much of which is quoted in his expert report. (RX 855 (Sahu, Rep.)). He reviewed hundreds of scientific publications concerning the degradability of plastic polymers and the biological mechanisms that support same. (RPFF ¶¶ 1632–33, 1729). Dr. Sahu reviewed all of the relevant tests concerning ECM plastics, and reviewed all available underlying raw data. (RPFF ¶ 1632). He contacted laboratories as part of his research on testing methodologies.

Dr. Sahu offered an opinion on the biodegradability of plastics. (RPFF ¶ 1731). Specifically, he testified that conventional plastics are capable of biodegradation, although at slow, almost negligible rates. (RPFF ¶¶ 1731–32). He explained that the ECM additive accelerates the natural biodegradation mechanisms for those plastics and creates additional weak points in the plastic that facilitate biodegradation. (RPFF ¶¶ 1722, 1724–27) He examined the relevant test data in this case, and he concluded that competent and reliable evidence proves that the ECM additive substantially accelerates plastics biodegradation, creating "biodegradable" polymers. (RPFF ¶ 1809)

2. Dr. Morton Barlaz

Dr. Morton Barlaz, Ph.D., has a B.S. in Chemical Engineering, and an M.S. and Ph.D. in Civil and Environmental Engineering. (RPFF ¶ 187). The academic focus of his graduate degrees was on biodegradation in landfills. (RPFF ¶ 188). He is the head of the Department of Civil, Construction, and Environmental Engineering at North Carolina State University. (RPFF ¶¶ 185–86). He has published at least 115 articles in the peer reviewed literature, most of which concern landfill science, biodegradation, landfill gas, or similar issues related to waste disposal and material degradation. (RPFF ¶ 189). Dr. Barlaz has been involved in researching solid waste issues since 1983. (RPFF ¶¶ 186, 191–95). An award-winning professor and researcher, Dr. Barlaz has also served as an editor for two prominent journals in the field of waste management and environmental engineering. Dr. Barlaz has been hired by the EPA as an expert in the fields of waste management and biodegradation. (RX 853 (Barlaz, Rep. at 27–8)). As a leading global authority in the field of waste management, Dr. Barlaz has advised Complaint Counsel's own witness (Dr. Tolaymat) on issues of biodegradation. (RPFF ¶¶ 197–200).

Dr. Barlaz offered an expert opinion concerning biological activity in modern landfills, finding landfills not to be "dry tombs" but to be replete with biological activity. (RPFF ¶¶ 1810, 1833, 1846-–56, 1860–61). Dr. Barlaz explained that the amount of biological activity in most U.S. landfills is substantial, as evidenced by the significant rates of methane production in landfills across the country. (RPFF ¶¶ 1836–37, 1840–41, 1846–49). Dr. Barlaz rejected many aspects of Complaint Counsel's landfill expert, Dr. Tolaymat's opinion, finding Dr. Tolaymat's discussion of "dry tomb" landfills to be misleading and erroneous. (RPFF ¶¶ 1860–61).

Dr. Barlaz also offered an opinion concerning the biodegradation testing performed on ECM plastics. (RPFF ¶¶ 1965–69). Dr. Barlaz performed a detailed statistical analysis of test data provided by laboratories that tested ECM plastics. (RPFF ¶¶ 1968, 1973, 1976–93). He testified that test evidence showing biodegradation of plastics infused with the ECM additive was of the same kind and quality of evidence upon which competent experts in the field often rely. (RPFF ¶¶ 1694–65, 1967–69). He concluded that, based on the data, the ECM infused plastics had clearly biodegraded far in excess of any amount that could be attributed solely to the additive or the test environment. (RPFF ¶¶ 1972, 1978, 1984, 2000–02). He testified that the D5511 tests performed on the ECM additive wherein biodegradation of the additive containing plastics was shown were appropriate predictors of biodegradation of those same plastics in landfills. (RPFF ¶¶ 1906–09). He concluded, therefore, that competent and reliable scientific evidence exists showing that ECM plastics are biodegradable in landfills. (RPFF ¶ 2001).

3. Dr. Ryan Burnette

Dr. Ryan N. Burnette, has a B.S. in Biochemistry, with minors in chemistry and environmental science, and a Ph.D. in Biochemistry and Molecular Biology—all from Virginia Tech's Department of Biochemistry and the Fralin Biotechnology Center at V.A. Tech. (RPFF

¶¶ 202, 204). He was an NIH fellow at Vanderbilt University's School of Medicine in the Department of Molecular Physiology and Biophysics. (RPFF ¶ 207). His biochemistry studies at Virginia Tech focused on biochemistry in the Department of Biochemistry which was commonly termed the "anaerobe lab," one of the nation's oldest and well-respected anaerobic microbiology departments, where he focused his research on signal transduction in anaerobic facultative bacteria. (RPFF ¶¶ 205–06, 209; Burnette, Tr. 2365).

Dr. Burnette has worked as an environmental consultant for multi-national companies like Hatcher-Sayre, Inc. (RPFF ¶ 211). He has performed substantial work in industrial, commercial, and landfill environments characterizing soil and groundwater. (RPFF ¶ 211). He was worked as a scientist on EPA superfund landfill establishment sites and remediation of same. He has been hired by the CDC and foreign governments. (RPFF ¶¶ 213–14).

Dr. Burnette regularly consults on issues of microbiology, including anaerobic microbiology. (RPFF ¶¶ 212–14). He has worked in microbiology labs across the country concerning issues of biological contamination, containment, and remediation. (Burnette, Tr. 2366–67). He has been hired by pharmaceutical corporations to address safety and containment issues related to "live" therapies like vaccinations. (RPFF ¶¶ 213–14; Burnette, Tr. 2367–68). Dr. Burnette's work experience and training has afforded him a broad expertise in the pathology of microorganisms and how bacteria interact with their environment. Almost none of his work (perhaps just 2%) involves serving as a consultant in legal cases. (Burnette, Tr. 2370).

Dr. Burnette offered an opinion concerning the various laboratory test environments used to assess biodegradation of materials. He explained that the test environments likely include many of the same microbiological species that would be found in a Municipal Solid Waste landfill and, so, it was appropriate to extrapolate data from the lab test into the landfill

environment. (RPFF ¶ 2074). Dr. Burnette also testified that the closed-system laboratory test has limitations, including the likelihood that microorganisms may die off or become ineffective for reasons that would not apply in the natural landfill environment. (RPFF ¶¶ 2041, 2043, 2079–93). Finally, he identified many species and enzymes capable of biodegrading plastics, and he explained that the test environment may actually lack the ecological depth to properly measure the full biodegradable potential of a material under narrow, controlled conditions. (RPFF ¶¶ 2045–59, 2070–73). Dr. Burnette was therefore of the opinion that test environments like the D5511 are competent and reliable to measure biodegradation in shorter tests, but the amount of biodegradation that eventually occurs in the natural setting is likely to be greater and continual. (RPFF ¶ 2042).

4. Dr. David Stewart

Dr. David Stewart is the President's Professor of Marketing and Law at Loyola Marymount University. (RPFF ¶ 218). He has served as a tenured member of the faculty and in various administrative roles at Vanderbilt University, the University of Southern California, and the University of California, Riverside. (RPFF ¶¶ 222–24). He has served on the editorial boards of twenty journals and regularly reviews all manuscripts submitted. (RX 601 (Stewart, C.V.)). He is the current editor of the *Journal of Public Policy and Marketing* and he is the past editor of the *Journal of Marketing* and the *Journal of the Academy of Marketing Science*. (RPFF ¶¶ 229–30).

Dr. Stewart holds three academic degrees in psychology, including a Ph.D. in personality psychology from Baylor University. (RPFF ¶¶ 219–20). His research has extensively examined how consumers and managers search for and use information in decision making, effectively

communicate with consumers, employ methods for the study of consumers and their behavior, and adopt effective and efficient marketing programs. (RX 601 (Stewart, C.V.)). He has taught courses to undergraduates, MBA students, Ph.D. students, and practicing managers for over thirty years. (RPFF ¶¶ 225–26). His expert opinions in the fields of consumer behavior, branding, marketing communications, marketing strategy, deceptive advertising, and intellectual property have been accepted and credited by the Federal Trade Commission and in Federal and State Courts. (RPFF ¶¶ 245, 252–54). In the late 1980's, a survey that he designed and implemented for the FTC in connection with a deceptive advertising case against Kraft was credited by the ALJ and cited by the full commission in its decision. (RPFF ¶¶ 246–47). He has also been retained by the FTC in cases against Novartis, POM Wonderful, QVC, Neurologic Labs, and John Beck. (RPFF ¶¶ 248–50). He has also been retained by Respondents in prior FTC matters, including *Pantron*, *Schering*, and *Guaranty Life*. (RPFF ¶ 251).

Dr. Stewart was asked to evaluated consumer impression of the unqualified "biodegradable" claim, among other claims. He was asked to evaluate the APCO and Synovate surveys, which the FTC relied upon in fashioning the Green Guides. (RPFF ¶ 805). He also provided an opinion concerning Dr. Shane Frederick's work, which included the use of a fundamentally and fatally flawed Google Consumer web application. (RPFF ¶¶ 598–99, 605–71).

Dr. Stewart discussed the survey results from his own well-designed and conducted telephonic survey. (RPFF ¶¶ 799–1038). He explained that consumers lack any consistent definition of the term biodegradable at issue in this case and share no common notion as to the rate at which plastics biodegrade. (RPFF ¶¶ 1004, 1009–12, 1025–26). He testified that Dr. Shane Frederick's survey results were flawed and unreliable. (RPFF ¶¶ 598–99, 605–71).

Finally, he explained that the APCO and Synovate studies were flawed and unreliable. (RPFF ¶¶ 550, 571, 661).

B. Respondent's Fact Witnesses

1. Robert Sinclair (ECM)

Robert "Bob" Sinclair is ECM's President and Chief Executive Officer. (RPFF ¶¶ 70, 72). Mr. Sinclair explained that ECM does not market or sell any product to any consumer. (RPFF ¶ 387). Rather, ECM markets and sells only one product, the ECM additive, and only to sophisticated plastic manufacturers. (RPFF ¶¶ 299, 365, 370, 392, 398). Indeed, a consumer has no use for the ECM additive because the additive can only be used during the manufacturing process of a plastic product. (RPFF ¶¶ 299). There is no way for consumers to purchase the ECM additive, which is not available online, e.g., via Amazon.com, for public purchase. (RPFF ¶¶ 361–62, 367). ECM's customers often have in-house counsel or outside counsel. (RPFF ¶ 416). They also usually either employ plastic engineers or are owned by a plastic engineer. (RPFF ¶¶ 417–19). Mr. Sinclair explained that no consumer can simply walk into a store front to purchase the additive, or even place an order online. (RPFF ¶ 361). ECM customers must directly contact ECM in order to purchase the additive, which can be done via facsimiles, e-mails, or telephone calls. (RPFF ¶ 362).

Mr. Sinclair explained the extensive relationship that ECM must develop with each potential new customer before the customer actually decides to purchase the ECM additive. (RPFF ¶¶ 301–08). ECM's new customers usually become aware of the ECM additive through others in the plastics industry, articles in trade magazines, or discussions at trade shows. (RPFF ¶¶ 305–07). After a potential customer initially contacts ECM to inquire about the additive,

ECM provides the potential customer with a packet of information. (RPFF ¶ 353). Mr. Sinclair often provides the McLaren/Hart report and other materials to ECM's potential customers to help the customer determine for itself whether the ECM additive is sufficient for the manufacturer's purposes. (RPFF ¶¶ 353–54, 356). Mr. Sinclair invited customers to perform independent testing of the ECM additive, corroborated by the record which reveals in excess of 33 independent tests performed by plastic company purchasers of the ECM additive. (RPFF ¶ 403). Prospective ECM customers were given, free of charge, a small sample of the ECM additive in order to test the additive and make sure that the additive was usable with the manufacturer's equipment and products. (RPFF ¶ 404). Mr. Sinclair works with customers to help customers understand how properly to integrate the ECM additive into their products. (RPFF ¶¶ 451–52). Once all of the potential customer's concerns and questions were answered, which took between six months and several years, the customer would then purchase the ECM additive. (RPFF ¶ 308). ECM provides a certificate of biodegradability to each customer if the customer desires and if the customer signs a statement stating that it will follow ECM's detailed manufacturing instructions for the additive. (RPFF ¶¶ 1344–45). ECM's certificate of biodegradability certifies that the plastic containing the ECM additive is "biodegradable" under the ASTM definition of "biodegradable," which definition reads:

> "A degradable plastic is defined as a plastic that is designed to undergo a significant change in its chemical structure under specific environmental conditions resulting in a loss of some properties that may vary as measured by standard test methods appropriate to the plastic and the application in a period of time that determines its classification. A Biodegradable Plastic is defined as a degradable plastic in which the degradation results from the action of naturally occurring microorganisms such as bacteria, fungi and algae."

(RPFF ¶¶ 1346–47).

Until three years ago, ECM represented that plastics manufactured with the ECM additive would biodegrade in between nine month and five years. (RPFF ¶ 309). That statement was based on the scientific conclusions supplied to ECM's prior owner, Patrick Riley. (RPFF ¶ 49). The prior owner performed aerobic and anaerobic testing of the ECM additive and concluded, based on the scientific results, that the additive would cause biodegradation of plastics within 9 months to 5 years. (RPFF ¶¶ 45-48). Robert Sinclair also performed aerobic and anaerobic testing of the ECM additive via placement of additive infused plastics in drums where aerobic and anaerobic testing took place as well as directly in garden plots, and witnessed the biodegradation of those plastics within the 9 month to 5 year time frame. (RPFF ¶¶ 51–54). The nine month to five year statements were never intended to be definitive statements of biodegradation rates, but were rather a discussion starter and a way to distinguish the ECM additive from quickly degrading and competing products such as oxo-degradable and compostables. (RPFF ¶ 309). The nine month to five year claims was qualified in the course of interactions during the six month to two year time frame of new customer consideration of the product. (*e.g.*, RPFF ¶ 474; RX 35–77). When customers inquired about the rate of biodegradation of their specific plastics if infused with the ECM additive, ECM explained that the specific rate of biodegradation varied greatly depending on a number of factors arising from where the plastic ends up after disposal and that, depending on those factors, could be much longer than 5 years. ECM permanently discontinued making the 9 months to five year claim three years ago. (RPFF ¶ 315). ECM now states that plastic containing the ECM additive "will biodegrade in any biologically-active environment (including most landfills) in some period greater than a year." (RPFF ¶ 318). ECM did not lose any customers when it changed its

qualifier from nine months to five years to greater than one year.[6] Mr. Sinclair explained that ECM did not lose business when it changed its qualifier because plastic manufacturers simply do not care how long it takes plastic containing the ECM additive to biodegrade so long as the plastic in fact biodegrades. (RPFF ¶¶ 322, 341, 360, 396). ECM customers want to know that plastic containing the ECM additive will biodegrade but do not want plastics containing the additive to biodegrade too quickly, because rapid biodegradation of plastics is associated with problems of plastic utility in the market, rendering the plastic's shelf life insufficient for commercial purposes. (RPFF ¶¶ 322, 341–42, 360, 396).

2. Kenneth Sullivan (ECM)

Ken Sullivan is ECM's Chief Financial Officer. (RPFF ¶¶ 86–7). Mr. Sullivan testified that ECM's customers are almost always much larger than ECM. (RPFF ¶ 395). Mr. Sullivan also testified that bioplastics, which compete with ECM plastics, come at a substantially greater cost than plastics containing the ECM additive. (RPFF ¶¶ 339–40, 388). Furthermore, Mr. Sullivan explained that companies choosing to invest in bioplastics must change their entire manufacturing process to accommodate the use of the new natural resins. (RPFF ¶¶ 333–34). ECM's customers purchase the ECM additive in part because it provides them with a biodegradable product without many of the drawbacks that come from bioplastics. (RPFF ¶¶ 329–31). Therefore, ECM offers a cost-effective means to achieve biodegradable plastics. (RPFF ¶¶ 41, 338–39).

Mr. Sullivan also testified regarding ECM's marketing efforts. (RPFF ¶¶ 301-07). ECM employs no sale force, but only one sales manager. (RPFF ¶¶ 351–52). Mr. Sullivan reiterated

[6] *Compare* RX 35-77 (typical emails sent to all customers advising of the change to qualifiers), *with* CCX 234 (orders by customer by year) (**the content of CCX 234 is *in camera;*** but the general discussion of customers is not).

that ECM does not target consumers in any of its advertising or marketing, and that ECM's customers are sophisticated industrial manufacturers. (RPFF ¶ 298). In all, ECM's advertising budget is less than $12,000 per year, which expense is primarily for website maintenance. (RPFF ¶ 301). ECM has no advertising plan and does not purchase any advertisements. (RPFF ¶¶ 302–04).

3. Thomas Poth (Eden Laboratories)

Thomas Poth owns and operates Eden Laboratories ("ERL") in Albuquerque, New Mexico. (RPFF ¶ 115). He runs ERL alongside Brian Essau, a Ph.D. in biochemistry. (RPFF ¶¶ 123-24). Mr. Poth and Dr. Essau performed a number of biodegradation tests of ECM amended plastics, including D5511 tests and similar tests modeled after the D5511 standard. (RPFF ¶¶ 406, 2218–19, 2241–42, 2259–60, 2284–85, 2303–04, 2322–23, 2346–47, 2363–65). In many (but not all) of those tests, the ECM additive was shown to produce a plastic that biodegraded substantially when compared with a negative control. (RPFF ¶¶ 2239–40, 2257–58, 2283, 2302, 2321, 2344–45, 2362, 2384–85).

Mr. Poth testified at the hearing and described, *inter alia*: his testing protocol; ERL's equipment and facilities; ERL's calculation of biodegradation; ERL's inoculum; and ERL's standard operating procedures with respect to biodegradation testing. (RPFF ¶¶ 2184–2210). Dr. Mort Barlaz testified that he visited ERL's laboratory (unrelated to this case), and that he had no reason to doubt that ERL's testing was reliable. (RPFF ¶¶ 2211–16).

4. Alan Johnson (Northeast Laboratories)

Alan Johnson owns and operates Northeast Laboratories, Inc., in Berlin, Connecticut. (RPFF ¶¶ 133–34, 2386–87). Northeast Labs ("NE Labs") performed a number of

biodegradation tests of ECM amended plastics, including D5511 tests based on the ASTM D5511 standard. (RPFF ¶¶ 2456–57, 2477–78, 2506–07, 2523–24, 2533-34, 2549–50, 2558–59, 2580–81, 2602–03, 2615–16). NE Labs designed its test protocol based on the input from Dr. William Ullman, a Ph.D. in microbiology and the former Director of the State of Connecticut's Public Health Laboratory. (RPFF ¶¶ 2396–98; Johnson, Tr. 1562). In many (but not all) of those D5511 tests, the ECM additive was shown to produce a plastic that biodegraded substantially when compared with a negative control. (RPFF ¶¶ 2474–76, 2500–05, 2521–22, 2530–32, 2548, 2557, 2577–79, 2600–01, 2611–12, 2625).

Mr. Johnson testified at the hearing and described, *inter alia*: NE Lab's testing protocol; NE Lab's equipment and facilities; NE Lab's calculation of biodegradation; NE Lab's inoculum; and its standard operating procedures with respect to biodegradation testing. (RPFF ¶¶ 2399–2429).

5. Dr. Timothy Barber (Environ Corp.)

Dr. Timothy Barber is a principal in the global research company Environ. (RPFF ¶ 104). He has a B.S. in chemistry and a Ph.D. in marine science with a specialization in chemistry. (RPFF ¶¶ 93–4; Barber, Tr. 2004). Dr. Barber is a well-qualified and credentialed scientist in the field of environmental science. (RPFF ¶¶ 95–109). Dr. Barber designed biodegradation studies that he then performed on plastics infused with the ECM additive. (RPFF ¶¶ 549, 2687). Based on the results of that testing, which used various endpoints to assess biodegradation, Dr. Barber concluded repeatedly that the ECM additive rendered plastics biodegradable. (RPFF ¶¶ 2701–03). He also conveyed that conclusion to ECM customers based on his testing. (RPFF ¶¶ 2701–03.

Dr. Barber testified at the hearing concerning the reports given to ECM, explaining why his laboratory results were sufficient to establish that the ECM amended plastics had biodegraded. (RPFF ¶¶ 2670, 2684–86, 2688–91). Dr. Barber also explained why closed-system laboratory tests are often inadequate to test for biodegradability long-term. (RPFF ¶¶ 2673–83). Dr. Barber also explained why certain types of plastics (e.g., polystyrene foams) were not conducive to his testing protocol. (RPFF ¶¶ 2901–05).

C. Complaint Counsel's Experts

1. Thabet Tolaymat

Dr. Tolaymat is an agency employee for the United States Environmental Protection Agency. (RPFF ¶ 2709). Not an independent expert, he is an employee of a sister government agency. (RPFF ¶ 2709). Dr. Tolaymat worked as an "expert" witness in this case while paid by the EPA. (RPFF ¶¶ 2710–11). He is not a senior scientist in EPA with expertise in landfill gases, although the EPA has scientists who are. (RPFF ¶¶ 2714–15). Although Dr. Tolaymat's opinion with respect to landfill activity ostensibly contradicts the EPA's published documents on methane production, Dr. Tolaymat did not consult with anyone at the EPA before authoring his report. (RPFF ¶ 2712). He did not discuss his opinion or testimony with a single colleague in the EPA. (RPFF ¶ 2717). Despite having been retained in this case to assist Complaint Counsel since 2010, Dr. Tolaymat spent just eighty (80) total hours on the case before testifying at his deposition. (RPFF ¶¶ 2719–20)

As discussed below, Dr. Tolaymat testified inconsistent with Complaint Counsel's other experts, testified inconsistently with ECM's expert Dr. Barlaz (who Dr. Tolaymat considers to be an expert in the field), contradicted himself repeatedly, and demonstrated a general lack of sophisticated knowledge in the relevant scientific areas.

2. Steven McCarthy

Dr. Steven McCarthy is a professor at UMass Lowell in Massachusetts. (McCarthy, Tr. 359). Dr. McCarthy testified for Complaint Counsel as to the ability of ECM amended plastics to biodegrade in a landfill. (McCarthy, Tr. 359–690). As explained in detail below (*supra* at 147), Dr. McCarthy has materially changed his position on the science throughout this case, creating a moving target with virtually no citation to apposite peer reviewed scientific literature and a preference for broad conclusory statements over detailed scientific explanation. (RPFF ¶¶ 1354–1581). Dr. McCarthy's theoretical criticisms of ECM plastics are unsupported by basic science or peer reviewed literature. (RPFF ¶¶ 784, 786–87, 789, 805–07, 1481–93, 1520–31, 1565–66). Dr. McCarthy has attempted to impose standards on ECM plastics that he does not require of himself when supporting his own competing biodegradable technologies and does not follow in his own published scientific research on biodegradable plastics. (RPFF ¶¶ 1449–80, 1539–64). Dr. McCarthy failed to consider whole areas of data when fashioning his expert opinion. (RPFF ¶¶ 1490–93, 1567-68). He adopted a litigation definition for the term "biodegradable" given to him by Complaint Counsel that is not supported by the science but that conveniently does mirror the Green Guides' definition. (RPFF ¶¶ 1360–69, 1532–34). He is a biased party with financial interests in the outcome of this litigation, and his testimony reflected that bias. (RPFF ¶¶ 1396–1448).

3. Shane Frederick

Dr. Shane Frederick testified as an "expert" witness for Complaint Counsel in the areas of consumer impression. (RPFF ¶ 275). Dr. Frederick attempted to validate the Commission's prior reliance on flawed consumer surveys through a new survey methodology, his Google Consumer Surveys. (RPFF ¶ 279, 826, 904–05). Dr. Frederick relied on a single question

approach via Google Consumer Survey, a flawed, untested, and unreliable approach that has never been used before in litigation of any kind to support a legal determination of consumer impression. (RPFF ¶¶ 278, 906, 979–88). Dr. Frederick chose to rely on such methods in an effort to save costs, which may have been motivated by the fact that Complaint Counsel paid him on a flat fee basis. (RPFF ¶¶ 895–903). Dr. Frederick's survey methodology suffered from a number of fatal flaws including, for example, the fact that he failed to blind his coders, failed to collect essential screening information from survey respondents, and asked only one question to each survey respondent. (RPFF ¶¶ 907–86). As discussed in more detail below, Dr. Frederick's so-called "survey" was a biased attempt to support Complaint Counsel's case, rather than to ascertain consumer impression objectively. (RPFF ¶¶ 279, 826, 904–05).

4. Frederick Michel (Rebuttal)

Dr. Frederick Michel testified in rebuttal to testimony offered by ECM experts Drs. Sahu and Burnette. (RPFF ¶ 281). Dr. Michel had been retained by Complaint Counsel since at least 2012, and Complaint Counsel had relied in this case on his single study of plastics in the market since at least February 2014. (RPFF ¶¶ 2997–3003). That single study was based on a test product contributed to Dr. Michel by an ECM competitor, Myers Company, (RPFF ¶¶ 2939, 2944–49), and said to contain an ECM additive (but there is no chain of custody present and no proof that the additive was properly manufactured). (RPFF ¶¶ 2916, 2941–44, 2950–54). Complaint Counsel first disclosed Dr. Michel as a "rebuttal" witness after the time ECM could have amended its own expert reports.[7] Dr. Frederick Michel testified almost exclusively based on the single study that he performed. (RPFF ¶¶ 907–86). Dr. Michel's study was an ASTM

[7] *See In re ECM Biofilms*, Order on Respondent's Combined Motion for Sanctions, To Exclude Expert Witness, and for Leave, Dkt. No. 9358 (July 23, 3014).

D5511 test that he conducted on various commercial plastics. (RPFF ¶¶ 1616, 1772). Although he published his study in the peer reviewed literature, Dr. Michel failed to disclose financial interests with competitors of ECM, which would have constituted an actual or potential conflict of interest under the publisher's conflicts policy. (RPFF ¶¶ 2963–83). That failure to disclose information to the peer-reviewer was a violation of the peer reviewed publication's, Elsevier's, rules governing the submission of peer reviewed literature. (RPFF ¶¶ 2957–60). Moreover, the peer reviewers never reviewed raw data from Dr. Michel's study, but only reviewed the manuscript that included Dr. Michel's summary of information. (RPFF ¶¶ 2960–62). Dr. Michel chose to run a D5511 gas evolution test to measure anaerobic biodegradability of the ECM plastic. (RPFF ¶¶ 1616, 1772). He also testified that experts in the field rely on gas evolution tests like the D5511 test to determine biodegradability. (RPFF ¶¶ 1775, 2925). The Michel test yielded inconclusive results. It showed no biodegradation of the test plastic (not even an amount equal to the biodegradation of the additive), but Michel undertook no effort to determine the precise cause of test failure, thus not ruling out mis-manufacture of the test plastic, death of the microbes in the inoculum, or the presence of a contaminant, such as an anti-microbial agent, in the test plastic itself, etc. (RPFF ¶¶ 2991–96). The inconclusive Michel test is therefore unreliable and cannot reasonably be credited as competent evidence in this proceeding.

D. Complaint Counsel's Fact Witnesses

Complaint Counsel elected not to call a single fact witness at hearing in support of its case, depending solely on deposition transcripts for certain witnesses, including mostly ECM customers. (RPFF ¶ 257). ECM objected on due process grounds, among others, explaining that while the FTC Rules of Practice technically permit the introduction of deposition testimony, the

sheer volume of fact depositions (20), in locations around the country (e.g., Honolulu, San Francisco, Minneapolis, Michigan, Connecticut, New York, Ohio, etc.), rendered it nearly impossible for a small corporation like ECM to afford legal representation at each deposition. Knowing that ECM was unable to provide attorneys at depositions, or that ECM was forced to appear telephonically, Complaint Counsel elected not to call any of its fact witnesses and, instead, opted to introduce what they (erroneously) considered one-sided testimony. (RPFF ¶¶ 256, 258). Although testimony of an out of court fact witness is entitled to little, if any, weight, when the witness could have been called to appear at trial,[8] in point of fact on the relevant question of the basis for purchases of the ECM plastic, almost every witness testified (even in the face of leading examinations) that it bought the ECM additive for infusion in plastics because it rendered the plastics biodegradable, not because it achieved biodegradation within any set time or by a set rate. (RPFF ¶¶ 605–725).

Deposition testimony derived from examination by counsel from one party only is viewed with skepticism by the courts, particularly, as here, where Complaint Counsel relied almost exclusively on leading inquiries, not affording the witness an opportunity to present all relevant background facts and circumstances. Direct, in the absence of cross, has always been viewed as dubious.[9] When out of court witnesses are available to testify but are not called, Courts routinely give little, or no, weight to the out of court statements in the deposition transcripts.[10] That is in no small part because it is critical for the finder of fact, here the

[8] *Pub. Serv. Co. of N.M.*, 11 FERC ¶ 63,002 (1980) (Harfeld, ALJ) (finding that although certain hearsay statements (i.e., depositions) are not excludable from administrative proceedings, they may be given little weight.)

[9] *Id*

[10] *Id.*

Administrative Law Judge, to see the witness testify and assess his or her credibility on the stand to determine the extent to which the witness is credible.[11] By calling no fact witnesses in support of its case, Complaint Counsel has denied the Administrative Law Judge the requisite basis to make critical character findings based on observation of the witness testifying, as well as the Administrative Law Judge's opportunity, and opposing counsel's, to make inquiry of the witness at trial on points for which elaboration would reveal factual underpinnings and responses indicative of credibility not arising from one-sided questioning at deposition.[12]

III. ARGUMENT

"The determination of whether Respondent's disseminated false advertisements in violation of the FTC Act requires a three-part inquiry: (1) whether Respondent's disseminated advertisements conveying the claims alleged in the Complaint; (2) whether those claims were false or misleading; and (3) whether those claims are material to prospective consumers." *In the Matter of Pom Wonderful LLC*, 9344, 2012 WL 2340406 (F.T.C. May 17, 2012) (Initial Decision at 211) (quoting *Kraft, Inc. v. FTC*, 970 F.2d 311, 313 (7th Cir. 1992)); *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1095 (9th Cir. 1994); *FTC v. Direct Marketing Concepts*, 569 F.Supp. 2d 285, 297 (D. Mass. 2008). In this case, the claims in question are few in number and accompanied by claim qualifications, which are further underscored by additional qualifications made by ECM president Robert Sinclair before purchases were made by sophisticated plastic manufacturer customers. This dialogue resulted in a transformation of the claims away from those listed by

[11] *Trial Practice*, 35 Stetson L. Rev. 1139, 1140 (2006) (explaining that thorough cross-examination is necessary to allow the fact-finder to consider the witness's responses to such questions and to ultimately determine the thoroughness and credibility of the witness's testimony)

[12] *Id.*

Complaint Counsel in the Complaint to ones that are accompanied by transparent and complete revelations concerning the product. ECM claimed that its additive would hasten biodegradation of plastics infused with it, but qualified the claim explaining that the rate of biodegradation for any piece of plastic was entirely dependent on the location where the plastic came to rest after customary disposal, the ambient environmental conditions present there, and the extent to which other biodegrading matter was present. (RPFF ¶¶ 378–79, 1080; RX 681 at 61). The representations made were neither false nor misleading, particularly in light of the fact that the sophisticated customers, the plastics manufacturers that purchased ECM's products, commonly conducted their own testing of the product and did not rely on any ECM claims, beyond that of biodegradation, as a basis for purchase but rather depended on the company's own testing and proof of product functionality and biodegradation before making a purchase. (RPFF ¶¶ 1083, 2129–2885). In the end, given these sophisticated purchasers well-versed in plastics manufacture and in testing of the ECM additive, claims made by ECM beyond biodegradation had no materiality and, even the claim of biodegradation carried with it little materiality to ultimate purchases in those common instances where the plastic manufacturer tested the product to determine on its own whether the product caused the company's own plastic to biodegrade. (RPFF ¶¶ 296–739).

A. Complaint Counsel Has the Burden of Production on Charges in the Complaint

Complaint Counsel has an irreducible burden of production for each element of the causes of action they bring in the Complaint. "The burden of production is the obligation to come forward with evidence of a litigant's necessary propositions of fact." *Chicago Bride & Iron Co. N.V. v. F.T.C.*, 534 F.3d 410, 425 (D.C. Cir. 2008) (quotation omitted). Having rested its case without presenting a single fact witness in support of its case, Complaint Counsel has

failed to meet its fundamental burden of production in support of the charges in the Complaint. On that basis, alone, the Complaint can and should be dismissed. *See, e.g., FTC v. Tashman*, 318 F.3d 1273, 1283 (11th Cir. 2003) (holding that FTC failed to meet its burden because limited testimony presented was not enough).

B. Complaint Counsel Has The Burden of Proof to Show that ECM Made Claims, That those Claims Were False or Misleading, and That the Claims Were Material

"Counsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto." 16 C.F.R. § 3.43(a); *see also* 5 U.S.C. § 556(d) (explaining that "the proponent of a rule or order has the burden of proof"). Regardless of the level of substantiation required, the FTC will bear the burden of proving advertising claims false or misleading. *See Sterling Drug, Inc. v. F.T.C.*, 741 F.2d 1146, 1150 (9th Cir. 1984); *Porter & Dietsch, Inc. v. F.T.C.*, 605 F.2d 294, 305 (7th Cir. 1979); *F.T.C. v.* Garvey, 383 F.3d 891, 900 (9th Cir. 2004) ("we put the burden of proving falsity or deception on the FTC"). To prove that an advertisement is false or misleading, the FTC must show (1) the existence of a "representation, omission, or practice," that is (2) "likely to mislead consumers acting reasonably under the circumstances," and that (3) "the representation, omission, or practice is material." *F.T.C. v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 124 (D. Conn. 2008) (citation omitted). Complaint Counsel must prove each element of its case by a preponderance of the evidence. *See, e.g., In re Adventist Health Sys./West*, 117 F.T.C. 224, 297 (Apr. 1, 1994) (explaining that "[e]ach element of the case must be established by a preponderance of the evidence"); *see also In the Matter of POM Wonderful, LLC*, 2012 WL 2340406, at *171 (F.T.C. May 17, 2012) (noting that "Complaint Counsel has

the burden of proving each of the foregoing factual issues by a preponderance of credible evidence").

Fundamentally, Complaint Counsel has failed to demonstrate that the sophisticated customers to whom ECM sells its additive were likely to be misled "under the circumstances." In particular, not even a significant minority of those customers has been shown to have relied on any claim made by ECM other than the biodegradability claim, which the evidence proves was true. (RPFF ¶¶ 799–1038). In that regard, the evidence in issue comes not from tests ECM commissioned but from tests commissioned by those same customers on the very plastics those customers infused with the ECM additive. (RPFF ¶¶ 1964–2885). In short, given the lack of reliance on any claim made by ECM (even the biodegradation claim because the sophisticated customers most commonly performed independent tests of the ECM additive), there is no basis in fact, science, or law to conclude that these sophisticated customers were likely to be misled under the circumstances.[13] Finally, the only issue the evidence reveals was material to ECM customers was that of biodegradation. (RPFF ¶¶ 1039–1351). But, again, biodegradation was not taken at face value before a customer made a purchase decision. Rather, the record establishes that ECM customers tested the ECM product on biodegradation grounds before choosing to purchase it for infusion in their plastic products. (RPFF ¶¶ 1039–1210, 1964–2885). Consequently, certainly biodegradation was the only subject matter material to a purchasing decision by even a significant minority of ECM customers, but any representation of biodegradation by ECM was not accepted without independent tests by the customers that, in reality, became the predicate for a purchase decision. (RPFF ¶¶ 1039–1210, 1964–2885).

[13] *See, e.g.*, RPFF ¶¶ 1039–1351.

There are two ways the FTC can prove that an advertisement is likely to mislead consumers. "One [way] is to carry the burden of proving that the express or implied message conveyed by the ad is false. The other [way] is to show that the advertiser lacked a reasonable basis for asserting that the message was true." *F.T.C. v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 135 (D. Conn. 2008) (citing *In the Matter of Thompson Med. Co., Inc.*, 104 F.T.C. 648 (1984)). The FTC must also establish materiality. "A 'material' misrepresentation is one that involves information that is important to consumers, and that is therefore likely to affect a consumer's choice of or conduct regarding a product." *F.T.C. v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 135 (D. Conn. 2008) (quoting *In Re Kraft, Inc.*, 114 F.T.C. 40 (1991)); *see also FTC Policy Statement on Deception*, Federal Trade Commission (1983)). As explained above, the ads in context of the sales presentations by ECM, which involved extensive interaction with customers over six months to several years, were between sophisticated parties that shared full disclosure of all material facts. (RPFF ¶¶ 297–433, 1039-1351. ECM had at all times a reasonable basis for every material statement made to its customers derived from its own testing and experience with the product and its customers independent testing and experience with the product prior to purchase. (RPFF ¶¶ 1964–2885).

C. Complaint Counsel Has Failed to Meet Their Burden to Prove that ECM Conveyed Implied Biodegradability "Rate" Claims

Extrinsic evidence includes survey results and other evidence governing how consumers perceive certain claims. *In Re Kraft, Inc.*, 114 F.T.C. 40, 121 (1991). The Commission can look at:

> Evidence not specifically showing how consumers understood the advertisements at issue before us, but showing how consumers might ordinarily be expected to perceive or understand representations like those

> contained in the ads we are reviewing. For example, we might look at the dictionary definition of a word to identify the word's common usages. Or we might look at principles derived from market research, as expressed by marketing experts, which show that consumers generally respond in a certain manner to ads that are presented in a particular way, and presume that consumer reactions to a particular ad before us would be consistent with the general response pattern. Where we apply such marketing principles, we will derive them from research presented in references generally accepted as reliable in the field of marketing. Such references may be cited by marketing experts called to testify in the proceeding.

In the Matter of Thompson Med. Co., Inc., 104 F.T.C. 648 (1984). The Commission may also consider evidence of how consumers would interpret an advertisement in a particular manner. *Id.*

ECM spends less than $12,000 per year on advertising, almost all of which is devoted to website maintenance. (RPFF ¶ 300).[14] ECM's claims are shared with specific, sophisticated customers during the long six month to several years' pre-purchase negotiations leading to a corporate sales agreement between the two entities. Mr. Sinclair credibly testified that the bulk of his discussions with customers is through verbal communication, or targeted emails.[15] Brochures and flyers are not shared with the public at large, but dispatched to specific corporations who have expressed interest in ECM's technology. (RPFF ¶¶ 329–432).

"Advertising is a form of promotion to anonymous recipients, as distinguished from face-to-face communication. In normal usage, an advertisement read by millions (or even thousands in a trade magazine) is advertising, while a person-to-person pitch by an account executive is not." *First Health Grp. Corp. v. BCE Emergis Corp.*, 269 F.3d 800, 803–04 (7th

[14] As is clear from the record, there is literally no evidence in this case that ECM's claims were designed to target end-consumers, that end-consumers have visited ECM's website, or that ECM receives considerable traffic to its website. To the contrary, the website is clearly designed for manufacturers of plastics. (RPFF ¶¶ 300–06, 367–69).

[15] *See, e.g.*, CCX 818, at 45, 52–53, 202.

Cir. 2001).[16] Therefore, an in person statement by a company's sales team is not "advertising." *Zurich Ins. Co. v. Amcor Sunclipse N. Am.*, 241 F.3d 605, 607 (7th Cir. 2001). Likewise, statements by a company's executive made in person to other executives cannot be called "commercial advertising or promotion." *First Health Group Corp. v. BCE Emergis Corp.*, 269 F.3d 800, 804 (7th Cir. 2001). Similarly, in order to constitute "promotion," materials must be "disseminated sufficiently." *Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 735 (9th Cir. 1999); *Seven-Up Co. v. Coca-Cola Co.*, 86 F.3d 1379, 1384 (5th Cir. 1996) (same).

Concerning claims made directly to, and between, ECM's customers that were *not* passed through the chain of commerce to a substantial audience, Complaint Counsel's theory of liability creates substantial policy concerns over the reach and scope of the FTC's jurisdiction. At the very least, prudential considerations should govern whether the FTC is empowered to regulate the terms of transactions or sales agreements between two sophisticated corporate entities and the weight given any such communications which were not "disseminated sufficiently."

"[I]n determining what claims are conveyed by a challenged advertisement, the Commission relies on two sources of information: its own viewing of the ad and extrinsic evidence. Its practice is to view the ad first and, if it is unable on its own to determine with confidence what claims are conveyed in a challenged ad, to turn to extrinsic evidence." *Kraft, Inc. v. F.T.C.*, 970 F.2d 311, 318 (7th Cir. 1992). Therefore, the FTC does not need to point to extrinsic evidence to determine whether an advertisement makes an objectionable claim. Generally the FTC's own view of the advertisement is sufficient. *Id*. at 319.

[16] Black's law definition defines an "advertisement" as "notice given in a manner designed to attract public attention." *See Black's Online Law Dictionary* (2d Ed.), *available at*, http://thelawdictionary.org/advertisement/ (last visited September 25, 2014).

The FTC must use extrinsic evidence to determine what the claim implies when the claim is not "reasonably clear from the face of the advertisement." *F.T.C. v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 126 (D. Conn. 2008). Similarly, *Thompson* held that the FTC must have extrinsic evidence when "the advertisement itself does not allow [the FTC] to conclude with confidence" that the advertisement at issue contains a particular implied claim. 104 F.T.C. 648, at ¶ 7. And as another case clarified, "if the language or graphic is susceptible to more than one reasonable interpretation . . . the district court must look to consumer data to determine what the person to whom the advertisement is addressed finds to be the message." *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007).

When an implied claim is at issue, "[t]he Commission will carefully consider any extrinsic evidence that is introduced, taking into account the quality and reliability of the evidence." *In re Stouffer Foods Corp.*, 118 F.T.C. 746, 799 (Sept. 26, 1994). Such extrinsic evidence includes "reliable results from methodologically sound consumer surveys." *Id.* In weighing survey evidence, the Commission "looks to whether such evidence is reasonably reliable and probative. Flaws in the methodology may affect the weight that is given to the results of the copy test or other consumer survey." *Id.* (citation omitted).

In this case, for the vast majority of products that eventually reach end-consumers, consumers only receive a "biodegradable" claim, often in the form of a logo or a small stamp on the packaging. Using the unscientific positions expressed in the Green Guides, Complaint Counsel has inferred that *every* unqualified "biodegradable" claim is actually a claim that a product will fully degrade within one year in the environment. The evidence directly refutes the notion that the political definition of "biodegradation" (complete break down into elements in nature within one year after customary disposal) matches the scientific definition and that the

political definition is commonly accepted by even a significant minority of ECM customers or plastics consumers. (RPFF ¶¶ 767–817).

1. Extrinsic Evidence of High Methodological Quality Reveals that ECM Did Not Make Implied Claims Concerning the Rate or Extent of Biodegradation

In order to determine what consumers believe "biodegradable" means, ECM retained the services of survey expert Dr. David Stewart, an expert whose surveys have often been credited by the ALJs at the agency and by the Commission itself. (RPFF ¶¶ 217–255, 1286). Dr. Stewart conducted a well-designed, live telephone interview survey based on established principles of survey research that are consistent with the guidelines for survey research offered in litigation as articulated in the Manual for Complex Litigation. (RPFF ¶¶ 1105, 1176–78; RX 856, at 16). In sum, Dr. Stewart concluded that consumers have no common understanding of the term "biodegradable."[17] In fact, consumers were asked "if something is degradable, how long do you think it would take for it to decompose or decay?" (RPFF ¶ 1306). In response, 39% of survey respondents stated that it depends on the material or type of product. (RX 856 at 25). No other single response was offered by more than **6%** of the respondents. (RX 856 at 25). As proven by Dr. Stewart's survey, no significant percentage of consumers think that products labeled "biodegradable" will degrade within one year or any specific time frame. (RPFF ¶¶ 1300–22). No significant percentage of consumers have enough understanding or knowledge of the concept of biodegradation to properly assess those claims. (RPFF ¶¶ 1300–22). Therefore, when ECM claims that their plastic products are "biodegradable," ECM is not implying to consumers that the products will biodegrade within one year or any other specific time frame or that the products

[17] *See* RPFF ¶ 1302 (Ninety-eight percent of the respondents to Dr. Stewart's survey do not believe that there is a uniform rate for materials biodegrading and that the rate really depends on the material); Stewart, Tr. 2577.

will completely break down into elements found in nature. Indeed, an overwhelming 98% of respondents believe that different types of products take different amounts of time to biodegrade, decompose, or decay (RPFF ¶ 1322; RX 856 at 26), thus vitiating any notion that consumers harbor a common view that plastics of all kinds should achieve a complete break down into elements in nature within one year after customary disposal.

a. Dr. Stewart's Telephone Survey was Well-Designed, Incorporated Open-Ended Clear Questions, and Closely Adhered to Established Principles of Survey Research.

A survey expert whose work has repeatedly been credited by ALJs of the FTC and the Commission itself, Dr. David Stewart designed a live interview telephone survey in order to determine how consumers who purchase products made from or packaged in plastic actually perceive the meaning of the term "biodegradability." (RX 856 at 15). Phone surveys are the most common form of survey used in marketing research. (RPFF ¶¶ 1106–08, 1176–78). The primary reason Dr. Stewart opted for a live telephone interview survey is because he was interested in "meaning." (RPFF ¶¶ 1106–08, 1288). In order to understand what people believe a term means, particularly a term for which little survey research exists, a competent researcher needs a real life interviewer appropriately trained to conduct research. (RPFF ¶¶ 1108–10). This survey also assessed the message that consumers take away from claims made by ECM. (RPFF ¶ 1296; RX 856 at 15). Dr. Stewart's survey used well-designed, non-leading, and clear open-ended questions that allowed real consumers to answer in their own words and to provide qualifications, contextual information, or other information that established a richer meaning of consumer responses than is typically obtained when only closed-ended questions appear (or single questions are posed without human interface) in a survey. (RPFF ¶¶ 1293; RX 856 at 15).

Dr. Stewart designed and conducted this survey in accordance with well-established principles of survey research offered in litigation, as articulated in the Manual for Complex Litigation. (RPFF ¶ 1289). To that end, the survey defined the relevant population as men and women over the age of 18 in the United States who reported that they had personally purchased a product in the past month that came in a plastic container or was made of plastic. (RX 856 at 17; RPFF ¶ 1243, 1292). From this sample, respondents were disqualified if they stated in response to screening questions that they did not have a general understanding of what the term "biodegradable" means. (RPFF ¶ 1209; RX 856 at 17). The actual sampling frame was constructed from a random digit dialing sample obtained from Scientific Telephone Sampling and an age enhanced list was obtained from Survey Sampling, Inc. (RPFF ¶¶ 1236–37; RX 856 at 17). Both of those companies are highly respected, well-known providers of samples for use in survey research. (RPFF ¶ 1242; RX 856 at 17).

Dr. Stewart determined that a sample size of 400 respondents was the sufficient amount of participants because that sample size provides, in the worst case, approximately plus or minus 5% of the true population statistics 95% of the time. (RPFF ¶¶ 1231–33; RX 856 at 18). The respondents' answers were accurately reported by well-trained interviewers who had been specifically trained in interviewing methodology, were under the supervision of highly qualified and experienced research supervisors, had been debriefed on the specific requirements and protocol for this survey, and had completed at least one practice interview. (RPFF ¶¶ 1260–63). Importantly, the interviewers were also randomly monitored by supervisors to assure that the interviews were conducted in the prescribed manner. (RPFF ¶¶ 1261–63). These interviewers and their supervisors were blind in the sense that they did not know for whom the survey was being conducted. (RPFF ¶¶ 1251–59).

Once the respondents were appropriately selected from a list of telephone numbers based on an algorithm employed by the Computer-Assisted Telephone Interviewing (CATI) system, interviewers clarified to potential respondents that the call was for research purposes and not telemarketing. (RPFF ¶¶ 1290–91). The interviewers and respondents then went through both parts of the survey. The first part contained screening questions, a "screener" in the survey vernacular (RPFF ¶¶ 1291–1292), and the second part was the main questionnaire. The screener was used to determine whether the respondent met the screening criteria and was a member of the relevant population. (RPFF ¶¶ 1269–70, 1279, 1292). Those questions ensured that the respondent was over 18, was age and gender representative within the sample, avoided those who work for a manufacturer of plastic products or a waste disposal organization, (RPFF ¶ 1292),[18] ensured that respondents had purchased a product in a plastic container or containing plastic within the past month, and ensured that respondents had a general understanding of the term biodegradable. (RPFF 1196, 1292–94).

Respondents who qualified in the survey sample based on the screen questions were asked a series of substantive questions in the main questionnaire. (RPFF ¶ 1202). All but two of the questions in the main questionnaire were open-ended questions, which have the advantage of allowing respondents to offer answers that are qualified, provide context, or are otherwise nuanced, and which are useful for clarifying terminology by gauging the meanings of words and for informing variability among respondents. (RPFF ¶ 1293).

The questions in the main questionnaire were clear and not leading. (RPFF ¶ 1278). The first few questions asked respondents about their perceptions of biodegradability generally.

[18] This exclusion was justifiable on the ground that these respondents would have atypical knowledge of the issues, and therefore would not be representative of the larger population. (RX 856 at 19–20).

(RPFF ¶ 1294). For example, Q4 asked, "If something is biodegradable, how long do you it would take for it to decompose or decay?" (RPFF ¶ 1295). The next set of questions asked the respondents to indicate in their own words what claims adapted from claims used by ECM mean to them. (RPFF ¶ 1295).

The survey was conducted by qualified persons following proper procedures. Dr. Stewart himself personally designed the survey. (RPFF ¶ 1320). A well-known survey research agency, California Survey Research Services (CSRS), coordinated interviewing and data tabulation. (RPFF ¶ 1325). The field work for the survey cost $37,500. (RPFF ¶ 1297). In addition, the survey was pre-tested by conducting a small pilot project, which confirmed that no changes to the survey design were necessary. (RPFF ¶ 1298). The coding of the responses to the open-ended questions was carried out by experienced staff members at CSRS who were double-blinded, and the codebook used was suggested by CSRS and approved by Dr. Stewart. (RPFF ¶¶ 1257–59, 1299). The coders themselves were blind to both the sponsor and the purpose of the survey (i.e., they were double blinded). (RPFF ¶¶ 1253–59). All verbatim responses were coded independently by two coders and any disagreements were resolved in discussion. (RPFF ¶ 1257).

b. Dr. Stewart's Survey Confirms that Not Even a Significant Minority of End-Use Consumers or ECM Customers Have a Single Definition of Biodegradation or Expectation as to the Rate at Which ECM Plastics Will Biodegrade

Dr. Stewart's survey first concluded that while consumers do have a conceptual understanding of what biodegradability is, that understanding is not material to any significant minority of consumers. (RPFF ¶¶ 1314–22). The survey also concluded that 68% of the respondents recognize differences in the rate of decomposition depending on the type of material

or the context. (RPFF ¶ 1332). The results also made very clear that the vast majority of consumers have an understanding that the process of biodegradability is highly varied and that it is not often a rapid process. (RPFF ¶ 1333). Furthermore, 98% of respondents believe that different types of products take different amounts of time to biodegrade, decompose, or decay. (RPFF ¶¶ 1308, 1311, 1322). Such differences, according to the respondents, include the type or size of the material, the context, or the environment. (RPFF ¶¶ 1308, 1311, 1322). Dr. Stewart concluded that consumers recognize significant time variances in decomposition, and that there is insufficient evidence to conclude that their understanding of the term biodegradability is restricted to decomposition processes that occur within one year or less. (RPFF ¶¶ 1300–22).

As for the questions which incorporated ECM's claims made to industrial purchasers, Dr. Stewart found that a common response included a lack of understanding, expressions of confusion, expressions of skepticism or disbelief, or a simple restatement of the claim. (RPFF ¶ 1337). That lack of understanding, confusion, and skepticism make it highly unlikely that these claims would be material to an end use consumer, even if the claims were directed right at the end use consumer. (RPFF ¶ 1338). In sum, Dr. Stewart's survey clarified that two of three criteria required for a finding of deception, a false belief attributable to actions of the marketer and that the claim be material to consumers, are not present in ECM's alleged advertising. (RPFF ¶ 1339).

Dr. Stewart also conducted a limited Manufacturers Pilot Survey in an attempt to ascertain whether more knowledgeable purchasers have a more common understanding of biodegradability. (RPFF ¶ 1340–41). To that end, ECM provided Dr. Stewart a list of representatives from customer organizations that were involved in the purchase of materials for the manufacturer of plastics. *See John Crane Prod. Solutions, Inc. v. R2R and D, LLC*, 861 F.

Supp. 2d 792, 799 (N.D. Tex. 2012) (citations omitted) (explaining that even if "a company's engineers may be distinct from the employees who purchased the [product] . . . [s]uch business transactions are at least as complex as transactions that other courts have classified as sophisticated"); (RPFF ¶ 1341).

Representatives from 10 of ECM's customers participated in this survey, which was also carried out by CSRS. (RPFF ¶ 1342). Like the consumer survey, this survey concluded that even among more knowledgeable and sophisticated customers there is substantial variation in opinions about how quickly a biodegradable product should take to decompose. (RPFF ¶ 1342). Dr. Stewart stopped conducting this survey after receiving only ten responses because Dr. Stewart believed he would run out of time before he could complete the survey and obtain any meaningful results. (RPFF ¶ 1344).

c. Complaint Counsel's Survey Expert Relies on an Incompetent Google Survey to "Correct" Incompetent Synovate and APCO Surveys

In support of the One Year Rule, the Commission relies on a survey conducted by APCO Insight, and dismisses a survey conducted by Synovate. (RX 195 at 121). According to the Commission, the APCO survey concluded that 60% of respondents expect that an item marketed as degradable will fully decompose in one year or less. The problem with the Commission's reliance on the APCO study is that the APCO study is rife with flaws, as acknowledged by both Dr. Stewart and Complaint Counsel's own expert, Dr. Shane Frederick. (RPFF ¶¶ 818–77). For example, the APCO study uses close-ended questions, which are unhelpful and misleading, as here when there are many possible answers among respondents.[19] Importantly, when beginning

[19] RPFF ¶ 846; RX 856, at 7; RX 858 (Frederick, Dep. at 165).

consumer perception work in a new area, open-ended questions are an essential tool. (RPFF ¶¶ 848–49).

One of the critical limitations of close-ended questions is particularly important where, as here, the FTC is trying to pigeon hole a consumers' perception of the term "biodegradability" into one uniform definition. Close-ended questions inherently suggest greater homogeneity within a sample of respondents than may actually exist because closed ended questions exist in a universe with only four or five possible response. (RPFF ¶¶ 859–865). Self-evident is the fact that even where there is maximum disagreement, 20% of respondents will nevertheless appear to agree on an answer to a question in which there are only five possible answers. (RPFF ¶¶ 860–63). This fact makes the FTC's "significant minority" argument problematic when they conclude that a significant minority of consumers believe something, when that alleged uniform belief is based upon a question that, if people answered wholly randomly, would be expected to yield 20% agreement on any one of the possible five answers. (RPFF ¶¶ 869–872).

Dr. Stewart explains that an example of misleading homogeneity is found in the APCO survey question regarding how long it should take for something to decompose if it is labeled biodegradable. (RPFF ¶¶ 869–72). In that question, four of the six response options are a year or less, so it is not surprising that 60% of respondents chose an option of one year or less. Indeed, random responses spread among the six options would result in 66% of the responses falling in one of the four categories related to one year or less. (RPFF ¶¶ 869–72). That is what one must expect when people are asked a question about which they have little knowledge—a near perfect proportion of random responses.

Well aware of the problems in the APCO survey, Complaint Counsel engaged the services of Dr. Shane Frederick in an attempt to support the One Year Rule. (RPFF ¶¶ 275–77).

Dr. Frederick, who, like Dr. Stewart, proclaims that open-ended questions are superior to closed-ended questions, performed his own "survey" using largely open-ended questions. (RPF ¶¶ 277–80). The problem for Complaint Counsel, however, is that unlike Dr. Stewart's survey, Dr. Frederick's survey still endeavored to pigeonhole responses into numerical categories after the fact and does not meet generally accepted standards for survey research. (RPFF ¶¶ 904–1104; RX 56 at 10). In fact, Dr. Frederick readily admits that he is not familiar with the standards that are used to determine the qualifications of survey experts in federal court or in proceedings before the FTC. (RPFF ¶¶ 878–84). Dr. Frederick is unfamiliar with the Reference Manual on Scientific Evidence, and has no "specific criterion in mind" as to what makes a survey valid. (RX 858 (Frederick, Dep. at 186)). In fact, Dr. Frederick does not "know what other people have written" regarding what constitutes acceptable survey principles that define a valid survey. (RX 585 (Frederick, Dep. at 186–187)). Complaint Counsel drafted substantial portions of Dr. Frederick's expert report, including citations and substantive content. (RPFF ¶¶ 885–94).

Perhaps Dr. Frederick's documented lack of knowledge about what constitutes valid surveys in the litigation context is the reason why he chose to conduct a Google Consumer Survey with no screening questions and with only one question per respondent in an attempt to support the One Year Rule.[20] He chose the Google Survey interface despite the fact that no Google Consumer Survey has ever been relied upon as evidence in an FTC proceeding, and that its use has never been approved of or validated in any peer reviewed literature. (RX 858 (Frederick, Dep. at 189); RPFF ¶ 903). Google Consumer Survey is simply unproven at best.

[20] Cost was also another factor. (RX 858 (Frederick, Dep. at 123–5)). This must be especially true because the FTC paid Dr. Frederick a flat fee of $40,000, of which Dr. Frederick was entitled to keep whatever amount he did not spend. (RX 858 (Frederick, Dep. at 8:11–15)). Of the $40k allocated to Dr. Frederick, he profited approximately $32,010, mostly by choosing cheap survey methodologies. (RPFF ¶¶ 899–904).

As Dr. Frederick recognizes, there are well constructed consumer internet panels available, that, for example, Dr. Stewart often uses. (RPFF ¶¶ 896–98). The reasons for the lack of support for Dr. Frederick's Google Consumer Surveys are obvious. (RPFF ¶¶ 915–1104). For one, there is no way to ascertain the degree to which the sample of respondents used in Dr. Frederick's Google Consumer Surveys are representative of any identifiable population. (RPFF ¶¶ 922, 1090). The sample itself is unknown and unknowable. That is because there is no verification of respondents with Dr. Frederick's Google Consumer Surveys; rather, information on respondents to Dr. Frederick's Google Consumer Surveys is merely inferred by Google from information associated with or that resides on a computer. (RPFF ¶ 1090). Dr. Frederick used no screener questions to assure that he knew who in fact was responding to any particular question and what the age was of the respondent. (RPFF ¶ 1092). He declined to pay the additional fee to include two-part questions that might have provided more direct information about the respondent population. (RPFF ¶ 1091).

Google survey generally works by giving internet users access to "premium content" in exchange for answering a question, as opposed to paying for a subscription. Therefore, the questions in Dr. Frederick's survey were, at best, a distraction and barrier to respondents whose objective it is to access information, not complete a survey. (RPFF ¶ 1095). That type of questioning creates a disinterest bias; a concept alien to Dr. Frederick at the time of his deposition. (RPFF ¶¶ 1095–96). That explains why so many respondents answered Dr. Frederick's survey with nonsensical answers. (RPFF ¶ 1096).

In addition, Dr. Frederick, and his students who acted as his coders, failed to accurately report the data received from the Google Survey. (RPFF ¶¶ 1097–1104). For example, Dr. Frederick coded nonsensical answers such as "1 second" as "less than one year." (RPFF ¶¶

1041–44). That may be because, unlike Dr. Stewart's survey which used well-trained coders, Dr. Frederick believes that coders only need to be able to read and follow directions.[21] Moreover, Dr. Frederick's survey failed to code accurate and relevant responses such as "don't know." (RPFF ¶¶ 1099–1100). Even more troublesome, however, is the fact that Dr. Frederick's supervising coder, Andrew Meyer, was aware that Dr. Frederick's research was going to be used by Complaint Counsel against ECM. (RPFF ¶ 1101). Dr. Frederick was likewise aware and yet he did most of the coding work. (RPFF ¶¶ 1034–1104). In short, the coders were not blinded, so bias infected the study. (RPFF ¶¶ 1034–1104).

In addition, as Dr. Stewart makes clear, even if Dr. Frederick's survey was valid—it is not—its results, like Dr. Stewart's survey results, suggest that there is considerable diversity among respondents in terms of their claimed knowledge about biodegradable products and their views about the time it takes various materials to biodegrade. (RX 856 at 13–14). Therefore, because Dr. Frederick's "survey" is plainly not valid as judged against generally accepted survey principles, and because its results do not show any uniform understanding amongst consumers about how long a biodegrade product takes to decompose, the concerns that both he and Dr. Stewart have regarding the APCO study cannot be alleviated by the existence of Dr. Frederick's "survey." (RPFF ¶¶ 878–1104; RX 858 (Frederick, Dep. at 151–52).

Dr. Stewart explained in detail that Dr. Frederick's Google Consumer Surveys failed to satisfy all seven of the generally accepted principles of survey research. In particular, Dr. Stewart found: (1) the survey did not properly choose and define a population because it was not clear what the population was (RPFF ¶ 918); (2) the sample population was not representative of

[21] *See* RX 858 (Frederick, Dep. at 168–169). Based on some of the initial coding disclosed to ECM by Dr. Frederick, it appears that Dr. Frederick's coders were even unable to read and follow directions correctly. (RX 856 at 13).

the population, or could not be determined to be representative (RPFF ¶¶ 918–923); (3) Dr. Frederick did not accurately report the data gathered (RPFF ¶¶ 923–26); (4) the data was not analyzed in accordance with accepted statistical principles (RPFF ¶¶ 927–32); (5) the questions that were asked were not clear (RPFF ¶¶ 933–35); (6) the survey was not conducted by unbiased qualified persons (RPFF ¶¶ 936–56); and (7) the process was not conducted to ensure objectivity (RPFF ¶¶ 936–64).

2. ECM Permanently Discontinued the "9 Month to 5 Year" Claim Three Years Ago and, So, It Is Not a Basis for Equitable Relief

Complaint Counsel bases this case on the mistaken assumption that it is a typical deceptive advertising case, but the record reveals this case to be *sui generis*. In nearly every deceptive advertising case brought before the agency save this one, advertising[22] involves paid solicitations of business to an audience of lay consumers who then purchase the product in issue without substantive investigation of its composition and utility. In stark contrast here, there is no advertising material to a purchase within the legal definition of the term.[23] (RPFF ¶¶ 300–303). Most companies hear of ECM by word of mouth from other companies or at networking functions. (RPFF ¶ 304). The customers are not lay consumers but sophisticated plastics manufacturers possessed of their own scientists, engineers, lawyers, and marketing departments. (RPFF ¶¶ 415–418; 433–604). Purchases are not made based on ECM's web site, ECM

[22] "Advertising" is defined by the FTC "to mean a notice or announcement that is publicly published and is paid-for." *In the Matter of R.J. Reynolds Co., Inc.*, FTC Dkt. No. 9206, 1988 WL 490114, at *2 (Mar. 4 1988); *see also First Health Grp. Corp. v. BCE Emergis Corp.*, 269 F.3d 800, 803–04 (7th Cir. 2001) (explaining that "advertising is a form of promotion to anonymous recipients, as distinguished from face-to-face communication. In normal usage, an advertisement read by millions (or even thousands in a trade magazine) is advertising, while a person-to-person pitch by an account executive is not").

[23] Indeed, ECM spends less than $12,000 per year on advertising, mainly for the maintenance of its web site. (RPFP ¶ 300).

information disseminated, or even ECM discussions but only after a six month to multi-year process of evaluation in which the company investigating the product actually manufactures a test batch of the plastic with the ECM additive infused, testing it to determine its utility for itself. (RPFF ¶¶ 296, 307). That process is not optional for ECM's plastic manufacturer customers, but a necessity because without actually manufacturing the company's own plastic with the additive included they cannot know whether the resulting plastic will be capable of mass production using the company's existing equipment, will be affordably produced, will result in a product that has the same functionality as the existing product, and will meet consumer expectations for the product. (RPFF ¶¶ 355, 401, 404).[24] Thus, we here deal principally not with commercial speech, but with fully protected non-commercial information exchange that is open (ECM encourages customers to test its additive in their plastic) between sophisticated parties, based on the customers' own evaluative testing, which forms the actual basis for each purchase, wherein the truths of utility and functionality are discerned through independent customer ascertainment.

The web site is of no utility to lay consumers because the additive is a pellet unusable except by plastics manufacturers; interest, if at all, from an individual not within a plastics company, is thus academic. (RPFF ¶ 298).

Over the past decade, the information ECM has exchanged with its prospective and actual customers has necessarily changed to accommodate an evolution of scientific understanding concerning how its additive technology works in landfill environments. In the first instance, ECM offered its "9 month to 5 year" degradable claim not as a performance claim, but as a means to distinguish its technology from competing technologies claiming to satisfy the short-

[24] RX 875, at 258 (the "vast majority" of ECM's customer "are very large and sophisticated companies").

term compostability standards,[25] a claim reasonably based on testing performed by the additive's inventor, Patrick Riley, (RPFF ¶¶ 43–48, 51), and by ECM's current President Robert Sinclair. (RPFF ¶¶ 51–54). Later, the FTC revised its Green Guides to recommend qualifications. (RPFF ¶ 313).[26] ECM has *always* qualified its marketed claims[27] and has explained to customers that the time frame for biodegradation is entirely dependent on a multiplicity of environmental factors. (RPFF ¶¶ 310–12).[28] ECM updated its website to include the following explanation:

> The basic concept is that biodegradation is a natural process that occurs around the world but at various speeds due to various conditions. Plastics with our additives behave like sticks, branches or trunks of trees. Due to this fact, we do not guarantee any particular time because the time depends on the same factors that the biodegradation of woods and most other organic materials on earth depend – ambient biota and other environmental conditions. Under specific composting conditions with additional accelerants sprayed on them, some customers have reported biodegradation in as little as a couple of months. Under the more usual, commercial composting conditions using high heat processes, a time frame of around some period greater than a year is a reasonable expectation.[29]

(RPFF ¶ 377). That type of information is characteristic of ECM's communications with all of its customers. (RPFF ¶¶ 378).[30]

Troubled with the concept that the FTC would require a specific rate of biodegradation (an impossible task given real world environmental variances), ECM has used disclaimer language that is consistent with the scientific evidence, conveying to every customer that, for each individual piece of plastic produced, the rate of biodegradation will vary, most often using

[25] RX 875 (Sinclair, Dep. at 274) (the 9 month to 5 year claim is intended "to distinguish [ECM] from shorter biodegradable alternatives—in other words, the composters").

[26] RX 173.

[27] RX 875 (Sinclair, Dep. at 277) (ECM "always qualified the claims").

[28] *See, e.g.*, RX 135.

[29] RX 681, at 61.

[30] *See id.* ("It is not a 'poof, it's gone' system but simply makes the plastic product biodegrade as if it were a stick or a branch off a tree rather than 'sticking around' for hundreds of years").

the example that a piece of plastic that ultimately ends up in a landfill in a frigid and dry climate will biodegrade at a much different rate than that ending up in a warm and moist climate. (RPFF ¶ 311). The evidence suggests that ECM customers are, in fact, only concerned with marketing a "biodegradable" plastic and, so, they did not base a purchase decision on rate of biodegradation at all (and considered ECM's statements concerning the "rate" of biodegradation only to the extent those claims were apparently mandated by the Federal Trade Commission).[31] We note further, that ECM's plastic manufacturing clients are veterans in the plastics business, very familiar with their products' functionality and disposition in the market and with the wide variety of competing biodegradable and compostable products in the market. (RPFF ¶¶ 433–604). They are the most well-informed as to biodegradation of their own products because they have to know whether their products will meet functional and environmental expectations. (RPFF ¶¶ 398–400).

Following the revisions to the Green Guides, ECM dispatched a truthful and non-misleading email to all of its customers explaining the FTC's requirements concerning biodegradable claims.[32] This e-mail, in response to the Green Guide revisions, explained:

> If you have evidence that your products with our additives will fully biodegrade in one year or less in the environment where it will be customarily disposed you may still make an unqualified claim of "biodegradable" for those products. But for most of our customers' plastic products with our additives whose customary disposal is in a landfill, they will not be able to use that unqualified claim.[33]

ECM continued by discussing the benefits of its product: "Municipal Solid Waste that biodegrades **slowly but surely over periods from a few years to tens of years** provides the

[31] *See* RX 87 (Blood, Dep. at 193).
[32] *See, e.g.*, RX 35–RX 77.
[33] *See* RX 35–RX 77.

(sic) [landfill gases] that is captured, processed and sold to the public renewable energy or even new chemical source. This is the end-of-life scenario that has made plastic products **with our additives** so ever-increasingly popular."[34]

Sophisticated ECM customers have understood that each product is unique, and biodegradation testing is likely required to assess how each specific product performs.

The evidence reveals that ECM has truthfully and accurately informed customers that the rate of degradation in the environment is highly variable and uncertain, and dependent on many factors. (RFPP ¶¶ 310, 311, 377, 421). ECM's customers were aware of the FTC's requirements in the Green Guides, and they tailored their advertising content according to those policies. (RX 35–RX 77; RX 871 (Blood, Dep. at 193)).

ECM always explained the actual rate of biodegradation for each specific plastic to customers as being an approximation that was, of course, subject to numerous disposal conditions. (RPFF ¶ 310). ECM explained to customers that it had seen products biodegrade in less than nine months in some conditions, however, conditions in an extremely dry or cold climate might result in biodegradation in far more than five years. (RPFF ¶ 311).
The time frame was always expressed as possible but not probable with the probability being dependent on actual conditions of the location where the plastic would ultimately be discarded. (RPFF ¶ 312). The FTC revised its Green Guides to prohibit unqualified biodegradable claims without suitable qualifications in 2012. (RPFF ¶ 313).

ECM stopped using the nine months to five year time frame approximately three years ago after the revision of the Green Guides was released. (RPFF ¶ 314). Mr. Sinclair felt that the literal interpretation of ECM's timeframe claims was more of an obstacle than a benefit, and

[34] RX 35–RX 77 (emphasis added) (collection of the same notice email send to customers after Green Guide Revisions).

ECM discontinued making such claims. (RPFF ¶ 315). Once the most recent revision of the Green Guides required a product to fully biodegrade within one year to make an unqualified "biodegradable" claim, ECM determined that it had to qualify its claim to satisfy the FTC regulation. (RPFF ¶ 316).

From that point on, ECM has stated that its plastics infused with the ECM additive would biodegrade in some timeframe greater than one year. (RPFF ¶ 317). ECM has no intention of ever making the nine month to five year claim again. (RPFF ¶ 318). As explained above, it is clear from the record evidence that ECM customers did not consider material to their purchase any claim of rate but, instead, depended on the general claim of biodegradability, which is borne out by those company's own tests, 33 of which are in the record and show the additive hastening biodegradation of the plastic itself. (RPFF ¶¶ 357–59, 431, 605–725; *infra* at 117).

3. Complaint Counsel's Straw Man Definition of "Biodegradable" is Unsupported by Science, and Arbitrary and Capricious

A court should "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706. An agency's decision is arbitrary and capricious when the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Manufacturers Assoc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983).

Review of agency action is "not merely perfunctory," the review should be a 'searching and careful' inquiry.'" *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795 (D.C. Cir. 1983); *Specialty Equip. Mkt. Ass'n v. Ruckelshaus*, 720 F.2d 124, 132 (D.C. Cir. 1983)

("when reviewing agency's determinations under "arbitrary and capricious" standard, "we must make a substantial and searching inquiry to ensure that the agency's decisions are the product of reasoned thought and based upon a consideration of relevant factors"); *Dickinson v. Zurko*, 527 U.S. 150, 155 (1999) ("[t]he APA requires meaningful review; and its enactment meant stricter judicial review of agency fact finding than Congress believed some courts had previously conducted").

Complaint Counsel's action against ECM is predicated on an arbitrary and capricious definition of "biodegradation" that results in a bias that favors rapidly degrading over more slowly degrading substances. *Compare* 16 C.F.R. § 260.7(b) (allowing "compostable" claims if the marketer has "competent and reliable scientific evidence that all the materials in the item will break down into, or otherwise become part of usable compost in a safe and timely manner in an appropriate composting facility, or in a home compost pile or device") *with* 16 C.F.R. § 260.8(c) (prohibiting "biodegradable" claims "if the items do not completely decompose within **one year** after customary disposal") (emphasis added). That definition does not arise from science, (RPFF ¶¶ 774–814), but is a policy choice, one that affects basic environmental policy nationally and, as explained below, although it is sought by Complaint Counsel to be a rule of decision in this case, cannot be because it is beyond the jurisdiction of the FTC, it being a regulatory province squarely within the enabling statutory powers of the EPA, not the FTC, to decide. *See infra* at 202 (Ultra Vires agency action).

In their Proposed Order, Complaint Counsel specifically explained that "[f]or unqualified biodegradability claims, any scientific technical protocol (or combination of protocols) substantiating such claims must assure complete decomposition within one year and replicate, *i.e.*, simulate, the physical conditions found in landfills, where most trash is disposed." *See*

Complaint, at 12 (¶4). In other words, for a product to be considered "biodegradable," the product must fully biodegrade within one year. Adoption of this One Year Rule is arbitrary (all manner of commonly recognized "biodegradable" substances, such as banana peels, orange peels, tree trunks, and paper, do not reliably break down into elements in nature within one year after customary disposal); adoption of the One Year Rule is capricious (it deviates from the peer reviewed scientific literature on "biodegradation" which in not a single instance of record includes the definition of biodegradation presented by Complaint Counsel); adoption of the One Year Rule is an abuse of agency discretion (it is not for the FTC, but for the EPA, to determine standards of biodegradability in relationship to landfills and by proscribing use of this essential term in identifying products of import for landfill disposal, the agency interferes, wittingly or not, with national environmental policy). (RPFF ¶¶ 774–814, 1522, 1523, 1538, 1895).

Complaint Counsel therefore creates out of whole cloth a "definition" of biodegradability for purposes of unqualified claims that is alien to the common definition of the term in the dictionary and to the scientific definition of the term in the peer reviewed literature, and compounds the error by failing to acknowledge that in the real world there is literally *no product or substance* commonly recognized as biodegradable that can reliably satisfy the definition: not a banana peel, not an orange peel, not a tree trunk, not paper, and certainly not a common plastic polymer.

a. The Scientific Definition of Biodegradation Conflicts with Complaint Counsel's Definition

The scientific experts in this case testified that many scientifically accurate definitions exist for terms like "biodegradable," "biodegrade," and "biodegradation." (RPFF ¶¶ 782–95, 797–805). The definitions for those terms are necessarily broad to accommodate a range of

potential mechanisms. For example, the Merriam-Webster dictionary defines "biodegradable" as something "capable of being slowly destroyed and broken down into very small parts by natural processes, bacteria, etc." or "capable of being broken down especially into innocuous products by the action of living things (as microorganisms)." (RPFF ¶ 780).[35] Other sources have defined "biodegradable" to mean "capable of being decomposed by bacteria or other biological means." (RPFF ¶ 781).[36] The definitions universally describe a biological process of breakdown and equally universally do not include either a time limit on the process or a specified degree of disintegration or elimination of the degrading product. (RPFF ¶¶ 774–81).

ECM's experts have testified that "biodegradation" is properly described as an *ongoing process*, and the word "biodegradable" refers, simply, to a material capable of undergoing that process. (RPFF ¶¶ 791, 793, 794, 798–800). Noticeably absent from scientific definitions of "biodegradation" or "biodegradable" is any reference to a specified rate, extent, or time period for degradation. (RPFF ¶¶ 798–800). Outside of this case, Complaint Counsel's experts have never used time or rate limitations in their published definitions of "biodegradation." (RPFF ¶¶ 806–07). It is a contrived distinction, an artificial construct divorced from the real world. It is a superimposed policy judgment, not a reflection of accepted meaning known to consumers or to ECM customers.

As understood in science, the term "biodegradation" refers to the process by which microorganisms, bacteria, fungi, etc., combined with their natural mechanisms of action, effect the breakage of plastic bonds through acids and enzymatic action. (RPFF ¶¶ 774–82, 790, 794).

---

[35] *See* "Biodegradable." *Merriam-Webster.com*. Merriam-Webster, n.d. Web. 22 July 2014, *available at* http://www.merriam-webster.com/dictionary/biodegradable.

[36] *See* "Biodegradable." *Collins English Dictionary*, 10th Ed. 2009 (July 22, 2014), *available at* http://dictionary.reference.com/browse/biodegradation.

By contrast, Complaint Counsel's experts were asked by Complaint Counsel to adopt a peculiar, artificial construct alien to the scientific literature for the definition of "biodegradable," to wit: "that the entire plastic will completely break down and return to nature (*i.e.*, decompose into elements found in nature) within one year after customary disposal (*i.e.*, incinerator, landfill, or recycling)." (RPFF ¶ 771).[37] Dr. McCarthy, Complaint Counsel's expert, testified that he prepared his expert report as a "collaborative effort between [himself] and complaint counsel." (RPFF ¶ 1360).[38] He testified that the definition of "biodegradable" which included the one-year limitation "was the definition that [he] used with respect for this case" throughout his report and in his expert opinion.[39] He admits that Complaint Counsel wrote that definition presented in footnote 1 of his expert report as:

> [B]iodegradable means that the entire treated plastic will completely break down and return to nature (*i.e.* decompose into elements found in nature) within one year after customary disposal (*i.e.* incinerator, landfill, or recycling).

(RPFF ¶¶ 269–70).

His contribution was the last sentence of the footnote, which presumptively equates without attribution this superimposed agency definition of the term with the scientific definition of the term. (RPFF ¶ 272). But during cross examination, Dr. McCarthy dissembled, admitting that he was entirely unaware of any instance in which a peer reviewed article concerning plastics biodegradation ever defined the term biodegradation as Complaint Counsel had. (RPFF ¶ 273). Indeed, Dr. Barlaz explained that the definition given by Complaint Counsel was nowhere present in the scientific literature. (RPFF ¶ 799). That understanding was mirrored by other experts who testified. (RPFF ¶¶ 798, 800).

---

[37] *See* RX 841 (McCarthy, Dep. at 20–21); CCX 891 (McCarthy's Rep, at p. 5, n.1).
[38] RX 841 (McCarthy, Dep. at 20).
[39] RX 841 (McCarthy, Dep. at 21).

The inherent absurdity of the definition came to the fore repeatedly throughout the hearing, as it had in Dr. McCarthy's deposition. (RPFF ¶¶ 1365–73, 1536–38). Asked whether a product could be considered "biodegradable" if it degraded 95 percent in 364 days, Dr. McCarthy testified that it "would not satisfy the definition." (RPFF ¶ 1392).[40] He maintained that position even though all other qualified experts in this case have accepted that a product will almost never biodegrade to one hundred percent, as most substances will leave behind some residue or humus. Dr. McCarthy's strained attempt to defend Complaint Counsel's erroneous definition of "biodegradable" continued:

> Q: Assuming that on day 365 [a product] was only 95 percent [biodegraded] still, but on day 366 it becomes 100 percent, would that satisfy the definition of biodegradable in [McCarthy's report]?
>
> A: That wouldn't satisfy the definition.[41]

(RPFF ¶ 1392).

Consider the implications, from a scientific perspective, of an FTC policy that limits the definition of "biodegradability" in that manner, excluding products that are obviously—and scientifically proven to be—"biodegradable" simply because the achievement cannot be documented within an arbitrarily one year time limit.

Perhaps most troubling is that no scientific article supports Dr. McCarthy's definition of biodegradable. Complaint Counsel's purported expert in landfills explained that even "rapidly degrading wastes" such as food waste and sewage sludge might take between 9 and 14 years to biodegrade fully.[42] Moreover, Dr. McCarthy himself has labeled "biodegradable" plastic polymers that he did not prove through testing would reliably biodegrade 100% within one year.

---

[40] RX 841 (McCarthy, Dep. at 28).
[41] RX 841 (McCarthy, Dep. at 29).
[42] Tolaymat, Tr. 153–54.

(RPFF ¶¶ 1451–64).[43] Indeed, under a sworn affidavit to the United States Patent and Trademark Office, Dr. McCarthy affirmed the validity of scientific evidence supporting as "biodegradable" a plastic polymer resin that by testing of only 45 days biodegraded by only 14%, Dr. McCarthy's '199 patent. (RPFF ¶¶ 1454, 1458, 1463, 1465, 1467, 1542).

Complaint Counsel's definition of "biodegradable" entraps every business in this field that it cares to charge, regardless of the scientific merits. The definition cannot be reliably satisfied by any company in the plastics biodegradation business and, so, any company charged will necessarily fail the arbitrary One Year Rule. Complaint Counsel's approach therefore becomes one where *no unqualified* claim concerning "biodegradation" can ever exist in the market, even if the products are, in fact, "biodegradable." Simply put, no company can establish a "rate" or "extent" of biodegradation because the environmental factors existing in MSW landfills are highly variable and uncertain, thus causing the One Year Rule to form a de facto absolute barrier to any biodegradation claim for products destined for disposal in landfills. (RPFF ¶¶ 1582, 1640–43, 1713, 1723, 1815, 1851, 1871–76). Significantly, Complaint Counsel put forth no evidence of any kind showing how a company in ECM's position should have, or even could have, established scientifically a set rate and extent of biodegradation in an MSW landfill. Just like a piece of paper, which may degrade rapidly or not at all—depending on environmental conditions—the concept of biodegradability is an intrinsic property of the material and not a process quantifiable by an arbitrary time limit of one year. (RPFF ¶¶ 65, 1893). Living things, microbes have their own predispositions to metabolize carbon chains and those predispositions are affected by many variables but one that certainly does not affect their actions is an FTC time clock.

[43] RX 362; RX 755, at 13.

Because plastics manufactured with ECM's additive satisfy the generally accepted scientific definitions of "biodegradable," and because there is no competent survey evidence to establish that a significant minority of ECM customers or lay consumers share a common understanding of the term or a set time period within which they expect 100% biodegradation of plastics to occur, the evidence does not support a conclusion of deception. The use of the claim "biodegradable" in marketing is, at worst, potentially misleading commercial speech for which the constitutional resort remains imposition of a reasonable and succinct claim qualification (such as, the actual rate of biodegradation depends on numerous environmental variables which may or may not be present in any given disposal location), not cease and desist orders that arbitrarily limit the right to communicate the term biodegradation because a set rate is not provided (which would be impossible to prove and misleading in every case) or because a set degree of decomposition is not provided (which would also be impossible to prove and misleading in every case).

b. The Anti-Competitive Effect of Enforcement of Complaint Counsel's Biodegradation Definition

Complaint Counsel's arbitrary and capricious definition of "biodegradable" substantially assures the defeat of competitive markets in biodegradable plastics by erecting an impenetrable barrier to use of the term "biodegradable" in those markets for all products except compostable bioplastics. In the case of compostables, the FTC has adopted a lenient definition that sets no time limit for the process of degradation and no complete requirement of elimination or dissolution of the compostable product. *See* 16 C.F.R. § 260.7 (allowing marketers to market their products as compostable if the marketer has "competent and reliable scientific evidence that all the materials in the item will break down into, or otherwise become part of usable compost in

a safe and timely manner in an appropriate composting facility, or in a home compost pile or device").

Private interest groups heavily lobbied the FTC to enact more demanding regulations for biodegradable plastics than for compostables, succeeding in that endeavor in the 2012 amendments to the Green Guides. (RPFF ¶¶ 1416–17). Among those groups were organizations like the Biodegradable Products Institute (BPI), which is a member-based organization representing compostable technologies,[44] and Metabolix, Dr. McCarthy's principal benefactor at UMass Lowell. (RPFF ¶¶ 1413–19). Indeed, both BPI and Metabolix also lobbied the FTC to take enforcement action against their competitor ECM. (RPFF ¶¶ 1413–18).

"Biodegradable" plastics are not the same as "compostable" products. While a "compostable" product might also be considered part of the "biodegradable" universe, the opposite is not true because the process of composting involves different environmental elements than those present in landfill environments.[45] Composting involves aerobic processes (with oxygen) as opposed to anaerobic processes common in landfills.[46] Because composters, including commercial systems, are actively managed to promote optimal conditions, composting is expected to yield higher rates of degradation at a faster interval than biodegradation in anaerobic environments such as landfills. (RPFF ¶¶ 327, 1693).

The ASTM has established testing protocols that assess the compostability of products including plastic polymers in the anaerobic environment. (RPFF ¶ 1426).[47] Partly because compostable systems benefit from rapidly degrading waste, the standards concerning "compostability" are generally pass/fail, whereby a product must degrade past a certain extent

[44] *See, e.g.*, RX 172.
[45] RX 875 (Sinclair, Tr. at 85).
[46] *Id.*
[47] *See, e.g.*, RX 367.

within a specified period of time before the product can be called "compostable."[48] Ironically, the FTC rules are the opposite, setting no time limit or extent of degradation for compostable biodegradation and setting an arbitrary one year time limit and a complete biodegradation requirement for biodegradable plastics. *Compare* 16 C.F.R. § 260.7 *with* 16 C.F.R. § 260.8.

The ASTM D6400 protocol is the "Standard Specification for Labeling of Plastics Designed to be Aerobically Composted in Municipal or Industrial Facilities."[49] That standard requires 60% biodegradation by biological processes during composting within 180 days.[50] Other similar standards (e.g., EN 13432) require 90% biodegradation in that time period.[51] Under the D6400 standard, a product that degrades only 59% in 180 days is not considered "compostable," but a product that degrades 61% would be "compostable."[52]

Witnesses (fact and expert) testified in this case that the ASTM body is a political and scientific arena, where methods/standards are sometimes driven principally by financial interests.[53] There are no membership requirements in the ASTM working groups that promulgate standards.[54] Any company or individual with a vested interest, and financial support, can participate in the voting process that results in industry standards.[55] Those standards have no legal precedence, and language in the standards that relates to legal standards can be ignored. The ASTM testing standards are relevant to the extent they embody methodologically sound methods to gather scientific data, which must then be interpreted.

---

[48] CCX 91.
[49] CCX 91.
[50] *Id.*
[51] *See* RX 772.
[52] CCX 91.
[53] Sinclair, Tr. 799–80; CCX 943 (Barlaz, Dep. at 95–98).
[54] CCX 943 (Barlaz, Dep. at 95–98).
[55] RX 875 (Sinclair, Dep. at 285).

Members of the compostable industry have heavily influenced the publication and revision of certain ASTM standards relating to plastics biodegradability testing.[56] Tests like the D6400 are tailored to rapidly degrading products that can perform well enough within the narrow 180 day testing period.[57] Those tests, however, are inadequate to measure the long-term biodegradability of more slowly degrading products, like plastics manufactured with ECM's technology. (RPFF ¶ 2672).[58] While it is not the case that ECM plastics are non-biodegradable, those products are not expected to degrade rapidly and, so, manufacturers of compostable technologies can use the unscientific claim language in the ASTM protocols to limit marketing claims by competitors.

The same outcome occurs with Complaint Counsel's definition of "biodegradable" which includes the narrow one-year limit. If Complaint Counsel succeeds in this case, products that cannot achieve rapid degradation in short periods of time will essentially be outlawed because under the One Year Rule they cannot lawfully communicate to the market that they are biodegradable when they degrade in a period of time greater than a year. Makers of compostable products, like some bioplastics or oxodegradable polymers, stand to gain a substantial market advantage as a direct and predictable result of the One Year Rule and Complaint Counsel's campaign of enforcement. (RPFF ¶¶ 322–23, 1412). After all, compostable products cost substantially more than the biodegradable additives (of which ECM is just one of many companies selling similar technologies) and without agencies of the government doing their bidding, the market favors ECM's technology from a cost-benefit standpoint. (RPFF ¶¶ 328, 330, 338, 345, 387, 706). Plastics manufacturers are less inclined to use the expensive

[56] *Id.* at 172.
[57] *Id.* at 263–264, 56.
[58] *Id.* at 89.

technology if a cheaper alternative exists that will produce an environmentally friendly, biodegradable plastic. (RPFF ¶¶ 636, 667, 671, 706). One solution is to restrict the market for "biodegradable" plastics such that only those expensive technologies qualify. Because the marketing interest lies primarily with "biodegradable" products, as opposed to biodegradable products that disappear within certain time periods, manufacturers are willing to pay for the most cost-effective product that satisfies the FTC's definition of "biodegradable." By eliminating alternatives through administrative regulation, ECM's competitors gain market share. (RPFF ¶¶ 322–23, 1412).

That process was evident here, where for years ECM's competitors directly lobbied FTC attorneys to pursue enforcement action against additive companies, including ECM. (RPFF ¶¶ 1413–19).[59] Representatives from BPI had open channels to FTC attorneys and frequently reported marketing claims by additive companies. (RPFF ¶ 1417).[60] ECM competitors, like Metabolix, Inc., the benefactor of Complaint Counsel's expert Stephen McCarthy, also lobbied for enforcement against additive companies and, in particular, against ECM. (RPFF ¶¶ 1413–15).[61] Groups like the BPI, and scientists affiliated with same, zealously lobbied the ASTM to incorporate limited language in biodegradability test standards that would (unscientifically) limit *claim language* based on test results. (RPFF ¶ 1416).[62] Finally, organizations like the BPI commissioned biased and methodologically unsound consumer perception studies in an attempt to persuade the FTC that end-consumers preferred rapidly degrading plastic products. (RPFF ¶¶ 826, 854). Whether wittingly or not, the Commission has rewarded those efforts by directly incorporating sections of BPI's comments (almost verbatim) into the 2012 Green Guide

[59] *See, e.g.*, RX 211.
[60] *See, e.g.*, RX 718–RX 733.
[61] RX 211.
[62] *See, e.g.*, RX 741.

revisions, and through enforcement actions such as that against ECM memorializing the arbitrary concept that a product must fully degrade within one year before it can be considered "biodegradable."

Perhaps in an effort to limit exposure to an apparent constitutional infirmity, the FTC explained in 16 C.F.R. § 260.8(c) that "unqualified" biodegradability claims were deceptive unless evidence showed complete degradation within one year, perhaps leaving room for qualified claims. In Section 260.8(d), the FTC explained that:

> Degradable claims should be qualified clearly and prominently to the extent necessary to avoid deception about:
>
> (1) The product's or package's ability to degrade in the environment where it is customarily disposed; and
>
> (2) The rate and extent of degradation.

See 16 C.F.R. § 260.8(d). That language is illusory, however, because there are no test methods sufficient to satisfy Complaint Counsel's heavy standards to prove a precise rate and extent of degradation occurring in a landfill environment (whether in landfills generally, specific landfills, or specific locations within individual landfills), nor could there ever be because so many variables affect the rate of biodegradation that it must be accepted as varying from location to location and time to time. (RPFF ¶¶ 1582, 1640–43, 1713, 1723, 1815, 1851, 1871–76).

In this case, Complaint Counsel has criticized ECM's reliance on ASTM standards because they do not "simulate or replicate" the landfill environment[63] (contradicting their own experts; Dr. Michel cleaves to ASTM standard D5511 as a demonstrative test of biodegradation and Dr. McCarthy has relied on gas evolution tests to prove biodegradability throughout his career). (RPFF ¶ 2919). Complaint Counsel's own experts have repeatedly used the very

[63] *See, e.g.*, RX 851 (Tolaymat, Dep. at 126–127).

methodologies Complaint Counsel condemn to prove that products biodegrade. (RPFF ¶¶ 1546 (McCarthy), 2768 (Tolaymat), 2917 (Michel)).[64] More significantly, Complaint Counsel and its experts have never explained precisely what type of scientific testing would be sufficient to show that a product biodegrades at a certain rate or to a certain extent within variable landfill environments (nor can they given that variability). (RPFF ¶¶ 1581–1605). When asked directly to explain what type of testing would be sufficient, an element to which Complaint Counsel has the burden, Complaint Counsel's experts demur, answering evasively and inconsistently. (RPFF ¶¶ 1581–88).[65]

Under its demanding (and unrealistic) definition of "biodegradation," no expert for Complaint Counsel has been able to identify the type, and accessibility, of evidence adequate to form a reasonable basis for making claims of biodegradability. *See In re Pfizer Inc.*, 81 F.T.C. 23 (1972). Its construct is a straw man, bereft of a competent scientific or survey evidentiary foundation, and calls for a set rate when nature delivers only variable rates. Indeed, even were the one year time limit applied to compostables, which the Commission in its rules and Complaint Counsel in its enforcement have assiduously avoided, the one year limit and the complete degradation requirement would not be capable of satisfaction. That is because the variable conditions in the environment, and particularly in landfills, make presupposition of a precise rate and extent of biodegradation impossible. (RPFF ¶¶ 1581–1605).

[64] *See* RX 362.

[65] Tolaymat, Tr. 218–19, 237–38, 239–54, 262–63, 296; McCarthy, Tr. 359–480.

The narrow FTC definition of biodegradation, and the absence of defined standards to support it, effects a change in national environmental policy due to its suppression of the entire non-compostable biodegradable plastics industry.[66]

c. The So-Called "One Year" Rule Was Based on Deliberately Skewed Market Data that Is Not Reflective of Actual Consumer Impression

For more than twenty years the FTC has required in 16 C.F.R. §§ 260.7–260.8 that companies possess evidence that a product or package "will completely break down and return to nature, *i.e.*, decompose into elements found in nature within a reasonable short period of time after customary disposal." However the concept of a "reasonably short period of time" was never defined, until 2012 when the FTC expressly stated:

> It is deceptive to make an unqualified degradable claim for items entering the solid waste stream if the items do not completely decompose within one year after customary disposal. *Unqualified degradable claims for items that are customarily disposed in landfills, incinerators, and recycling facilities are deceptive because these locations do not present conditions in which complete decomposition will occur within one year.*

See 16 C.F.R. § 260.8(c) (emphasis added). Because the overwhelming majority of products are destined for Municipal Solid Waste (MSW) landfills (73.89%),[67] that so-called "One Year Rule" effectively defined the term "biodegradable" for nearly all disposable consumer goods. As

[66] The FTC's nearly flawless record in administrative enforcement actions only adds to any apprehension. *See* David Balto, "FTC's winning streak is over," TheHill.com (Feb. 11, 2014) (quoting Chairman of the House Judiciary antitrust subcommittee Spencer Bachus (R-Ala.): "With this kind of record and an unbeaten streak that Perry Mason would envy, a company might wonder whether it is worth putting up a defense at all in a system in which the FTC brings a complaint, the case is tried before an administrative law judge at the FTC, and the FTC holds the authority to overturn a decision adverse to the agency").

[67] RX 511, at 13.

explained below, the One Year Rule contradicts generally accepted peer-reviewed science on biodegradation, which defines biodegradation as a process without an arbitrary one year limit.

The landfill environment is highly variable and heterogeneous, from one landfill to the next, but also within each landfill itself, making commonly known biodegradable substances, like banana peels, orange peels, tree trunks, and paper not reliably biodegradable within a single year or to the extent of a complete break down into elements found in nature.[68] (RPFF ¶¶ 1582, 1640–43, 1713, 1723, 1815, 1851, 1871–76). Predicting precise rates of degradation sufficient to satisfy the Commission is thus scientifically impossible, whether the product is an additive, like ECM's, or a compostable product, like those favored by the FTC's compostable rule, 16 C.F.R. § 260.7(b), which contrary to the biodegradation rule, 16 C.F.R. § 260.8, includes neither a time limit nor a complete break down into elements found in nature requirement.

The One Year Rule is scientifically baseless. Experts agree that even the most biodegradable substances (including food waste, etc.) will not biodegrade in an MSW landfill within one year. (RPFF ¶¶ 804, 805, 1523, 1538).[69] That means the FTC's "One Year Rule," which defines the "reasonably short period of time" for degradation, is unattainable for every single product on the market. Although the rule effects national environmental policy governing waste disposal, the rule was based not on sound science, but on what the FTC claimed was consumer perception of degradable claims.[70] When national environmental policy is effectively struck based on consumer perception (which, as we shall see is a misperception of public opinion in any event), it replaces rational science with arbitrary and capricious decision-making and it

[68] *See* CCX 893, at 8 (noting that composting accounts for just 11% of disposal waste when recycling is excluded).

[69] *See* RX 853, at 11; CCX 893, at 16.

[70] *See* Green Guide Policies, at 3.2

succeeds in aggravating rather than militating the environmental goal of lessening pollution. (RPFF ¶¶ 1594–1605).

The FTC explained that its One Year Rule was supported by "[t]he available consumer perception evidence." [71] FTC explained that:

> In a survey by APCO Insight, 60 percent of respondents expected that an item marketed as degradable without qualification will fully decompose in less than one year. The Commission concludes that this survey is a more reliable indicator of consumer perception than the Synovate study in which only 25 percent of respondents had the same expectation.[72]

In doing so, the Commission rejected another survey that had a higher sample size (the Synovate study).[73] In the Synovate study, ninety-three percent (93%) of all respondents thought it was acceptable to label a product "biodegradable" provided the product would decompose in a landfill.[74] The FTC rejected the Synovate study and based its Green Guide recommendations on the APCO study instead.[75] FTC explained that "[b]oth studies may be faulted for lacking control groups and presenting the timeframe questions with close-ended, rather than open-ended, answers, but they nevertheless are *the only studies in the record*."[76] Based on a well-designed telephone survey from Dr. David Stewart, ECM here presents current and reliable survey evidence that establishes the One Year Rule to be void of a basis in consumer perception and, thus, wholly arbitrary and capricious. (RPFF ¶¶ 1105–1344).[77]

The FTC chose the APCO study because, "[u]nlike the APCO study, the Synovate study results suggest that respondents' answers may have been not only biased, but also influenced by

---

[71] RX 195, at 121.
[72] RX 195.
[73] RX 195 at 118–122.
[74] RX 673.
[75] RX 195, at 118–122.
[76] *Id.* at 121 n. 409 (emphasis added).
[77] RX 856.

a tendency to avoid extreme answers."[78] FTC also explained that "respondents were informed that 'non-biodegradable plastic products take hundreds of years to decompose,'" but "[s]uch statements are absent from most marketing contexts, and did not appear in the APCO questionnaire."[79] Moreover, according to FTC, the design of the Synovate study revealed a "pattern of responses, together with the absence of choices in the range of less than one year," which "suggests that some respondents were avoiding an extreme response."[80] Accordingly, the "Commission conclude[d] that the proportion of consumers expecting full decomposition in under one year would be closer to 60 percent rather than 25 percent."[81]

ECM's expert in consumer psychology often relied upon by the Commission and FTC Administrative Law Judges, Dr. David Stewart, testified that the One Year Rule was based on flawed evidence and remains uncured by the patently unreliable Google Consumer Survey evidence from Complaint Counsel's expert, Dr. Shane Frederick. (RPFF ¶¶ 826, 848, 850–55, 865, 870–71, 877).[82] Dr. Stewart testified, and his consumer survey data revealed, that no consensus exists (not even from a significant minority of consumers) as to the meaning of the term biodegradable or as to an expectation of a precise time within which a plastic would biodegrade. (RPFF ¶¶ 1315–18, 1331–36). Indeed, a whopping 98% of respondents explained that they expected biodegradation rates to vary dependent upon variable environmental conditions and the type of plastic involved. (RPFF ¶ 1311). In short, as to rate of biodegradation, consumers expect it to vary and do not expect reliable achievement of complete biodegradation within one year after customary disposal. (RPFF ¶ 1312).

[78] RX 195, at 121.
[79] *Id.* at 122.
[80] *Id.* at 195.
[81] RX 195.
[82] RX 856.

The so-called "reasonably short period of time" for degradation after customary disposal must be examined through the scientific evidence, which reveals that void of biodegradable additives conventional plastics will last, at least, for thousands of years in the environment. Thus, plastics which biodegrade in decades, or even hundreds of years, are environmentally beneficial as they degrade in reasonably short periods of time when compared with non-biodegradable plastics. The evidence shows that ECM plastics should be compared not with an arbitrary and capricious "One Year Rule," but with untreated plastics that have an almost indefinite existence in the environment.

D. Complaint Counsel Failed to Meet Their Burden of Showing that ECM's Unqualified Biodegradation Claim Is False or Misleading in Any Material Respect

ECM Biofilms has proven that plastics made with its additive technology will biodegrade within a reasonably short period of time under conditions of customary disposal, particularly when compared with conventional, untreated plastic products. "Two theories have been used to prove that an advertisement is deceptive or misleading: (1) the 'falsity' theory or (2) the 'reasonable basis' theory." *In the Matter of Pom Wonderful LLC,* 9344, 2012 WL 2340406 (F.T.C. May 17, 2012) (at 234) (citing *Pantron I,* 33 F.3d at 1096). Where the "issue of whether Respondents' claims were deceptive turns on the nature and quality of Respondents' substantiation … the falsity and reasonable basis theories collapse into the same inquiry: did [Respondents] possess adequate substantiation to make such a claim?" *Id.* (quoting *FTC v. QT, Inc.*, 448 F.Supp. 2d 908, 966 (N.D. Ill. 2006)).

Proof of deception requires an analysis of the evidence as follows:

> [T]he Court must first determine what level of substantiation Defendants were required to have for their advertising claims, and this determination is a question of fact. Then, the Court must determine whether the Defendants

> possessed that level of substantiation … Defendants have the burden of establishing what substantiation they relied on for their product claims. The FTC has the burden of proving that the Defendants' purported substantiation is inadequate…

FTC v. QT, Inc., 448 F. Supp. 2d at 959 (citations omitted). For efficacy claims, the Commission must determine the level of substantiation by applying the *Pfizer* factors. *In re Pfizer, Inc.*, 81 F.T.C. 23 (July 11, 1972).

In sum, ECM has produced competent and reliable scientific evidence proving that plastics manufactured with its additive biodegrade anaerobically and aerobically. ECM's laboratory testing, in light of the totality of scientific evidence, prove that ECM's additive causes plastics infused with it to be biodegradable in biologically active landfills.[83]

First, ECM has produced 30+ independently performed gas evolution studies that tested various ECM-infused plastics of ECM customers against negative controls (i.e., untreated, conventional plastics that are known to degrade very slowly). Those tests included anaerobic lab work (e.g., ASTM D5511, BMP), and aerobic lab work related to composting (e.g., ISO 14855, UNI EN 14046). (RPFF ¶¶ 2129–2659). Results in those 30+ tests revealed biodegradation of the ECM plastic, not the additive alone. (RPFF ¶¶ 1899–1933, 1964–2037, 2129–2659). The biodegradation was measured by the amount of gas produced. (RPFF ¶¶ 1964–2009, 2129–2659). Researchers can determine the amount of biodegradation in the test article by comparing the carbon in the gas emitted from treated vessels with the carbon emitted in the blank inoculum and the control vessels. (RPFF ¶¶ 1964, 2202). The amounts of biodegradation observed in ECM's many positive tests was sufficient to conclude that the plastic polymer, and not just the ECM additive, had biodegraded substantially. (RPFF ¶¶ 1964–2009; 2129–2659). The accuracy

[83] *See infra* at 117 (table).

of those results was also confirmed by D6579 testing that compared molecular weights of the negative control versus the test plastic after biodegradation testing. (RX 838 at 73).

Second, ECM supported its gas evolution data with qualitative analyses performed by leading environmental scientists. (RPFF ¶¶ 2660–2706). Tests of the ECM additive infused plastics in landfill simulated conditions demonstrated that the plastic was biodegradable by gravimetric endpoints. (RPFF ¶¶ 2693–94). Dr. Timothy Barber (Environ Labs) further concluded that the ECM additive caused PVC polymers to degrade under simulated landfill conditions based, in part, on gravimetric endpoints, but also through an evaluation of free chloride atoms present in the test vessels. (RPFF ¶¶ 2694–2697).

Third, ECM confirmed that anaerobic biodegradation witnessed in the laboratory environment would translate into the real word conditions of a landfill. ECM has proven that Municipal Solid Waste (MSW) landfills are biologically active enough to support significant biodegradation in most instances. (RPFF ¶¶ 1810–1898). The anaerobic processes that result in landfill biodegradation are similarly present in the laboratory tests. (RPFF ¶¶ 2041–42). Moreover, the laboratory tests demonstrate that ECM plastics are intrinsically biodegradable when compared with untreated plastics. (RPFF ¶ 1814). As a biodegradable material, the plastics will biodegrade when environmentally favorable conditions exist for biodegradation. (RPFF ¶ 1628).

Fourth, ECM determined through various studies, including extended gas evolution studies and those where labs re-inoculated, that biodegradation of plastics would continue beyond the short testing periods so long as living biota remained present. The primary question is whether plastic made with the ECM additive is intrinsically biodegradable, to which one of the leading authorities in landfill science, Dr. Barlaz, testified in the affirmative. (Barlaz, Tr. 2218).

Because if the plastic is "biodegradable," it will continue to biodegrade whenever the environmental conditions support same, just like a piece of copy paper. (Barlaz, Tr. 2217-18). Where tests have shown a decrease in biodegradability, ECM's experts have explained that the test environment is almost always the cause, because closed-system laboratory tests are not designed to be operated for long duration tests, and the microorganisms will die over time.

Fifth, ECM determined based on peer-reviewed literature and expert opinion that conventional plastics of the type most ECM customers use can be enzymatically biodegraded by enzymes naturally produced by bacteria and microorganisms. (RPFF ¶¶ 1629–70, 1699–1765).

Sixth, ECM has debunked the scientific theories posited by Complaint Counsel's experts in their efforts to prove that additive technologies (not just ECM's) are inefficacious. Each of those arguments are theoretical, never once proven through actual testing. For example, Complaint Counsel speculates (together with its experts Drs. McCarthy and Michel) that a "priming effect" could have been responsible for positive test data in ECM's testing. (RPFF ¶¶ 2010–37, 2083–85, 2121–28). However, they present no scientific evidence of the effect occurring in anaerobic environments and make no attempt through the record evidence to prove the theory. They also offer no proof in the peer-reviewed literature for their theory, and each of ECM's experts believed the theory unproven and unreliable. Indeed, Dr. Barlaz affirmatively proved based on a statistical analysis of the results contained in tests of ECM additive containing plastics that the amount of biodegradation present could not be attributed to the additive alone but had to arise from the plastics themselves. (RPFF ¶¶ 2129–2885).

Complaint Counsel's expert Dr. McCarthy, the foremost proponent of the "priming effect" theory in this case is not a credible witness. Dr. McCarthy essentially works for ECM's competitors, most notably Metabolix, his primary sponsor at UMass-Lowell. (RPFF ¶¶ 1398–

1406). He has received substantial research funding (millions of dollars) from Metabolix. The intellectual property he invented that was patented in the '199 patent (RX 761; RX 757) is exclusively licensed to Metabolix, and provided McCarthy and UMass Lowell royalties. (RPFF ¶¶ 1399–1404). He is, therefore, personally and financially interested in the success of ECM's competitors, who, in turn, stand to profit if the FTC forecloses the biodegradable additive industry. The same competitors who hire Dr. McCarthy have directly lobbied the FTC to act against additive manufacturers, including ECM by name. (RPFF ¶¶ 1413–14).

In FTC proceedings, credibility is always in issue. (ALJ, Tr. 1526, 1706). It is for the judge to make character findings in instances where testimony, particularly of experts, is evasive, false, misleading, or perjurious. *Cota v. Tucson Police Dep't*, 783 F. Supp. 458, 464 (D. Ariz. 1992) ("When sitting as a finder of fact, a trial judge necessarily determines the credibility of expert witnesses."). Dr. McCarthy's expert opinions are unreliable not only because he has a direct financial stake in the outcome of the litigation (which, itself, is disqualifying[84]), but also because his testimony repeatedly dissembled with numerous contradictions evinced between his statements at hearing and those at deposition. (RPFF ¶¶ 1360–1580).

ECM's experts, including the proffered expert Dr. Grossman (Dr. McCarthy's colleague), have all testified to fundamental flaws and lack of scientific integrity in Dr. McCarthy's scientific analysis in this case.[85]

---

[84] "[T]he nature and extent of a witness's motives and his interest in the outcome of the case bear importantly upon an evaluation of the witness's objectivity, his bias, and the weight to be accorded his testimony." *United States v. IBM Corp.*, 66 F.R.D. 215, 219 (S.D.N.Y. 1974); *Nemir v. Mitsubishi Motors Corp.*, 200 F.Supp.2d 770, 774 (E.D. MI 2002) ("The more subjective and controversial the expert's inquiry, the more likely the testimony should be excluded as unreliable.").

[85] *See, e.g.*, Sahu, Tr. 1772–73 (explaining that Dr. McCarthy's litigation definition of "biodegradable" is not found anywhere in the peer reviewed literature); Sahu, Tr. 1871 (testifying that Dr. McCarthy's theory on pro-oxidants as an exclusive means to promote

Finally, no test failing to show biodegradation of a plastic infused with the ECM additive was subject to any causal analysis sufficient to prove that the additive failed to biodegrade as opposed to other causative bases for test failing, such as death of the bacteria in the inoculum, mis-manufacture of the test plastic, the presence of anti-microbial additives in the test plastic, or other ambient environmental conditions in the test environment not hospitable to biodegradation. (RPFF ¶¶ 2886–2908). Thus, each test failing to show biodegradation of the test plastic begets a question, not an answer, unless an evaluation is undertaken to determine causality. Failed tests without a causal nexus remain inconclusive, not negative, and cannot be deemed proof that the ECM additive itself failed to cause the plastic in issue to biodegrade. (RPFF ¶¶ 2886–2908).

Moreover, in light of Dr. Barlaz's analysis of the tests that do show biodegradation of plastics infused with the ECM additive, ECM has particular proof that the plastic, and not the additive alone, biodegraded. That affirmative proof is causally based and definitive. Thus, the totality of the scientific evidence, consists of numerous tests showing plastics themselves biodegrading when infused with the ECM additive and a subset of tests that were inconclusive. The inconclusive tests do not in any way negate the affirmative proof because they do not involve causal proof that the ECM additive was incapable of performing as opposed to other ambient test conditions required for a valid assessment. (RPFF ¶¶ 2886–2908).

1. ECM Additive Efficacy Depends on Strict Adherence to ECM Manufacturing Instructions

---

biodegradation is not supported); Sahu, Tr. 1894–97 (explaining that Dr. McCarthy's use of gas evolution testing contradicts Dr. McCarthy's own testimony); Barlaz, Tr. 2247 (explaining that Dr. McCarthy's decision to completely dismiss all ECM testing was surprising and unscientific); Barlaz, Tr. 2277–80 (explaining that Dr. McCarthy's priming effect theory is not supported); Burnette, Tr. 2400 (explaining that, as a microbiologist, Dr. Burnette had never observed or seen in research a priming effect theory that Dr. McCarthy posited).

ECM sells a "MasterBatch Pellet" that includes a biodegradable component along with an otherwise non-biodegradable (or conventional) plastic carrier resin. (RPFF ¶¶ 1671; RX 371; RX 656; RX 681). The formula for the "active" component is a trade secret. (RPFF ¶ 2; RX 371). ECM offers a "load rate" of 70% in its pellets, meaning that every pellet will contain approximately 70% of the "active" biodegradable formula, along with 30% conventional polymer resin. (RPFF ¶ 744). ECM prescribes that plastics manufacturers blend the pellet into their plastics according to precise instructions and at a 1% rate, resulting in a uniform distribution of the pellet throughout the plastic and at a level that ensures maximum utility without compromising the plastic or the additive's integrity. (RPFF ¶ 745).

Like many other plastic additives (e.g., coloring agents), manufacturers introduce the ECM additive into the plastic during the initial blending process. (RPFF ¶¶ 747–49). Plastics are commonly manufactured using one of several techniques, including extrusion molding, injection molding, or blow molding. (RPFF ¶ 750). For instance, extrusion molding involves a heated plastic compound continuously injected through a long die cast in the desired shape. (RPFF ¶ 751). The plastic is cooled under blown air and hardens into items such as thin films which are eventually coiled or cut. The manufacturing process, while common to many plastics manufacturers, can be complicated as the manufacturer must achieve a uniform distribution of the ECM additive in the final product for the additive to work. (RPFF ¶ 745). ECM issues certificates of biodegradability to customers only after those customers have signed letters pledging to maintain the 1% load at a uniform distribution in the plastic. (RPFF ¶ 1345). Moreover, ECM customers have experienced burning and scorching of the additive as they

attempt to adjust their manufacturing process. (RPFF ¶¶ 363, 1675–77; RX 130).[86] Burning or scorching of the additive is one manufacturing error that can render the ECM additive inefficacious. (RPFF ¶ 1675). Similarly, failing to include the additive in sufficient amounts or in a uniform distribution would also render the additive ineffective. (RPFF ¶¶ 764–65). Because the additive is hydroscopic, leaving open ECM's moisture sealed container in which the additive is transported can also render the additive ineffective. (RPFF ¶¶ 762–63).

ECM's customers manufacture many plastic polymers, but the bulk of the plastics incorporating ECM's technology consist of three: polypropylene (PP), polystyrene (PS), and polyethylenes (PE). (RX 458; RX 522). Over seventy (70) percent of ECM plastics are PE plastics. (RPFF ¶ 754).

ECM offers a cost-effective means to achieve biodegradable plastics. (RPFF ¶ 41; RX 335). There are competing technologies available, such as "bioplastics," which are biodegradable plastic polymers or resins derived from biological substances instead of petroleum. (RPFF ¶¶ 325–26); RX 748; RX 678). Bioplastic can be non-biodegradable, such as bio-based polyethylene, or they can be biodegradable such as PHA. Many of those technologies will produce an end-product that biodegrades more rapidly or readily in an industrial composting operation than plastics made with the ECM additive in a landfill. (RPFF ¶ 327; RX 725; RX 178). However, those competing technologies come at a substantial cost and risk to functionality. (RPFF ¶ 328; RX 335). Companies choosing to invest in most bioplastics must change their entire manufacturing process to accommodate the use of the new natural resins.

[86] Customers have observed difficulties in manufacturing plastics with the ECM additive, and have needed to incrementally adjust their manufacturing system to avoid burning. *See, e.g.*, RX 130 at 007221 (based on temperature and other manufacturing settings, the ECM customer "had poor adhesion as well as unacceptable edge weave and pulsing in the die. The outer edges of the resin coming out of the die were brown in color" which would indicate burning).

(RPFF ¶ 333; RX 520). The bio-based polymers are almost always significantly more expensive. (RPFF ¶¶ 333, 338). Additional additives are needed to stabilize the bioplastics for the intended use of the end product. (RPFF ¶ 335). After all, the primary purpose of a plastic product is to serve a function in the market which may demand considerable tensile strength and rigidity, not to biodegrade in landfills. The bioplastics are often suitable only for certain limited uses in the market. (RPFF ¶¶ 346, 328–48). There are thus many reasons why a plastics manufacturer might not be able (or not want) to use competing technologies that come at substantial cost and may compromise plastic strength or functionality. (RPFF ¶¶ 328–48).

ECM's customers balance the need for their product's performance (i.e., tensile strength, shelf-life, etc.) with the objective of achieving greater plastic biodegradability. (RPFF ¶¶ 344–45).[87] They must ensure that the product meets consumer use expectations first and foremost and thereafter ensure that biodegradability is hastened after customary disposal. Favoring a too rapid biodegradation ordinarily necessitates diminution of tensile strength, shelf-life, etc. (RPFF ¶¶ 334, 340, 347). ECM customers perform testing on their finished ECM-infused plastic before ordering product precisely to determine if biodegradability occurs in ways that will not compromise product functionality when in use. (RPFF ¶ 401; RX 413; RX 412). Because the ECM additive can accomplish a biodegradable plastic with load rates of just over 1% by weight and ordinarily do so without compromising plastic functionality when in use, plastics manufacturers' dual goals of functionality and biodegradability can be satisfied. (RPFF ¶¶ 338–48; RX 326; RX 520). On balance, then, they can satisfy customer demand for functionality and

[87] *See, e.g.*, CCX 811 (Hong, Dep. at 44)) (noting that the company experimented for one year with ECM's additive to determine if it could be incorporated into their process). As explained by the manufacturer, "ECM at that time said it's biodegradable, but it doesn't do us any good if we can't use it through our machines. So what we were doing was putting the additive inside of our plastics to see if it could actually run through our extruders and then be cut and sealed as plastic bags." *Id.*

also promote their interest in lessening environmental impact by causing a plastic to break down faster than it otherwise would without the ECM additive present after that plastic is discarded. The ECM additive thus offers manufacturers the flexibility to add a biodegradable plastic to their line, without having to substantially alter business operations or disappoint consumers. (RPFF ¶¶ 339–40).

2. The Type of Scientific Evidence That Experts Agree is Competent and Reliable to Prove Biodegradability

The amount of substantiation experts in the field would agree is reasonable "must be examined in relation to each field being evaluated." *POM*, 2012 WL 2340406, at *206. Currently, for "biodegradation" studies, all experts agree that gas evolution laboratory-scale reactor tests are competent and reliable evidence, which evidence ECM has produced more than two dozen favorable tests. (RPFF ¶¶ 2129–2659).

The FTC has not defined what constitutes "competent and reliable scientific evidence" in the context of biodegradable advertising. However, based on the *Pfizer* factors, the standard to be applied in this case must be lower than standards applied in other FTC proceedings that concern advertisements containing medical or health claims. For example, in the medical context, the Commission demands that advertising claims be substantiated by double-blind, randomized, placebo-controlled clinical trials. *Thompson Med. Co., Inc. v. Fed. Trade Comm'n*, 791 F.2d 189 (D.C.Cir.1986); *Bristol-Myers Co. v. Fed. Trade Comm'n*, 738 F.2d 554 (2d Cir.1984); *In the Matter of Pom Wonderful LLC, Roll Global LLC, Stewart A. Resnick, Lynda Rae Resnick & Matthew Tupper*, 155 F.T.C. 1, 28 (2013). The standard to apply in this case must necessarily be lower than the standard for advertising claims related to food products which purport to have health benefits—"one well designed, randomized, and double-blind, placebo-

controlled clinical trial involving an appropriate sample population and endpoint." *POM*, 2013 WL 268926, at *43. While these standards obviously cannot apply to biodegradability, they are important benchmarks to demonstrate that ECM's "competent and reliable scientific evidence" need not be as high as that mandated in *Thompson*, *Bristol-Myers*, and *POM*, which standard was, essentially, of the more demanding thresholds suggested by the experts. *See Statement of Commissioner Ohlhausen*, 2014 WL 587857, at *1 (F.T.C. Jan. 7, 2014) ("[T]he burden for substantiation for health- or disease-related claims about a safe product . . . should be lower than the burdens imposed on drugs and biologics because consumers face lower risks when consuming the safe product."). In assaying what is "reasonable" to prove efficacy claims, the proper point of reference is what the scientific community considers reliable proof. In that regard, the record from ECM experts and Complaint Counsel's own is clear: gas evolution testing, of the kind relied upon by ECM here, is generally accepted (even relied upon by McCarthy in practice despite his expert report statements to the contrary). (RPFF ¶¶ 1467, 1766). That evidence, complemented by a detailed explanation of the mechanism of action derived from basic science, support the conclusion that the ECM additive causes plastics to biodegrade faster than plastics lacking infusion of the additive. (RPFF ¶¶ 1581-2706).

3. The Absence of Any Standards or Tests to Prove Rates of Biodegradation in Landfills

In assessing whether a Respondent possessed a reasonable basis, this Court must first determine what level of substantiation the advertiser is required to have for advertising claims. *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1096 (9th Cir. 1994); *FTC v. Sabal*, 32 F.Supp. 2d 1004, 1008-09 (N.D. Ill. 1998). Complaint Counsel has offered no proof whatsoever of what scientific evidence would be sufficient to support biodegradable "rate" claims in landfills. (RPFF ¶¶

1581–1605). Because Complaint Counsel contends that ECM should have made a qualified claim that involved the "rate" of biodegradation under the "One Year Rule," and the absence of a "rate" is a central issue in their request for relief, the absence of record evidence on "rate" testing means Complaint Counsel cannot support essential aspects of its case. Moreover, because there is no generally accepted method to test for "rate," the scientific materiality of rate claims is nil.

Dr. Barlaz testified that the primary scientific concern related to biodegradability is whether a material is intrinsically biodegradable, not whether it biodegrades within a certain time period in a particular location on earth, or particular location within a landfill. (RPFF ¶¶ 1891–1898). For example, a piece of copy paper may biodegrade at varying rates and, in fact, it may never biodegrade unless the environmental conditions are appropriate, (Barlaz, Tr. 2218–19), yet no expert in this case disputes that paper is "biodegradable." (Barlaz, Tr. 2218–19). ECM's product testing, as explained below, proves that plastics properly infused with the ECM additive are intrinsically biodegradable, meaning that they will biodegrade in a reasonably short period of time compared with conventional plastics, provided the environmental conditions are suitable for biodegradation of biodegradable materials. (RPFF ¶¶ 1899–1933, 1964–2009, 2129–2885). That, indeed, is the qualified claim ECM gives to its customers wherein it routinely explains that the ECM additive will cause plastics to biodegrade in environments where organic matter is biodegrading. (RPFF ¶¶ 320, 377, 1352).

Landfill environments are alive with biodegrading material but are highly variable in the rates of biodegradation from one location to the next and even within points in a single landfill. (RPFF ¶¶ 1582, 1640–44). Moisture levels, temperature, and surrounding materials (e.g., foods waste, paper, wood, yard clippings, etc.) vary dramatically even within the same landfill. (RPFF ¶¶ 1582, 1640–44, 2065, 2807). That variability renders a precise prediction of rates of

biodegradation impossible, because the very same article may biodegrade almost not at all on one side of a landfill, but rapidly biodegrade on the other. (RPFF ¶¶ 1581–1605, 1723). Because of that variability, no one can predict the precise environmental conditions of disposal, ergo adding to the illogic and arbitrariness of Complaint Counsel's definition of biodegradation as necessitating 100% break down into elements in nature within one year of customary disposal.

Complaint Counsel provided no testimony or evidence concerning what competent and reliable evidence would be required to prove the rate that a product will biodegrade in an MSW landfill. (RPFF ¶¶ 1581–1605). No expert, including none of Complaint Counsel's experts, provided any evidence establishing the type or sufficiency of scientific proof that ECM should have possessed to support rate claims. (RPFF ¶¶ 1581–1605). Rather, biodegradation rate is generally understood to be a variable condition, dependent upon numerous environmental factors. (RPFF ¶¶ 1581–1605, 1723).

When questioned repeatedly concerning which tests, if any, can be used to prove the rate of biodegradation in an MSW Landfill, Dr. Tolaymat testified evasively, providing no clear answer. (Tolaymat, Tr. 219–21). He explained that no one test could establish the rate of biodegradability. (Tolaymat, Tr. 261–62). He made no attempt to explain what kind and quantity of evidence, if any, would support the type of rate qualifiers in Complaint Counsel's proposed Order filed earlier in this case. (RX 851 (Tolaymat, Dep. at 120)). He did, however, concede, against the avowed position of Complaint Counsel, that gas evolution studies like the ASTM D5511 and BMP tests were competent and reliable to test for intrinsic biodegradability. (RPFF ¶¶ 2751–52).

Dr. McCarthy did not provide testimony concerning the specific type of testing required to demonstrate the rate of biodegradation in an MSW landfill. (McCarthy, Tr. 359–480). He

did, however, testify at length concerning the types of scientific studies that might be used to assess biodegradability of polymers generally, including gas evolution tests of the type ECM presented in this case. (McCarthy, Tr. 359–480). Dr. McCarthy even testified that the "rate" of biodegradation can vary within a plastic, with faster rates for certain regions and slower rates for others (e.g., crystalline regions). (McCarthy, Tr. 477). Because the formation of crystalline regions of a polymer is unpredictable, variable, and depends on the manufacturing process, that means each specific plastic, like a fingerprint, could have a different overall lifespan and rate of biodegradation even if disposed under the identical conditions.

Dr. Morton Barlaz testified that there was no uniformly accepted method to extrapolate rate data from laboratory scale testing to field-scale landfills. (Barlaz, Tr. 2282). He explained that it is "very, very difficult to measure rates at either – at field scale either for individual components or for bulk waste, so all we have is the lab." (Barlaz, Tr. 2282).

Dr. Barlaz also testified that the rate of biodegradation in landfills is largely irrelevant. (Barlaz, Tr. 2283–84; RX 853 (Barlaz, Dep. at 12). Because the residence of waste in a landfill is intended to be infinite, if a material is biodegradable, then it would not matter from a landfill science perspective if that material biodegrades within ten years or many years. (RX 853 (Barlaz, Rep. at 12); Barlaz, Tr. 2283–84). In fact, products that would very rapidly biodegrade in landfills present environmental concerns because the methane released during that short and rapid biodegradation would not be captured by landfill operators. (Barlaz, Tr. 2284–85).

Methane is produced when products biodegrade. (RPFF ¶¶ 1813, 1840). Methane is a powerful greenhouse gas emission that contributes to climate change. (Barlaz, Tr. 2285). As methane gas increases in the atmosphere, it contributes to warming of the atmosphere, which most environmental scientists believe damaging to the planet. (Barlaz, Tr. 2286). The EPA's

Landfill Methane Outreach Program (LMPO) has an express mission to reduce greenhouse gases emitted from landfills. (RPFF ¶ 2877). Landfills remain one of the largest man-made sources for methane emissions on the planet. (RX 967). Yet EPA regulations do not require landfill owners to install gas collection systems until five years after waste burial. (Barlaz, Tr. 2285).

If a product biodegrades completely within one year, that product will not take up space in a landfill, but the methane produced will not be captured and will have less desirous environmental consequences than simply storing the product in a landfill for a longer period of time. (Barlaz, Tr. 2285–86). Thus, through critically acclaimed research published in the peer-reviewed literature, Dr. Barlaz demonstrated that based on decay rates the slower a product biodegrades in a landfill environment, the better that product is for the environment after disposal. (Barlaz, Tr. 2287–88). Dr. Barlaz explained:

> The reason we make products is for people to use them, not to throw them in a landfill… What we're trying to do here is ask, given the fact that waste exists and waste is generated, what's the best thing to do with it and what's the best way to design a product, without impending its functionality, to minimize environmental impact."

(Barlaz, Tr. 2288). Complaint Counsel has offered no evidence that contradicts or rebuts that logical conclusion, which causes EPA policy in favor of reducing greenhouse gas emissions squarely at odds with Complaint Counsel's biodegradation definition in favor of complete biodegradation of plastics within one year after customary disposal. *Compare* RX 967 (LMOP citing methane emissions as problematic greenhouse gases), *and* RPFF ¶¶ 1593–1605 (rapidly biodegrading products present a risk of increased methane emissions), *with* 16 C.F.R. § 260.8(c) (promoting rapidly degrading materials under mistaken theory that physical disappearance is, by itself, the only environmental objective).

4. Competent and Reliable Biodegradation Testing Methods Relevant to This Case

Every expert in this case agreed that gas evolution laboratory testing is competent and reliable to assess biodegradability. (RPFF ¶¶ 1608–1628). In fact, each of Complaint Counsel's relevant witnesses (Drs. Tolaymat, McCarthy, and Michel) actually relied on gas evolution testing when performing their own biodegradation tests outside of this litigation. (RPFF ¶¶ 1608–1628).

In 2010, Dr. Tolaymat chose a biomethane potential test, or "BMP," to determine whether commercially available plastic products were biodegradable. (RPFF ¶ 2768). The BMP test is not at all representative of a landfill—at least not the landfill that Dr. Tolaymat envisions in his testimony. (RPFF ¶¶ 2756–2772). The BMP is a "liquid state" test operated under almost completely saturated moisture levels. (Barlaz, Tr. 2222). In many tests, the BMP also involves grinding or screening the test material, the use of nutrients to bolster the bacteria, and higher temperatures. (RPFF ¶¶ 1902–1904). Yet, Dr. Tolaymat himself chose to use that BMP test to specifically verify whether commercially available plastic products were biodegradable as they claimed. (RPFF ¶ 2768). Dr. Tolaymat even conceded in his expert report that ASTM D5511 tests are competent and reliable to measure a product's intrinsic biodegradability. (CCX 893) ("ASTM D5511 … can provide data about anaerobic biodegradation"). Dr. Tolaymat has never run a carbon-14 test to determine the biodegradability of plastic polymers. (RPFF ¶ 2852).

In 2012, Dr. Michel chose to run an ASTM D5511 gas evolution test to determine if various plastic polymers were anaerobically biodegradable. (RPFF ¶ 1772). Dr. Michel did not run a carbon-14 test. He has never run a carbon-14 radiolabeled test on plastic polymers. (RPFF ¶ 1773). In fact, in his testimony, Dr. Michel zealously defended the use of a D5511 test to determine the biodegradable nature of a plastic product. (RPFF ¶ 1775).

Dr. McCarthy testified that gas evolution, or "respirometric" testing is used by scientists to assess biodegradability. (RPFF ¶ 1618; (McCarthy, Tr. 413–14). In 1999, Dr. McCarthy relied on gas evolution testing similar to the D5511 test to assess whether his plastic polymer blend with certain polyester plastics was biodegradable. Dr. McCarthy relied on that data, including evidence of only partial biodegradation, to conclude that his plastics were fully biodegradable without limitation. (RPFF ¶¶ 1540–50). In one such test, Dr. McCarthy observed 14% biodegradation of a polymer (polylactic acid or PLA) after 45 days, which Dr. McCarthy defined in his '199 patent and in his testimony as a "biodegradable polymer." (RPFF ¶¶ 1540–50).

ECM's experts each testified that gas evolution tests are competent and reliable scientific evidence to assess biodegradation. Dr. Sahu testified that the laboratory reactor tests were generally relied upon by scientists to show the biodegradability of materials. (Sahu, Tr. 1792). Dr. Barlaz testified that data from gas evolution testing was competent and reliable evidence of biodegradability, and that scientists in the field generally rely on same, including D5511 tests. (Barlaz, Tr. 2245–46). Dr. Burnette testified that gas evolution tests, like the D5511 test, are useful for predicting some baseline performance in landfill settings. (Burnette, Tr. 2435–39).

Thus, while other tests exist and are helpful to provide support of affirmation, none is generally used for proof of biodegradation other than the gas evolution tests used here in proof of ECM product efficacy. The competent and reliable evidence recognized by experts in the field remains gas evolution, laboratory-scale reactor testing. (RPFF ¶¶ 1766–1809). Carbon-14 radiolabeled testing, even if feasible or practical, is experimental and is in fact ultimately a gas evolution test that is run just like an ASTM D5511 test only with the carbon-14 markers included. (RPFF ¶¶ 1771–1801).

a. Gas Evolution Reactor Tests (e.g., ASTM D5511)

A gas evolution reaction is a chemical reaction that produces gas, in this case, methane and carbon dioxide.[88] The process of biodegradation involves the cleavage of carbon bonds from the substrate, which are then combined with available hydrogen and oxygen to produce methane and carbon dioxide. (RPFF ¶ 1732).[89] In a gas evolution test, the laboratory exposes test articles to conditions that theoretically favor biodegradation, and then gas emissions are monitored. (RPFF ¶ 1883–84, 1897). By comparing the levels of gas emitted from the test vessel, the laboratory can measure the amount of gas produced from the test articles themselves. (RPFF ¶ 1912).[90] Figures of methane and carbon dioxide gas are shown below:

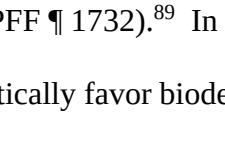


Figure 2. Carbon dioxide diagram (demonstrative)

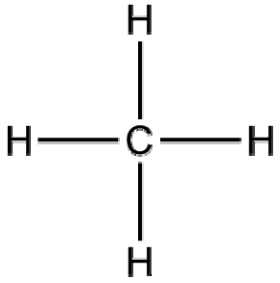


Figure 1. Methane diagram (demonstrative)

Gas evolution tests generally have several common characteristics. Within a closed, watertight vessel, test articles are exposed to "inoculum" that is comprised, in part, of leachate from local municipal waste stations. (RPFF ¶ 1909).[91] The leachate therefore contains microbes that would also be present in the environment.[92] Some tests bolster the inoculum by adding minerals and food to grow the bacterial colonies before the test period begins.[93] Laboratories

[88] *See* RX 853 (Barlaz, Dep. at 8).
[89] *Id.* at 8–9.
[90] *Id.* at 8–9.
[91] *See* RX 385, at 3.
[92] *See, e.g.*, RX 854 (Burnette, Rep. at 5–6).
[93] *See* CCX 84, at 3 (§ 9) (ASTM D5511 Standard).

usually incubate the inoculum for a period beforehand to stabilize the material for testing. (RPFF ¶¶ 2192, 2785).[94] The test articles are mixed with the inoculum in the test vessel and, for anaerobic testing, the vessels are flushed with gases like Nitrogen to eliminate most oxygen content that might remain. (RPFF ¶ 2425).[95] Gas collection tubes are connected to the test vessel, and gas produced by the vessel is gathered and later measured. (RPFF ¶ 2645).[96] The laboratory records the total amount of gas produced, and the ratios of methane gas to carbon dioxide. (RPFF ¶ 1915, 2202).[97] A diagram of the typical ASTM D5511 gas evolution test is

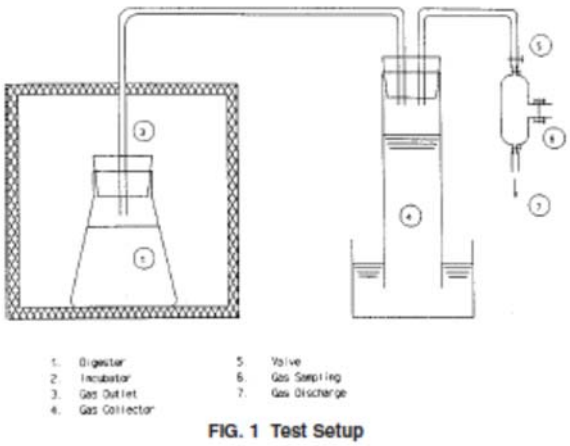


FIG. 1 Test Setup

Figure 3. ASTM D5511 Setup (RX 356 at 2)

presented below:

See RX 356, at 2 (ASTM D5511-12).

Results of the tests are based, in part, on the theoretical carbon yield for a test sample. (RPFF ¶¶ 1975, 2202, 2847, 2848).[98] A sample can contain only so much carbon, and the amount of carbon in a sample can be calculated based on the molecular formulas for the substrate

[94] *Id.*
[95] *See, e.g.*, RX 873 (Ullman, Dep. at 46).
[96] *See* RX 356, at 2 (D5511 test method, summary and apparatus).
[97] *See* CCX 84.
[98] *See* RX 864 (Barlaz, Dep. at 119–20).

plastic. (RPFF ¶¶ 1967–68).[99] The gas evolution tests, like ASTM D5511, also test against negative controls, positive controls, and inoculum blanks. (RPFF ¶¶ 1913–14). As is relevant here, the negative control is often a copy of the test plastic without the additive technology. (*See e.g.*, RPFF ¶¶ 2223, 2246).[100] The inoculum blank is a test vessel that simply records gas production from the inoculum by itself. (RPFF ¶ 1933). The positive control is always cellulose, which is a rapidly biodegrading substance like filter paper. (RPFF ¶ 2127).[101] The positive control serves only to indicate whether the test environment had sufficient life (e.g., fungi, microbes, bacteria, etc.) to adequately measure biodegradation. [102] The positive control is important because closed-system laboratory vessels are inhospitable to long-term testing. (RPFF ¶ 2820).[103] However, the positive control is not an indication of how the test article should perform comparatively.[104] Biodegradation should be assessed relative to the negative control instead. (*See e.g.*, RPFF ¶¶ 2544, 2567, 2591, 2593).

The laboratory can determine the level of gas attributable to the samples by subtracting the gas known to have been produced by the inoculum blank. (RPFF ¶ 2631).[105] The inoculum contains living organisms that will emit gases while digesting other parts of the solid waste within the inoculum mixture.[106] The laboratory can determine the proper gas level attributable to the test vessel by comparing the overall gas levels of the inoculum blank to those of the test article and negative control. (RPFF ¶ 2202–03).[107]

---

[99] *See* RX 356, at 4 (§ 12).
[100] *See, e.g.*, RX 860; RX 839; RX 836; RX 838.
[101] *See* RX 864 (Barlaz, Dep. at 17); RX 356, at 4 (§ 13).
[102] *See* RX 356, at 4 (§ 13.2);
[103] *See* RX 870 (Barber, Dep. at 125–127); RX 854, at 23 ¶ 64.
[104] *See* RX 854, at 24, 25 ¶ 74.
[105] *See* RX 356, at 4 (§ 12).
[106] Tolaymat, Tr. 300.
[107] *See* RX 356, at 4 (§ 12).

The laboratory calculates the percentage of biodegradation by comparing the level of gas attributable to the test sample with the theoretical maximum yield of gas from that same sample.[108] In sum, because the gas emissions contain carbon, the test sample can only contain so much carbon, and the inoculum will produce only a certain amount of carbon. Based on those calculated limits, researchers can conclude that excess carbon recorded in the gas emissions represent a certain fraction of the carbon that had once been locked within the test article.[109]

Gas evolution tests for biodegradation come in many iterations, but industry has consistently relied on variations of the ASTM D5511 standard because it is efficient and cost-effective.[110] In 1994, the ASTM first published the standard titled "Determining Anaerobic Biodegradation of Plastic Materials Under High-Solids Anaerobic-Digestion Conditions, ASTM D5511." The purpose of the ASTM D5511 standard was to test for intrinsic anaerobic biodegradability of samples. (RPFF ¶ 1898). The D5511 test is designed to record data under accelerated conditions.[111] Thus, the test calls for environmental conditions that hasten the appearance of measurable biodegradation effects.[112] The temperature of the test is increased to around 52 degrees centigrade.[113] The solids content is lowered to 20%, meaning the test is performed under rather wet conditions (80% moisture).[114]

---

[108] *Id.*

[109] *See, e.g.,* RX 864 (Barlaz, Dep. at 134–41).

[110] In fact, when measuring the anaerobic biodegradability of various plastics, one of Complaint Counsel's proposed experts, Dr. Frederick Michel, also used an ASTM D5511 protocol. Similarly, Complaint Counsel's other experts, Dr. McCarthy and Dr. Tolaymat, have used gas evolution tests similar to the ASTM D5511 test to support claims of biodegradability for his bioplastic polymers. (RPFF ¶¶ 1546 (McCarthy), 2768 (Tolaymat), 2917 (Michel)).

[111] CCX 83.

[112] *Id.*.

[113] *Id.*.

[114] *See* RX 356; RX 855, at 41–49.

Landfill conditions are highly variable, and differ greatly from one landfill to the next, and even within each individual landfill. (RPFF ¶¶ 1582, 1640–43, 1713, 1723, 1815, 1851, 1871–76).[115] In any landfill, there are pockets that likely exhibit conditions similar to the D5511, but also pockets that may be considered less conducive to microbial or fungal life. (RPFF ¶¶ 1644, 1781, 2807). The variable and unpredictable nature of landfills substantially limits the ability to predict with certainty how the D5511 test data would transfer into the natural environment. (RPFF ¶¶ 1582, 1640–43, 1713, 1723, 1815, 1851, 1871–76). However, scientists can and do predict that the mechanisms of action observed in the D5511 test also occur in the natural environment, including in landfills. (RPFF ¶ 2109–13).[116]

b. BMP Testing

Biomechanical Methane Potential (or "BMP") testing is a gas evolution test that is designed to measure potential biodegradability of a test sample. The BMP test is performed in a liquid environment, with very high moisture content. (RPFF ¶¶ 1899–1905).[117] BMP testing varies significantly from one laboratory to another. (RPFF ¶ 1901).[118] In many instances, BMP testing calls for grinding the test product and screening it through a 1 mm screen. (RPFF ¶ 1903).[119] That process, if used with ECM's products, would likely dissociate much of the ECM additive from the host plastic, thus nullifying the product's efficacy.

[115] *See* RX 864 (Barlaz, Dep. at 38–40).
[116] *See* RX 854 (Burnette, Rep. at 26–27).
[117] *See* RX 864, at 73–75.
[118] *See* RX 851 (Tolaymat, Dep. at 146).
[119] *See id.*, at 134.

The ASTM D5511 test is comparable to the BMP test and the D5511 test presents conditions more like the natural environment. (RPFF ¶¶ 1907–08).[120] Dr. Tolaymat agreed that the D5511 test is likely more representative of the landfill environment than the BMP test that Dr. Tolaymat himself used to test plastics for biodegradability in landfills. (RPFF ¶¶ 2756–58, 2781).

Dr. Barlaz, ECM's expert witness, had performed several tests of ECM plastics including the ECM additive. He performed those tests prior to, and independent of, his role as an expert witness in this case. (RPFF ¶¶ 2626–2638). In at least one of those tests (RX 952), Dr. Barlaz obtained data showing that the plastic article had biodegraded substantially more than the amount reasonably attributed to the additive.[121] Moreover, Dr. Barlaz observed that the gas production was consistent throughout the 60-day test window, indicating that when he stopped the test at 60 days the product had likely not finished biodegrading.[122]

Drs. Sahu, Burnette, and Barlaz also testified that the presence of inconclusive tests does not nullify favorable tests, which clearly indicate that the ECM plastic has degraded. (RPFF ¶¶ 2886–2908).[123] A test may produce inconclusive results for many reasons that have nothing to do with the plastic substrate, not least of which is the death of the bacteria in the inoculum, a persistent problem. (RPFF ¶¶ 2890, 2894–96).[124] In particular, variables in the manufacturing process could result in a product that lacks the ECM additive in substantial parts, or the test environment may not be conducive to the longer duration testing required. (RPFF ¶¶ 2905–06). The ECM additive can be "scorched" or burned during the manufacturing process, and that

[120] *See, e.g.*, RX 851 (Tolaymat, Dep. at 138); RX 870 (Barber, Tr. at 101–02); RX 864 (Barlaz, Dep. at 74–75).
[121] Barlaz, Tr. 2269-72; RX 952.
[122] Barlaz, Tr. 2269-72; RX 952.
[123] *See, e.g.*, RX 864 (Barlaz, Dep. at 140–41).
[124] *See* RX 854 (Burnette, Rep. at 27 ¶ 82).

burning would render the additive ineffective. (RPFF ¶¶ 363, 758, 761, 1675, 1676, 1680). Similarly, the manufacturer's inability to mix the ECM additive uniformly could result in plastics that actually lack the additive, or include it at lower amounts (or on the surface only). (RPFF ¶¶ 337, 745, 752, 764, 1742–43). In addition, a lack of care in storage of the ECM additive resulting in the moisture protective seals being removed and the additive exposed to dry conditions can render the additive ineffectual. (RPFF ¶¶ 762–63).

c. Qualitative Testing

ECM has produced qualitative testing that demonstrates the presence of biodegradation through qualities such as mass loss or gravimetric calculations. (RPFF ¶¶ 2660–2706). Dr. Timothy Barber is a renowned environmental scientist at Environ Corp.[125] Environ is a global leader in environmental and human health testing. Dr. Timothy Barber is a principal working out of Environ's Ohio group. (RPFF ¶ 104).[126] He designed a test based on the conditions of an ASTM D5526 test that would measure biodegradation of test samples based on weight loss over time. (RPFF ¶¶ 2687–90).[127] Dr. Barber testified credibly that the gas evolution tests had limitations when testing slowly degrading substances over long duration studies. (RPFF ¶ 2672).[128] His test results demonstrated that ECM's additive would render plastics such as PVC

[125] *See* (Barber, Dep. at 246–61).
[126] *See id.* at 256–57.
[127] *See, e.g.*, RX 573; CCX 791.
[128] *See* RX 870 (Barber, Dep. at 106) ("The measurement of carbon dioxide and methane are required under those test protocols are designed for relatively short periods of time. Because we needed to run these test out to 17, 23 months, we needed to use a protocol that did not require the capture and analysis of metabolic gases…"); *Id.* at 125–26 ("One of the challenges … of trying to maintain an active microbial community in a static enclosure is how long you can maintain a functioning microbial community, and this was something in part of why we made modifications to some of the pre-existing ASTM protocols, because we knew we would have to run these tests 12 to 18 months").

fully degradable with a 1.9 year half–life. (RPFF ¶ 2704).[129] He confirmed his gravimetric endpoints by looking at free chloride content in the test solution, noting that the chloride ions would have come from the degraded sections of the PVC plastic. (RPFF ¶ 2670).[130] Dr. Barber also reviewed test data from other laboratories concerning ECM's additive technology.[131] He was convinced based on the test results that ECM's technology produced a biodegradable plastic. (RPFF ¶ 2685).[132] He conveyed that opinion to ECM customers, stating expressly that ECM's additive rendered plastics biodegradable. (RPFF ¶¶ 2700–02).

Dr. Barber also measured the presence of free chloride molecules in his BioPVC study. (RPFF ¶ 2695). He used the chloride ions to determine whether the biodegradation observed based on weight loss was a product of the source plastic degrading at the level of the carbon chain. (RPFF ¶ 2670). Drs. Sahu and Burnette both confirmed that the measurement of free chloride was a significant element, which adds further scientific confirmation that the ECM additive results in the biodegradation of the actual plastic by deconstructing the carbon chain. (RPFF ¶¶ 2662, 2670).

Other qualitative tests included electron microscopy performed of degraded ECM samples. Those tests revealed visual evidence of microbiological formation and attack on the ECM-treated plastics. (RPFF ¶ 2705).[133] Several other laboratories have demonstrated ECM's effects through qualitative evidence as well. ECM employees, including the inventor and the

---

[129] *See* RX 254, at 1 ("[t]he environmental half-life of bioPVC under aerobic conditions is estimated at 1.9 years").

[130] *See* RX 370, at 6; RX 259 ("Certification of Results," noting that "an increase in soil leachate chloride content and reduction in tensile strength was observed, indicated the PVC molecules were being effectively degraded").

[131] *See* RX 269 ("ChemRisk" report).

[132] *See, e.g.*, RX 870, at 90 ("the polyethylene film provided to me … purportedly containing the ECM additive was determined to be biodegradable in our study").

[133] *See infra* at 117 (table).

former owner of ECM, Mr. Riley, and the current president Mr. Sinclair and the Chief Financial Officer Mr. Sullivan, performed tests of the ECM additive in gardens, backyard soils, and in 50-gallon drums to assess aerobic and anaerobic biodegradation in real-time. (RPFF ¶¶ 45–47, 51–54, 2703).[134] In most instances biodegradation was observed and, in the case of the tests by Mr. Riley, Mr. Sinclair, and Mr. Sullivan, complete biodegradation of the test plastic occurred within a 9 month to 5 year interval. (RPFF ¶¶ 49, 54).

d. Radiolabeling Tests Are Not Required

At the outset, radiolabeled carbon-14 testing is not a unique testing method, as it involves the same type of gas evolution testing that ECM had run, and that Complaint Counsel's experts had run, to assess biodegradability. (RPFF ¶¶ 1790–91, 1953). The radiolabeled carbon-14 test is simply a "marker" test, whereby the test is able to more accurately record biodegradation of test samples when the amount of biodegradation is perceived to be very small. (RPFF ¶¶ 1954–55). Dr. Barlaz testified, by contrast, that when the amount of biodegradation in the test vessel is substantial, as it was in many ECM tests, the conclusion that the test plastic is biodegrading can be clearly established without the need for carbon-14 testing. (RPFF ¶ 1955).

In fact, no expert who testified in this case has ever run a carbon-14 radiolabeled test of plastic polymers to assess biodegradation. (RPFF ¶¶ 1612, 1617, 1767, 1771, 1773). ECM's experts along with Dr. Tolaymat testified that radiolabeled testing is unnecessary and not the industry standard. (RPFF ¶¶ 1771, 1774, 1776–1809, 1952–1963). Dr. Sahu had investigated whether radiolabeled testing was possible for the ECM product. (RPFF ¶ 1778). He discovered that it was not, and, while test sites are available to run the actual tests, he was unable to readily

[134] *See* CCX 818, at 63–69; CCX 820, at 8–9.

find a manufacturer that would *synthesize* the proper polymer with the carbon-14 marker. (RPFF ¶ 1779).

Complaint Counsel's rebuttal expert casually included an "estimate" for carbon-14 testing, ostensibly to suggest that such testing was possible. (RPFF ¶ 3002). But Dr. Michel included no supporting documentation concerning that estimate or its applicability in the context of polymer testing. (RPFF ¶ 3002). His estimate was clearly a hypothesis based on lab time, without any consideration of the practicalities of that testing in the context of plastic polymers. (RPFF ¶ 3002). Significantly, Dr. Michel has never performed a carbon-14 test on plastic polymers and, so, his estimate does not mention or address the difficulties mentioned in detail by ECM's witnesses. (RPFF ¶ 2922). Dr. Michel also recommended the use of a company that produces radiolabeled material, and that company, American Radiolabeled Chemicals, was shown through Dr. Barlaz to have improperly labeled radioactive material in prior projects. (RPFF 1959–1962).

Complaint Counsel's experts have suggested that ECM should have performed ^{14}C radiolabeling tests to demonstrate that the plastic itself degrades during the gas evolution tests.[135] Complaint Counsel's reliance on ^{14}C radiolabeling tests is misplaced for several reasons. First, the test is entirely impractical, and no one runs it. (RPFF ¶¶ 1775, 1963). Not even Complaint Counsel's expert, Dr. McCarthy, who competes against ECM in the market, has performed ^{14}C testing on his technology (yet it is he who describes it as definitive in his expert report). (RPFF ¶ 1767).[136] Radiolabeling is very expensive and difficult to perform. (RPFF ¶ 1774).[137] ECM would need to find a plastics manufacturer capable of manufacturing a radiolabeled polymer

[135] *See, e.g.*, CCX 891, at ¶ 891.
[136] *See* RX 841 (McCarthy, Dep. at 90); RX 362.
[137] *See* RX 853 (Barlaz, Rep. at 9); RX 855 (Sahu, Rep. at 47–48).

with the ECM additive included in such a way that the ^{14}C content does not mix with the additive. (RPFF 1778–79, 1789).[138] Many laboratories can perform ^{14}C testing if given a suitable sample, but few if any companies are willing to prepare the radioactive plastic sample for eventual testing.[139] Because ^{14}C is a radioactive isotope, the manufacture would need to operate under strict radioactive hazard containment conditions, and undertake massive burdens to decontaminate their facility following production. (RPFF 1893–94).[140] The costs associated with that form of testing are extreme; Complaint Counsel has not been able to produce a single example of a competitor using ^{14}C testing to support biodegradation claims, although there are many competing companies selling biodegradable technologies.

Furthermore, even assuming that ^{14}C testing was feasible, the ultimate test of the plastic must still be performed for biodegradation. That test would still be a *gas evolution* test similar or identical to the D5511 test. (RPFF ¶¶ 1790–91, 1953).[141] So the insistence on ^{14}C testing actually contradicts Complaint Counsel's central theory of this case, which is that gas evolution studies do not simulate or replicate the landfill environment. Radiolabeled testing is just one *kind* of gas evolution study, run under similar conditions as the tests now in the record. If Complaint Counsel's concern is that ASTM D5511 tests do not simulate landfills, then the radiolabeling test does not alleviate those concerns. Put simply, the kind of testing needed to provide Complaint Counsel what it considers competent and reliable scientific evidence of plastics biodegradation does not exist.

---

[138] *See* RX 842 (Sahu, Dep. at 113–16).

[139] *See Id.* (explaining that ECM had attempted to obtain prices for radiolabeling testing but was unable to find manufacturers capable or willing to manufacture the radioactive components for testing).

[140] *See id.*, at 116–23.

[141] *See id.*, at 321–22 (expressing concerns that Complaint Counsel had not seemed to appreciate that radiolabeled products must still undergo gas evolution testing, like ASTM D5511 testing, to test for biodegradability).

Dr. Barlaz testified that the only advantage to carbon-14 testing comes where the laboratory is measuring "minute" amounts of biodegradation. (RPFF ¶ 1954). According to Dr. Barlaz, where the laboratory is measuring substantial amounts of methane and carbon dioxide, the carbon-14 test does not "buy[] you anything." (RPFF ¶1955). Dr. Barlaz confirmed Dr. Sahu's testimony, and explained that it would be hard to find someone who could make the properly radiolabeled plastic for testing. (RPFF ¶ 1958). He testified that carbon-14 testing is not generally accepted in the relevant scientific community as necessary to show biodegradation of materials. (RPFF ¶ 1963).

Dr. McCarthy attempted to dismiss positive ECM test results because, according to Dr. McCarthy, they cannot show whether crystalline or recalcitrant sections of the polymer had degraded. (RPFF ¶ 1460). Dr. McCarthy's reliance on carbon-14 testing as a solution is erroneous for at least three reasons:

First, Dr. McCarthy has himself used straight gas evolution testing, not carbon-14 testing, to conclude that a plastic which degrades less than 50% (in some cases less than 15%) is completely biodegradable. (RPFF ¶¶ 1453, 1498, 1507, 1509). Dr. McCarthy makes no mention of his crystallinity theory when it comes to his own testing of his own products.[142]

Second, Complaint Counsel offered no evidence showing that the carbon-14 testing would even address Dr. McCarthy's concerns and, in fact, it would not. Dr. Barlaz testified that when you have a polymer that consists of more than one compound, the researcher must carbon-14 label the molecule precisely where you want it, and that is very difficult to accomplish. (RPFF ¶ 1956). Dr. Sahu explained that the formation of amorphous v. crystalline sections of a

[142] *See, e.g.*, RX 928; RX 940; RX 942.

polymer is unpredictable, variable, and subject to the manufacturing process.[143] Thus, a manufacturer would carbon-14 label a polymer not knowing whether the radiolabeled sections are within amorphous or crystalline regions, defeating Dr. McCarthy's premise altogether. (RPFF ¶ 1800). Complaint Counsel has provided no specific evidence on how this type of testing would be accomplished to overcome those concerns.

Finally, Dr. McCarthy's entire theory of amorphous v. crystalline regions is contradicted by the scientific evidence. Unsurprisingly, Dr. McCarthy made no attempt to explain what percentage of a thermoplastic polymer might be "amorphous" vs. "crystalline."[144] He testified erroneously that amorphous and crystalline regions do not overlap but are separate and distinct within a plastic and conveyed the equally erroneous notion that crystalline regions are impenetrable such that carbon chains within them could not be broken by enzymatic activity of microbes.[145] That theory was rejected based on commonly accepted biochemistry (a field in which McCarthy admitted he is not expert, RPFF ¶ 1355)) in the testimony of ECM's expert Dr. Sahu.[146] Dr. McCarthy, self-admittedly not a chemist (RPFF ¶ 1355), testified that "the polymer has a crystalline region and an amorphous region…"[147] McCarthy never explained that "thermoplastic" polymers of the kind manufactured by ECM customers (e.g., LLDPE bags) are amorphous or at most semi-crystalline. (RPFF ¶¶ 1554–55). In any event, McCarthy's theory of the impenetrability of crystalline regions and of their complete segregation of the amorphous was refuted based on generally accepted biochemistry in Dr. Sahu's testimony when Dr. Sahu

[143] Sahu, Tr. 1797–1800.
[144] McCarthy, Tr. 359–690.
[145] McCarthy, Tr. 618–620.
[146] Sahu, Tr. 1797–1800.
[147] McCarthy, Tr. 477.

explained that "crystalline portions and amorphous portions randomly occur[] within each other in the same article."[148]

E. ECM Possesses a Reasonable Basis, and at Least Competent and Reliable Scientific Evidence, that the ECM Additive Causes Plastics to Biodegrade in Landfills

The *Pfizer* factors demonstrate that biodegradable claims need not meet a high standard of competent and reliable evidence. The FTC has the burden of showing that a particular claim was made without a reasonable basis. *See FTC v. Braswell*, 2005 WL 4227194 (C.D. Cal. Sept. 27, 2005); *F.T.C. v. Medlab, Inc.*, 615 F. Supp. 2d 1068, 1079 (N.D. Cal. 2009); *FTC v. Pantron I Corp*., 33 F.3d 1088, 1096 (9th Cir.1994). In order to have a reasonable basis to make the claim at issue, an advertiser must possess "competent and reliable scientific evidence" to substantiate that claim. *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 1156–57 (9th Cir.1984). To help determine what constitutes "competent and reliable scientific evidence," the FTC has recognized two types of claims: establishment and non-establishment claims. *See Thompson Med. Co., Inc. v. F.T.C.*, 791 F.2d 189, 194 (D.C. Cir. 1986). Establishment claims contain express or implied representations about the level of support for a particular claim (i.e., the claim states that a product has been found to be superior by scientific tests). *Id.* For such claims, the advertiser must possess the level of proof claimed in the ad. *Id.*

In contrast, a non-establishment claim is a simple claim of efficacy. *Id.* For such non-establishment claims, "the reasonable basis inquiry has been defined more flexibly." *Id.* This standard is a "flexible standard" that calls for an evaluation of a variety of factors suited to the particular case at hand. *Direct Mktg. Concepts, Inc. v. F.T.C.*, 581 F. Supp. 2d 115, 118 (D.

[148] Sahu, Tr. 1800.

Mass. 2008). Therefore, the Commission's "reasonable basis cases have identified several factors that [the Commission] will weigh in determining the appropriate level of substantiation for objective advertising claims." *In the Matter of Thompson Med. Co., Inc.*, 104 F.T.C. 648, at ¶ 70 (Nov. 23, 1984). The relevant factors are: "(1) the product involved; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and 6) the amount of substantiation experts in the field would agree is reasonable." *Id.* These factors are used to weigh the benefits and costs of developing substantiation for the claim. *In the Matter of POM Wonderful LLC*, 2013 WL 268926, at *30 (F.T.C. Jan. 16, 2013).[149]

The level of proof required to meet the *Pfizer* test in this case is significantly reduced because all of the *Pfizer* factors favor a more relaxed standard.

1. The Products Involved Do Not Affect Consumer Health or Safety, or the Performance of the Products While Used by Consumers

Regarding the first factor, the product involved, the Commission has made clear that products like drugs—which improve physical welfare—as opposed to products that to those not claimed to have drug effects, "require[] a relatively high level of substantiation." *Thompson*, 104 F.T.C. 648, at ¶¶ 71–72; *see also POM*, 2013 WL 268926, at *48 (noting that the respondents "made claims regarding serious diseases"); *In the Matter of Removatron Int'l Corp.*, 111 F.T.C. 206, at *14 at n. 20 (Nov. 4, 1988) (noting that a drug or product that directly affects human safety requires more substantiation).

[149] ECM has not made any "establishment" claims to end-consumers. To ECM's sophisticated manufacturing customers, it has disclosed the types of tests shown to have resulted in biodegradation. To the extent ECM's disclosure of its test data and names of test standards is an establishment claim, the claim is truthful and non-misleading. ECM does possess the tests its claims to have, and those tests do show that ECM's technology creates a biodegradable plastic.

ECM does not market products like drugs, foods, medical devices, or dietary supplements; it sole product is designed to cause plastics to biodegrade more rapidly than plastics not containing the ECM additive. (RPFF ¶ 40). ECM has not made any claims that its product effects human or animal health; it has made no claims concerning serious diseases or health conditions. Moreover, significantly, ECM has never sold product to end-consumers. (RPFF ¶ 389). ECM sells a plastic additive to plastics manufacturers that, when manufactured correctly, will help render the finished plastic biodegradable in a landfill over time.

The intended use of ECM's product is of relevance only after end use consumers have discarded it in customary disposal. Whatever benefit is achievable through ECM's product comes after the customer or user has relegated the product for disposal. ECM's product has no performance benefit or utility to consumers at the time of purchase or during their productive use of it. For this reason, Dr. Mort Barlaz credibly testified that the actual product performance in a landfill environment was almost irrelevant to a consumer. When discussing rates of degradation, he explained:

> I estimate a half-life of three years and the actual half-life is six years or one-and-a-half years, it's inconsequential for the performance of the landfill. Either way there is biodegradation occurring because the material is in the landfill, in essence, forever. That's what I mean by infinite retention time. Whether we are off a few years in either direction, it doesn't really seem to matter.[150]

So, too, here, where the question involves the nature of the product, an item advertised only for its benefit after customers throw it away should be subject to much less scrutiny than other products that have a chance to hurt or harm consumers during use.

[150] CCX 943 (Barlaz, Dep. at 109–110).

2. The Type Of Claims Made Are General Efficacy Claims that Are Subjective

The second factor is the type of claim being made. One type of claim that requires a high a level of substantiation "is a claim that refers to specific facts or figures, rather than making generalized descriptions of the product's capabilities." *Thompson*, 104 F.T.C. 648, at ¶ 72. Therefore, a generalized claim, such as "biodegradable," would require a lower level of substantiation than a more specific claim.

ECM's claims presented to sophisticated manufacturing corporations conveyed the simple point that ECM plastics were "biodegradable" within a reasonably short period of time. Those corporations only considered material to a purchase the fact of biodegradation, not rate, which fact they themselves discerned upon independent confirmatory testing. (RPFF ¶¶ 605–725). Such claims are thus of little consequence to purchases made based on a customer's own independent evaluation and are, at most, general efficacy claims, and should be regarded as nothing more under the *Pfizer* analysis.

3. The Benefits of a Truthful Claim and Ease of Developing Substantiation for the Claims

The third and fourth factors are often considered "in conjunction with each other." *Thompson*, 104 F.T.C. 648, at ¶ 74. The Commission's "concern in analyzing these factors is to ensure that the level of substantiation [the Commission] require[s] is not likely to prevent consumers from being told potentially valuable information about product characteristics." *Id.*; *see also Removatron*, 111 F.T.C. 206 at n. 20 ("These two factors together seek to ensure that the level of substantiation we require is not likely to deter product development or prevent consumers from being told potentially valuable information about product characteristics").

Consumers can be prevented from being told potentially valuable information about product characteristics when the cost of developing substantiation for these claims would be high in comparison to the amount of sales the product can earn. *Id.* at ¶¶ 74–75. So, the Commission will not require substantiation that, because of its probative costs, will become infeasible. *POM*, 2013 WL 268926, at *49.

ECM's product provides an environmentally-friendly alternative to conventional plastics. Unlike companies selling compostable technologies, or more expensive bioplastics, ECM's technology lives within the reality that the bulk of waste is deposited in landfills. While waste reduction and alternative processing techniques are laudable, they are in the minority today. Moreover, because financial considerations are always paramount to ongoing businesses, most companies are unable to undertake the extreme costs associated with emergency technologies like bioplastics. ECM offers a middle ground alternative, permitting companies to improve the environment in the long-term without incurring substantial increases to their cost bases. The ECM additive works, and it reduces the environment lifespan of many conventional plastics by a very substantial margin.

Because the technology works, many manufacturers gain access to a commercially viable solution that might encourage more plastics manufacturers to choose environmentally-friendly upgrades over conventional plastics used today.

Imposition of strict, and unobtainable standards here will chill innovation and prevent plastic manufacturers' access to valuable information concerning products that biodegrade in a progressive manner, over time. A product that biodegrades over a period of decades is not irrelevant in the market simply because it will not degrade within one year. ECM and its customer base have taken steps to evaluate biodegradability through laboratory testing and a

fully informed industry has chosen to buy the ECM products cognizant of the test results showing that it causes biodegradation of plastics and not dependent upon proof of any particular rate of that biodegradation. (RPFF ¶ 355). Moreover, the testimonial evidence reveals biodegradation that is slow and progressive actually inures to the benefit of the environment and to all life on earth because it reduces greenhouse gas emissions deleterious to the environment and opposed by national environmental policy set by the EPA. (RPFF ¶¶ 1593–1605).

Complaint Counsel's experts have failed to identify any generally accepted and practicable alternative form of biodegradability testing to the gas evolution testing performed on ECM additive containing plastics. Dr. McCarthy's statements, however, are revealing. Dr. McCarthy wrote that a "study must last long enough for the sample to reach at least 60% biodegradation" in a D5511 context. (CCX 891 (McCarthy, Rep. at 15–16)). That, of course, contradicts Complaint Counsel's argument which depends on proof of 100% biodegradation. (RPFF ¶¶ 1455, 1462, 1540). According to Dr. McCarthy, companies can also perform ^{14}C radiolabeling tests. (CCX 891 (McCarthy, Rep. at 15–16)). In the end, both of Dr. McCarthy's requirements are excessive and impractical, and not even McCarthy uses them in his own original scientific research or patent. (RPFF ¶¶ 1542–50). Rather, in his own work outside of his testimony to the Court, Dr. McCarthy accepts as little as 14% biodegradation over 45 days to support a conclusion that the plastic is biodegradable. (RPFF ¶ 1547).

First, because ECM's product slowly degrades when compared to more rapidly degrading items like cellulose, the ECM product would need to perform very long-term testing to reach the 60% value. For instance, in one ECM test of a polyethylene polymer, the test revealed about 50% biodegradation over 900 days of testing. (RPFF ¶¶ 2456–2476; RX 836). Extensive testing

is expensive and, obviously, time consuming and, given the inherent vulnerabilities of death of the bacteria in the inocula, very difficult to maintain.

Note, also, that Dr. McCarthy would require test conditions that mirror the landfill sites (e.g., temperature, moisture content, etc.). McCarthy is actually proposing that a company come as close to an *in situ* landfill study as possible. What if a product results in biodegradation in a landfill in 25 years? When compared with a conventional plastic that takes thousands of years to biodegrade, that 25 year span is a substantial benefit but it would not be within the arbitrary and capricious one year limit advocated by Complaint Counsel and ensconced as an effective rule in the Green Guides. However, under McCarthy's strict criteria, he would need testing of at least 15 years duration before those products could hit the market.[151] Most pharmaceutical cancer drugs are tested and approved in half that time.[152]

In the meantime, consumers would be purchasing and using conventional plastics without the additive, having been deprived of predictable biodegrading benefits, predictable based on accelerated gas evolution tests. (RPFF ¶¶ 338–39). Some degree of accelerated testing is necessary, therefore, in the real world. That accelerated testing includes generally accepted protocols like the D5511 test, which ECM customers ran repeatedly with positive results. (RPFF ¶¶ 1619–21, 1804–08). The D5511 testing, and similar gas evolution testing, provides a reasonable basis for biodegradability claims as the scientific literature in this field reflects, and ECM possesses that requisite level of proof.

---

[151] *See also* Tolaymat, Tr. 245-50 (suggesting, without scientific support, that a company may need to test a product for 20 years to make a biodegradable claim).

[152] *See* Frequently Asked Questions, The University of Arizona Cancer Center, m azcc.arizona.edu ("[m]any standard treatments used today are the result of past clinical trials, which involve a strict and rigorous, multi-step process that takes eight years on average to complete."), *at* http://azcc.arizona.edu/patients/clinical-trials/faq (last visited Sep. 25, 2014).

Dr. McCarthy also posits that ^{14}C radiolabeling should be required. That level of testing is impractical, excessively costly, and largely unavailable. (RPFF ¶¶ 1775–1800, 1952–1963 (Barlaz)). Dr. McCarthy himself has labeled products "biodegradable" without resort to radiolabeling testing. ECM's experts each agree (and apparently also one of Complaint Counsel's experts, Dr. Tolaymat, based on his testimony in deposition)[153] that radiolabeling tests are not required to prove the type of claims at issue here.

4. The Consequences of a False Claim are Negligible and Complaint Counsel has Provided No Record Evidence Suggesting that any Consumer Could Have Been Harmed Through a False Claim

Under the fifth factor, the consequences of a false claim can be divided into either health or economic consequences. *See Thompson*, 104 F.T.C. 648, at ¶¶75–76 (noting that false claims can be "injurious to health and economically harmful"). In order to be economically harmful, the economic harm suffered by consumers must be "material" and "substantial." *See POM*, 2013 WL 268926, at *50, n. 31 (noting that a one year supply of the POM Juice costs at least $780); *Removatron*, 111 F.T.C. 206 at n. 20 (noting that the device at issue cost approximately $4,000, and required treatments that cost $35 per hour over a period of years).

Here the consequences of a false claim are not demonstrated in the record. Complaint Counsel has offered no proof of any consumer harm, which is understandable given that the product benefit of biodegradation occurs after a consumer has permanently discarded, or thrown away, the plastic, i.e., after the consumer has finished his or her productive use of the plastic. Assuming, for this factor only, that ECM's product was ineffective, the consequences of a false claim would not be material or significant to anyone. Complaint Counsel has not offered

[153] Dr. Tolaymat testified that radiolabeling was not used frequently because it "could be as expensive as doing [testing] in a landfill." *See* Tolaymat Tr. at 246-47.

evidence of an environmental detriment. Landfill operators are not designing landfills, or making waste management decisions, on the basis of whether ECM additive containing plastics biodegrade within one year or a hundred. Plastic products treated with ECM additive are disposed of in the normal course, along with other non-degradable plastics. As Dr. Barlaz testified, because the intended use is for infinite retention in the landfill, a false or misleading claim has no material consequence. (RPFF ¶¶ 1593–94; Barlaz, Tr. 2283–84). Whether the product performs precisely as advertised in the landfill is impossible to confirm in the real world because of the inherent variability of disposal conditions.

Dr. Barlaz testified that materials which degrade slowly over time in landfills are far better for the environment than fast degrading materials that may produce methane before the landfill operators are prepared to harvest landfill gases. (Barlaz, Tr. 2280–84). The result of that fast degrading product would be a net contribution to methane gas emissions. (Barlaz, Tr. 2280–90). Thus, according to Dr. Barlaz's well-supported testimony, if ECM's biodegradable claims are false, then there is no environmental detriment, injury, or harm caused by the landfilling of the ECM products. (Barlaz, Tr. 2280–90). In other words, a product that degrades fast has a higher global warming potential than slowly degrading products (or those that do not degrade at all). (Barlaz, Tr. 2286–90).

Moreover, if the product does not biodegrade rapidly (e.g., rate), the end consumer never discovers that fact and experiences no consequential injury of any kind. That is in contradistinction with other commercial products, whereby the consumer suffers direct loss or injury during use of the product. The purchasers or consumers here are the corporate entities that infuse their plastics with ECM's product in commerce. There is no evidence that those companies sell ECM plastics to end-consumers for the biodegradable performance of the plastic;

indeed, most products containing the ECM additive are invisible in that respect to the end-use consumer or, if identified as biodegradable, as Dr. Stewart's survey confirms, are not understood to mean anything in particular by consumers. (RPFF ¶¶ 1105–1344). Even if we assume ECM's product does not perform as well as advertised, none of ECM's customers have been denied the economic benefit of a bargained for transaction; to the contrary, they receive the plastic they seek and it performs as they expect it; after they discard of it, it retains no value to them and, so, they are not harmed if it fails to biodegrade by any set rate in a landfill.

That point notwithstanding, ECM has always indicated to its direct customers that the period for biodegradation is highly variable and depends on environmental factors. (RPFF ¶¶ 309–12, 320, 377–78, 1352). ECM's customers reasonably understood, therefore, that biodegradation could occur over significant periods of time. Those customers have even tested ECM's product and reviewed ECM's scientific literature. Customers purchasing the ECM additive for altruistic environmental reasons had the information necessary to assess ECM's claims, and suffered no economic injury as they made claims based on that information.

5. The Competent and Reliable Scientific Evidence Proves that ECM's Additive Renders Conventional Thermoplastics "Biodegradable"

More than thirty individual tests from multiple laboratories show plastics made with ECM's additive will biodegrade in various environments, including MSW landfills. (RPFF ¶¶ 2129–2706). ECM's test data (including the inconclusive test results) reveal that Complaint Counsel's criticisms are unfounded or unsupported. Here we address the various levels of proof ECM supplied proving that its additive technology renders non-degradable plastics "biodegradable" in landfill conditions. We will then address each of the scientific criticisms upon which Complaint Counsel erroneously rely to condemn ECM's product.

When compared with conventional plastics, plastics manufactured with ECM's additive degrade over varying lengths of time in MSW landfills. ECM has consistently explained to its customers that the ECM additive is "not a poof and it's gone" technology.[154] The test data and peer-reviewed literature demonstrate that ECM plastics will, in fact, biodegrade where untreated plastics will not. (RPFF ¶¶ 1964–2009, 2129–2706). Complaint Counsel posits a number of criticisms without the benefit of testing or peer reviewed literature in support, but ultimately their position distills to the following points not supported by the scientific evidence: (a) that ECM's accelerated testing has not shown that ECM's technology causes the conventional plastic to become biodegradable in a landfill environment because the tests do not precisely mirror conditions in a landfill, (b) no test has been run long enough to show complete degradation of a plastic containing an ECM additive; and (c) the results of ECM's positive tests are attributable to factors other than plastics biodegrading.[155] Given the many tests favoring ECM, and the overwhelming weight of the scientific evidence on both the mechanism of action present and the proof of biodegradation in a wide range of plastics, those positions are scientifically invalid and contradicted by the totality of the scientific evidence.

The crux of Complaint Counsel's position is that test data revealing amounts of biodegradation less than cellulose, a very rapidly degrading substance, are irrelevant because ECM cannot extrapolate test results beyond the four corners of each test report. However, ECM has shown through peer-reviewed literature, expert testimony, and test data that the relative amounts of biodegradation observed in ECM tests are quite substantial when compared to non-

[154] *See, e.g.*, RX 680 ("It's not a 'poof it's gone' system but simply makes the plastic product biodegradable as if it were a stick or a branch off a tree rather than 'sticking around' for hundreds of years."); RX 371, at 4 (same); RPFF ¶ 378.

[155] *See, e.g.*, RX 865 (Complaint Counsel stating to another regulated entity that "we have serious concerns about these additives and whether they work at all," and later explaining that the additive companies "would have to shut down and close [their] doors").

degrading conventional plastics and are generally accepted by experts as predictive of biodegradation of plastics in landfill environments (even consistent with Dr. McCarthy's own extrapolation methodology undergirding his '199 patent for "biodegradable" plastic polymers).[156] ECM has established through test data and other scientific evidence that products manufactured with ECM's additive will continue biodegrading to completion in the landfill environment. (RPFF ¶¶ 1621, 1891–1898).

The following representative tests have shown that plastics manufactured with ECM's technology biodegrade significantly:

Test	Year	Method	Duration	Plastic/ECM	% Biodeg.
McLaren/Hart (RX 269)[157]	1999	Scientific Evaluation and Review of existing study data (anaerobic/aerobic report)	15 days 22 months	ECM Pellet 5% ECM Film	24% (pellet) Qualitative evidence of biodegradation (film)
Univ. of NM Electron Microscopy	2006	Scanning Electron Microscope (SEM) images of treated test samples	n/a	Treated bubblewrap	Qualitative evidence of biodegradation
Univ. of NM Electron Microscopy	2007	Scanning Electron Microscope (SEM) images of treated test samples	n/a	Treated PS foam	Qualitative evidence of biodegradation
SSCCP (RX 465)	2009	UNI EN 14043/2003,[158] aerobic[159] degradation test of Italcom product	91 days	PET PVC Film	4.95% (PET)[160] 50.09% (PVC) 4.80 (Film)

[156] *See* RX 362.

[157] Respondent/Complaint Counsel Exhibit Nos. RX 269, CCX 266E, CCX 268A.

[158] Some of the SSCCP tests involved the grinding of test samples in liquid nitrogen to obtain particles with sizes of <1 mm. The grinding process, which could separate the additive components from the plastic, is likely to significantly reduce, if not nullify, any expected biodegradable effect achieved through biofilm formation and quorum effects.

[159] Aerobic tests are relevant to prove the mechanism of action and intrinsic biodegradability of ECM plastics.

[160] Averages of three datasets recorded.

Test	Year	Method	Duration	Plastic/ECM	% Biodeg.
SSCCP (RX 467)	2013	ISO 14855, UNI EN 14046, aerobic degradation ,Colplast	91 days	Unknown	11.9%
SSCCP (RX 468)	2013	ISO 14855, UNI EN 14046, aerobic degradation, Colplast	91 days	Unknown	6.96%
Ecologia Applicata s.r.l. (RX 273)	2010	UNI EN ISO 14855, aerobic degradation, for Co.ind. s.c.	180 days	PP/1%	19.3%
Sondor (RX 274)	2011	Sondor Biofoam degradation test	775 days	Various/2%	Qualitative evidence of biodegradation (mass loss, etc.)
Environ (RX 275)	2012	Environ PS & PE testing for FP International (modeled after ASTM D5338 & D5511)	120 days	PS & PE/1%	>5%
Ecologia Applicata s.r.l. (RX 276)	2011	UNI EN ISO 14855, aerobic degradation, for Colplast S.r.l.	180 days	Polyammide & Nylon/% unknown	46.67%
Intertek India (RX 277)	2012	D5511, ISOE Printpack Industries, PVT, LTD, sample sheet	45 days	Sample sheet unknown	Qualitative evidence of biodegradation; gas data; no negative control
Clemson Univ. Study (RX 388-91)	2009	*In situ* testing of various treated samples for Dispozo Products Inc.	477 days	EcoPure	Qualitative evidence of biodegradation
Case Western (RX 278)	n/a	Prof. Morton Litt SEM Examination of ECM plastic in	n/a/	n/a/	Qualitative evidence of biodegradation
Eden 092511B (RX 248)	2011	ASTM D5511, for FP International	120 days	Airbag film/1%	11.5% 15.2%
Eden 070312C (RX 839)	2012	ASTM D5511, for Shields Bag & Printing	22 weeks	Film/1%	7.9%
Eden Fellows (RX 403)	2012	ASTM D5511 for Fellows	197 days	Amended film/1%[161]	71.8% 16.1%

[161] The Fellows product was treated with additional biodegradable elements.

Test	Year	Method	Duration	Plastic/ECM	% Biodeg.
Eden FPI (RX 402)	2014	Updated ASTM D5511 standard for FP International	290 days	1% ECM film 1.75% ECM film	5.5% 11.5%
Eden FPI (CCX 548)	2013	Modified ASTM D5511 for FPI EPS Samples	291 days	Expanded PS/1%	30.4%
Eden Smithers (RX 401)	2013	ASTM D5511 for Smithers Oasis	148 days	Foam/1.1% Foam/3%	2.4% 5.8%
Eden FPI (CCX 546)	2011	ASTM D5511 for FP International	977 days	Air bag (TKN)/1% Air bag (HOP)/1%	36.7% 39.8%
Environ (RX 254)	2008	Anaerobic study based on ASTM D5526	180 days	Amended PVC	2.7% (based on gravimetric data)
NE Labs N0843980 (RX 399)	2008	ASTM D5511 study for Bio-Tec Environmental LLLC	14 days	PP Sheet	8.4% (based on gravimetric data)
NE Labs N0946510-01 (RX 398)	2009	ASTM D5511 study for Masternet Ltd.	15 days	PE/1%	4.91%
NE Labs 1048742-01 (RX 405)	2010	ASTM D5511 study for Eco SmartPlastics	45 days	LDPE/1.5%	7.37%
NE Labs 1048819 (RX 396)	2010	ASTM D5511 study for Eco SmartPlastics	43 days	PET	7.01%
NE Labs 1150851 (RX 395)	2011	ASTM D5511 study for Sweet Tape Enterprise (M) Sdn. Bhd.	45 days	PP	4.54%
NE Labs 1150851 (RX 394)	2011	ASTM D5511 study for Tycoplas Sdn Bhd	15 days	PS foam	5.89%
NE Labs 1253020 (RX 393)	2012	ASTM D5511 study for National Tree Co.	15 days	PVC PE	9.89% 5.75%
NE Labs 1048036 (RX 392)	2011	ASTM D5511 study for Transilwrap Co.	233 days	Film Laminate	7.85% 8.53%

Test	Year	Method	Duration	Plastic/ECM	% Biodeg.
NE Labs N1048340 (RX 836)	2013	ASTM D5511 study for Pregis (PPC)	900 days	PE Poly Bags/1%	49.28%
OWS PFR-1 (RX 263)	1998	Aerobic Biodegradation under controlled composting conditions (ISO 14855)	45 days	5% film 5% natural film	4.5% 2.6%
OWS PFR-4 (RX 265)	1999	High Solids Anaerobic Digestion (HSAD) concept test	15 days	ECM pellet	24.0%
OWS PFR-5 (RX 266)	2000	Aerobic Biodegradation Under Controlled Composting Conditions (40 Gal Trash Bag)	45 days	Treated bag	5.2%
OWS BFI-1 (RX 268)	2010	High Solids Anaerobic Digestion (HSAD) Test for Covidien	15 days	PP	3.9%
Eden MicroTek (CCX 534)	2011	ASTM D5511 test for MicroTek	811 days	PE	17.9%
Eden EcoLab (CCX 547)	2013	ASTM D5511 test for EcoLab	452 days	Film	19.6% 46.5%
NE Labs 1149980 (RX 838)	2011	ASTM D5511 & D6579 tests for Minigrip	365 days	LDPE/LLDPE/ 1.5%	17.07%
NE Labs 1048215 (RX 863)	2010	ASTM D5511 test for Dansko	15 days	Rubber/2.5%	1.5%[162]

a. Testing of the ECM Additive Confirms that It Accelerates the Biodegradation Process

Dr. Barlaz reviewed many of the gas evolution studies involving the ECM amended plastics. (Barlaz, Tr. 2247). He examined the raw data produced by Northeast Laboratories and

[162] The unconventional use of the ECM additive in a rubber polymer produced a degradation rate of 1.5% (which was less than the percentage of the additive), which supports the reliability of the Northeast Labs results by demonstrating that tests results have been varied.

Eden Laboratories, particularly the data concerning methane generation from the test substrate and methane generation from the inoculum that would be the background methane. (Barlaz, Tr. 2247–48). For those tests where Dr. Barlaz had triplicate data (e.g., raw data), Dr. Barlaz performed statistical analyses, including T-tests, to determine whether there were statistically significant differences between the methane generation in the reactor with test substrate and the methane attributable to the inoculum alone. (Barlaz, Tr. 2248).

For other studies where triplicate data was not available, Dr. Barlaz examined the ratios of methane generation in the test material plus inoculum to methane generation from the inoculum only. (Barlaz, Tr. 2248). Dr. Barlaz concluded for those studies that ratios varied, but the ratios were generally significant even at the lower end. (Barlaz, Tr. 2248–49). From those ratios, Dr. Barlaz determined that the methane generation in the test vessels could be attributable to the test substrate, which suggests that the substrate was undergoing anaerobic biodegradation and conversion to methane. (Barlaz, Tr. 2249, 2260–62). Dr. Barlaz prepared a spreadsheet of his statistical calculations. (Barlaz, Tr. 2250; RX 472). Dr. Barlaz had also updated his spreadsheet to include additional calculations based on the data. (Barlaz, Tr. 2251; RX 968).

To address the question of whether only the ECM additive had biodegraded, Dr. Barlaz estimated the amount of methane that could theoretically be produced by the ECM additive alone. (Barlaz, Tr. 2251–53). Dr. Barlaz made certain conservative assumptions about the ECM additive when calculating the amount of potential methane. (Barlaz, Tr. 2252–53). Dr. Barlaz's conservative calculation was that one gram of ECM additive would produce 933 mL of methane gas. (Barlaz, Tr. 2253). Based on that calculation of 933 mL, Dr. Barlaz looked at the methane yields in the test vessels during biodegradation testing, and determined that the amount of biodegradation exceeded the amount that could potentially be sourced from the additive.

(Barlaz, Tr. 2253–54). Dr. Barlaz's calculation of the potential methane yield of the ECM additive is likely conservative because of the assumptions he made. (Barlaz, Tr. 2254). Dr. Barlaz assumed the additive was 50% carbon. (Barlaz, Tr. 2254). Polyethylene, by contrast, is almost 90% carbon. (Barlaz, Tr. 2254).

Dr. Barlaz also calculated the methane yield of the ECM additive based on the formula for the ECM additive that Dr. McCarthy used in his expert report at page 24, footnote 17 of his report, which was said to be the result of reverse engineering of the ECM product. (Barlaz, Tr. 2254–55; CCX 891 at 24 n.17). Based on Dr. McCarthy's assumptions about the ECM additive's contents, Dr. Barlaz calculated a methane yield for the ECM additive of 838 mL per gram. (Barlaz, Tr. 2255; RX 968). Using Dr. McCarthy's assumptions, the data produced in the gas evolution tests suggests that even more of the substrate plastic (not the additive) biodegraded because the ECM additive would have had a lower potential methane yield. (Barlaz, Tr. 2255–56). Using the Minigrips NE Lab study as an example (RX 838), Dr. Barlaz explained the arithmetic summarized in his spreadsheet. (Barlaz, Tr. 2256–57; RX 968). Dr. Barlaz calculates the weight of the ECM additive (in grams) by multiplying the percentage of the ECM additive load rating (in the Minigrips test, 1.5%) by the starting weight of the entire test plastic. (Barlaz, Tr. 2256–57). Because Dr. Barlaz has calculated the amount of total methane potential from one gram of ECM additive, he can then determine the total amount of methane possible in the ECM additive in each specific test by multiplying the actual weight of the ECM additive by the conservative 933 mL calculation (or 838 mL if using Dr. McCarthy's assumptions). (Barlaz, Tr. 2256–58). His calculation of the ECM additive methane potential is set forth below, using a 1.5% load rating as an example:

- (25 g Plastic Sample) x 1.5% (ECM Additive) = 0.375g (the weight of the ECM Additive)

- (933 mL CH4/gm ECM additive) x (0.375g ECM additive) = 349.875 mL total CH4 possible from ECM Additive

- 3,837.3 mL of **net** CH4 (subtracting out inoculum) – 349.875 mL CH4 from ECM = 3,487.425 mL CH4 (which came from the **test plastic**).

(RPFF ¶¶ 1973–1988).

Dr. Barlaz also calculated the net methane for each test vessel, which he did by subtracting the mean triplicate methane data from the inoculum blanks from the test vessels. (Barlaz, Tr. 2257–58; RX 968 (Summary Sheet)). For those studies where Dr. Barlaz had raw data, he calculated T-tests. (Barlaz, Tr. 2257). The T-statistic is the most common statistical test after a calculation of the average. (Barlaz, Tr. 2259). Dr. Barlaz also calculated standard deviations for tests where he had triplicate data, however the T-test is superior in that it also takes into consideration the elements of standard deviation. (Barlaz, Tr. 2264). Dr. Barlaz looked for a 95% certainty in the statistics that he ran, which would mean that the researchers are 95% "certain that you got the right answer." (Barlaz, Tr. 2260). Dr. Barlaz's t-statistics were generally well below the .05 that indicates statistical significance at the 95% level. (Barlaz, Tr. 2257). Dr. Barlaz's mathematical process is explained in his testimony. (Barlaz, Tr. 2257–59). Dr. Barlaz explained that where the methane produced from the test vessel is not attributable to the inoculum, and not attributable to the ECM additive, then the biodegradation must come from the plastic substrate itself. (Barlaz, Tr. 2258). Dr. Barlaz's calculations are also conservative because "it's not proven" that the ECM additive would completely biodegrade on its own while locked within the plastic without also having the plastic biodegrade along with the additive. (Barlaz, Tr. 2258). Dr. Barlaz also analyzed the ratios of methane to carbon dioxide in the lab tests. (Barlaz, Tr. 2261–62). A ratio of methane to carbon dioxide that is greater than 1:1

respectively is a good indication that the anaerobic environment was behaving properly. (Barlaz, Tr. 2262–63). Gas evolution testing also does not account for carbon that may have been cleaved from the substrate but converted to cell mass instead of gas. (Barlaz, Tr. 2263–64). Therefore, the biodegradation numbers calculated by the laboratories based on gas data alone are a lower limit of the carbon conversion than was actually realized. (Barlaz, Tr. 2263–64).

Based on his statistical analyses and the test data he reviewed concerning ECM amended plastics, Dr. Barlaz testified that competent and reliable scientific evidence confirms that plastics manufactured with the ECM additive are anaerobically biodegradable. (Barlaz, Tr. 2264–65). Dr. Barlaz testified that "[b]ased on checking of the lab reports, there were numerous examples where specific plastics were shown to anaerobically biodegrade to methane." (Barlaz, Tr. 2175). Stated differently, the test data clearly proves that, for many tests, the test plastic biodegraded far in excess of the biodegradation that could have possibly been due to degradation of the ECM additive alone, even assuming that the microbes could have completely digested the additive first (a *scientific non sequitur* because the additive when properly manufactured is evenly mixed throughout the plastic).

Significantly, the Northeast Labs test results were confirmed through other standards, including the ASTM D6579, which is a standard for calculating molecular weight averages and molecular weight distribution in the test sample vs. the negative control. (RX 838). The NE Lab's Minigrips test (RX 838) had reported approximately 17% biodegradation of the test sample after 365 days of testing. (RX 838). The test sample consisted of LLDPE plastic bags with a 1.5% ECM additive. (RX 838). In its August 1, 2012 Analytical Report (RX 838), NE Labs demonstrated that the plastic "zip bags" treated with the 1% ECM additive had a molecular weight that was approximately 16% less than the untreated test sample. (RX 838 at 73 (8/1/2012

Report)). Both the "number average" and the "weight average" molecular weights of the 1.5% ECM treated plastic had declined by about 16%, as measured using a different ASTM standard, ASTM D6579. (RX 838 at 73 (8/1/2012 Report)). NE Labs reported in its analysis that the "change in molecular weight is measure of bulk deterioration." (RX 838 at 73 (8/1/2012 Report)). Thus, the molecular weight testing under ASTM D6579 confirmed the gas evolution endpoint, which Dr. Barlaz had already determined was (a) statistically significant and (b) was clear, competent, and reliable evidence that the *plastic* and not the additive was biodegrading. (RX 968).

A large majority of the ECM tests reveal positive evidence of biodegradation in excess of what can be attributed to the additive alone. (RPFF ¶¶ 2129–2706). Moreover, not every NE Labs test showed evidence of substantial biodegradation. In 2010, the NE Labs testing for Dansko on rubber shoe parts produced evidence of 1.5% biodegradation in 15 days of testing, at an ECM load rating of 2.5%, undermining any claim that NE Labs testing is always positive. (RX 863).

Although the data was available to Complaint Counsel's experts just as it was for ECM's experts, none of Complaint Counsel's experts performed the expected expert task of statistical analyses of the data at issue in this case. (RPFF ¶¶ 2449, 2454–55, 2853–57, 2999). They did not perform the calculation that Dr. Barlaz performed concerning the methane potential of the ECM additive, even though Complaint Counsel's witnesses agreed that it would be scientifically logical to do so. (RPFF ¶¶ 2449, 2454–55, 2853–57, 2999).

b. Complaint Counsel's Criticisms of ECM's Testing are Theoretical and Lack Empirical Support

Despite the overwhelming evidence of ECM's additive causing plastics to biodegrade, Complaint Counsel presents a variety of theories, including ones that are inconsistent with one another, in an effort to discredit the entire body of scientific evidence. None of those theories, taken alone or in combination, overcome the totality of the evidence showing that ECM's additive, when properly blended within major plastic resins (e.g., PP, PS, and PE), will produce a biodegradable plastic that biodegrades in landfills. In short, Complaint Counsel would have the Administrative Law Judge rule that each of the dozens of independent, positive ECM tests is flawed to the point of irrelevance, and that the ALJ should construe inconclusive tests to be what they are not, negative tests proving the additive ineffectual, in order to credit Complaint Counsel's theory of the case. Consider the following arguments crucial to Complaint Counsel's position:

i. ECM's testing conditions adequately simulate or replicate landfill settings

There are no practical tests that precisely simulate or replicate all landfill conditions, and Complaint Counsel has offered no such method through its experts, but tests showing that one or more common bacteria in a closed test environment do biodegrade plastic and are generally accepted as predictive of biodegradation in landfills where far greater numbers and kinds of biodegrading bacteria and fungi are present. (RX-756 at 6–12; RX-853 at 7–9; RX-865 at 41–47). Dr. Barlaz testified that attempting to "simulate" precisely a landfill environment might require testing that spans 100 years. (Barlaz, Tr. 2212). He explained that "it's not practical to try to simulate that kind of ecosystem at the time scale in the laboratory." (Barlaz, Tr. 2212).

Dr. Sahu agreed that accelerated testing was the generally accepted means to measure biodegradability, essentially a time accelerated microcosm of part of the landfill environment. (Sahu, Tr. 1924). Although Complaint Counsel's witnesses repeatedly stressed the need to "simulate" precisely a landfill, they provided no evidence or example of a test that would actually achieve that measure of simulation. (RPFF ¶ 1619). With the high variability of landfill conditions, it would be impossible to truly simulate the natural environment. (RPFF ¶¶ 1618–23, 1885).

According to Complaint Counsel, no test can actually simulate or replicate the landfill environment and, so, every test must be rejected. That position is contrary to the generally accepted scientific evidence which routinely extrapolates from closed system tests to the landfill environment. (RPFF ¶¶ 1620–21). The flawed nature of that argument is most apparent when considering that Complaint Counsel's own experts relied on the *same* testing methodologies as ECM to prove that products were biodegradable in the landfill environment. For instance, Dr. Frederick Michel performed an ASTM D5511 to assess whether seven plastics would be considered anaerobically biodegradable in the environment. (RPFF ¶¶ 1609–1611, 1616). Dr. McCarthy, Complaint Counsel's lead scientific witness, performed similar gas evolution studies to determine that his own technology was aerobically and anaerobically biodegradable. (RPFF ¶ 1611; RX 756). Dr. Tolaymat, Complaint Counsel's landfill expert, testified that a BMP test should be used to measure biodegradability, which is a gas evolution test arguably less representative of a landfill than the D5511 standard. (RPFF ¶¶ 2721, 2751-2761).

In short, Complaint Counsel has failed to identity a single test or analysis that it concludes is generally accepted evidence of biodegradation in a landfill other than the gas evolution tests actually performed on the ECM additive containing plastics. Therefore, their

theory appears to be that no such claim could ever be substantiated based on what the scientific community accepts, which is a false premise built on a constitutionally infirm preference for blanket censorship.

ii. Microbes Are Capable of Biodegrading Conventional Plastics

Complaint Counsel argues that extrapolation of data from the D5511 test environment into the landfill is scientifically inappropriate because (1) the test environment does not simulate or replicate the landfills; and (2) several studies involving ECM plastic appear to "plateau." ECM expert Dr. Ryan Burnette, a microbiologist with expertise in anaerobic microbiology, testified that landfills (and most environments) have been shown to contain an assortment of microbiological life, and that biodegrading microorganisms present in the D5511 laboratory environments are a subset of those present in landfills. (RPFF ¶¶ 2038–2128; RX 854 at 6–14). He and Dr. Sahu testified that microorganisms have been shown to degrade polymers through processes such as enzymatic digestion, and that microorganisms responsible for biodegradation in laboratory environments thrive and metabolize matter in landfill settings. (RPFF ¶¶ 1629–1670, 2038–2128).

Moreover, Dr. Burnette explained that the so-called "plateau" effect (wherein evidence of biodegradation levels off during testing) is likely the result of limitations of the close-system lab test. (RPFF ¶¶ 2076–2093). The lab environment is a closed, finite system that prevents microbial growth and succession, like a fish tank that is never cleaned or emptied. Thus, it is not accurate to describe the conditions of a D5511 test as "optimal" in long term tests. (RPFF ¶ 2118). For instance, feedback inhibition occurs much more rapidly (and is permanent) in a laboratory environment, whereas in the natural environment the flow of liquid and the settlement

of materials would be expected to disperse or diffuse levels of enzymes and byproducts that limit cellular metabolism. (RPFF ¶¶ 2082–2086).

Finally, in some instances, the evidence suggests that the testing conditions to begin with were never adequate to support biodegradability testing. For instance, in at least several of the tests that did not show biodegradation of plastics said to be infused with the ECM additive, the positive control (cellulose) plateaued prematurely along with the test article.[163] That is what happened with Complaint Counsel rebuttal expert Dr. Frederick Michel's test, albeit other methodological problems also plague his testing.[164] Because cellulose is well-established to completely mineralize and biodegrade, the plateau is a sure sign of death of microbial life in the test environment.[165]

ECM's additive permits the biodegradability of otherwise non-biodegradable plastics by (1) facilitating the breakdown of plastic polymers into smaller chains suitable for enzymatic digestion and (2) fostering the formation of biofilms at or around the plastic, which, in turn, weaken and break the carbon bonds in polymers through enzymatic and acidic digestive processes. (RPFF ¶ 1722; RX 855, at 27–29). ECM's expert, Dr. Ranajit Sahu, is an expert in environmental and applied sciences. (RPFF ¶¶ 151–179). He has over twenty years of experience in environmental, mechanical, and chemical engineering, much of which includes work related to landfills and materials used in landfill construction (e.g., plastic polymers). (RPFF ¶ 164; *see also* RX 842 (Sahu, Rep. at 26–32)). He explains that the peer-reviewed literature and testing data shows plastics to be biodegradable in time, and that the ECM additive acts to exponentially increase the rate of biodegradation. (RPFF ¶¶ 1629-1765).

---

[163] *See id.* at ¶ 33; RX 755, at 4.
[164] *Id.*
[165] *See* RX 870 (Barber, Dep. at 153–54).

Dr. Sahu explained that bacteria can achieve initial adherence to plastics via weak interactions, such as hydrophobic, van der Waals, temperature, and other variable interactions. (RPFF ¶¶ 1658–61; RX 854, at 14). All plastics contain these weak points, but the ECM additive multiples the weak points for invasion by diffusing the biodegradable additive throughout the plastic. (RPFF ¶¶ 1726–27). Biofilms have been shown to grow and accumulate on substrates, including plastics, for purposes of degradation, arising at these points of weakness in the plastic. (RPFF ¶¶ 1724–27). Studies in the peer-reviewed literature have documented that bacteria and fungi are able to use natural and synthetic plastics as food sources. (RPFF ¶¶ 1728–1731). Much research has been dedicated to the ability of microbes to degrade plastics such as Polyethylene (PE).[166] Anaerobic bacteria in landfills (and present in the laboratory tests) release enzymes that have the ability to weaken and eventually break carbon bonds. (RPFF ¶¶ 2042–2074). The breakage of carbon bonds results in the destruction of plastic polymers which are capable of retaining their integrity as plastic only if carbon bonds remain intact. (RPFF ¶¶ 2094–2098).

iii. Complaint Counsel's Theory that Biodegradation Does Not Occur in Landfills Is Scientifically Erroneous

Dr. Morton Barlaz is Professor and Head of the Department of Civil, Construction, and Environmental Engineering at North Carolina State University. (RPFF ¶¶ 182–200). He has a B.S. in chemical engineering and an M.S. and Ph.D. in Civil and Environmental Engineering. (RPFF ¶¶ 182–200; RX 853, at Exh. 3 (Barlaz, M., Curriculum Vitae)). His M.S. and Ph.D. research focused on biodegradation in landfills. Complaint Counsel's witness, Dr. Tolaymat, recognizes Dr. Barlaz as an authority in the area of biodegradation. (RPFF ¶¶ 2724–2727). Dr.

[166] *Id.* at 18 (citing, e.g., *Phanerochaete chrysosoporium, Rhodococcus rubber, A. oryzae, Brevibacillus borstelensis, Penicillum simplicissim YK*).

Barlaz testified that Dr. Tolaymat's view of landfill science was flawed and anachronistic. Dr. Barlaz explained that landfills are characterized by their biological activity and are not, as Dr. Tolaymat describes them, "dry tombs." As Dr. Barlaz testified, most U.S. landfills produce a substantial amount of methane and carbon dioxide gas—directly resulting from biological activity in the form of biodegradation. (RPFF ¶¶ 1846-1849, 2877–2885).

Thus, Complaint Counsel misleads by characterizing modern landfills as "dry tombs" wherein little or no biodegradation can occur. Landfills do indeed permit biodegradation in substantial quantities. (RPFF ¶¶ 1846–1849, 2877–2885).

Landfills are also characterized, however, by their environmental diversity. (RPFF ¶¶ 1640–43, 1851). The moisture content, temperature, density, and composition of MSW landfills change constantly, differ substantially from one landfill to another, and differ significantly from one cell in a landfill to another in the same landfill. (RPFF ¶¶ 1640–43, 1851). There is also variability in the actual time required before the microbiological system becomes established for anaerobic biodegradation following waste disposal. (RX 853, at 6).

That high degree of variability makes difficult any exact prediction of the time for biodegradation. (RPFF ¶¶ 1640–44). Nonetheless, Dr. Barlaz explains that gas evolution tests (such as the ASTM D5511) are useful and accepted as indicative of a substance's ability to biodegrade anaerobically, albeit not as a test of rate of biodegradation. (RPFF ¶ 1627). Moreover, if a product is shown to degrade anaerobically in a test environment, then it is also likely to biodegrade in a landfill, but perhaps at a slower rate. Thus, the dichotomy between the landfill and the test environment relates to the speed with which biodegradation occurs, not whether biodegradation occurs at all. (RPFF ¶¶ 1922; RX 853, at 7–8).

Landfills are responsible for mostly anaerobic degradation, but also a limited amount of aerobic degradation. For instance, the emission of carbon dioxide gases from landfills around the country indicates the presence of oxygen, which can be trapped within the landfill or released during the degradation of other MSW components. (RPFF ¶ 1842).

Dr. Barlaz has also assessed many of the scientific studies for which the parties possessed raw data. (RPFF ¶ 1965). Moreover, Dr. Barlaz explained that outside the context of this litigation he actually visited Eden Laboratories to review the sufficiency of that lab's test methods and facilities, finding the lab well and properly run. (RPFF ¶¶ 221–16). Dr. Barlaz explained that the positive tests in the record before this Court are indicative of biodegradation in excess of the ECM additive (contrary to Dr. McCarthy's "priming effect" theory). (RPFF ¶ 1969; RX 864 (Barlaz, Dep. at 175–76)). He explained that "reactor tests" of the kind ECM presents provide "results on what is possible in a landfill given appropriate environmental conditions." (RX 853 (Barlaz, Rep. at 8)).

Complaint Counsel's purported expert in landfills, Dr. Thabet Tolaymat, lacks the education, experience, or training sufficient to opine on the issues central to this case. (RPFF ¶¶ 2707–2885). Dr. Tolaymat admittedly lacks an understanding of the microbiology and bacterial communities at work in the landfills or test environments. (RPFF ¶¶ 2796–2803; RX 851 (Tolaymat, Dep. at 225–26)). Although he testified as an "employee of the federal government," his antiquated opinions concerning "dry tomb" landfills are inconsistent with the EPA's regulation of those landfills and the EPA's statutory goals, not to mention the testimony of a man he identified as an authority, Dr. Morton Barlaz. (RPFF ¶¶ 2707–16, 2724–27, 2877–85). Dr. Tolaymat prepared his expert report, which may have far-reaching consequences for environmental policy, without consulting anyone expert in the areas he is not at the U.S. EPA.

(RPFF ¶¶ 2711–16). Not a single EPA employee or representative reviewed Dr. Tolaymat's work product to determine if his views were consistent with those of that agency. (RPFF ¶¶ 2711–16). Dr. Barlaz testified that Dr. Tolaymat's report is erroneous on certain fundamental points concerning landfills, landfill management, and biodegradation testing.

Dr. Barlaz testified that Dr. Tolaymat's report is erroneous on certain fundamental points concerning landfills, landfill management, and biodegradation testing. For example, Dr. Barlaz explained that Dr. Tolaymat's opinion was misleading because Dr. Tolaymat suggested that biodegradation only occurs in bioreactor landfills, and Dr. Tolaymat also adopted a very narrow definition of bioreactor landfill. (RPFF ¶ 1852). Dr. Barlaz testified that the term "dry tomb landfill" is misused because the implication of the term and the implication of Dr. Tolaymat's report was that if a landfill is not actively adding moisture to a landfill, then it is a dry tomb landfill, which is false. (RPFF ¶ 1855). Dr. Barlaz "strongly disagree[d]" with Dr. Tolaymat's opinion that *in situ* landfill testing was important to document the anaerobic biodegradability of a material. (RPFF ¶ 1394). Dr. Barlaz also explained that Dr. Tolaymat had referenced lysimeter testing that Dr. Barlaz himself performed with Chris Bareither at the University of Wisconsin and had incorrectly implied that Dr. Barlaz and Chris Bareither had measured methane generation in the lysimeter test when in fact they did not measure methane generation at all. (RPFF ¶¶ 1936–37). Lastly, Dr. Barlaz found Dr. Tolaymat's suggested use of lysimeter studies to be unscientific because it would be extremely difficult to gather useable, representative biodegradability data from a large lysimeter design. (RPFF ¶ 1950).

iv. The Positive Laboratory Tests do not Have Fatal Methodological Flaws

Complaint Counsel failed to produce any evidence concerning why the methodology of ECM's gas evolution studies was flawed.[167] Although Complaint Counsel's witnesses dismissed the tests as inadequate, they did so largely without explanation and in no instance did they provide an empirical analysis explaining precisely what made any test result invalid. (*See, e.g.*, RPFF ¶¶ 2443–44). By contrast, ECM experts testified in detail why they viewed the test results revealing biodegradation of test plastics caused by the ECM additive to be consistent with generally accepted scientific principles and practices for determining biodegradation. (*See, e.g.*. RPFF ¶¶ 1967–1971, 2541).

Complaint Counsel, through argument of counsel, previously identified a series of so-called methodological "flaws" to justify its categorical rejection of the over 33 tests showing the ECM additive causes biodegradation. Significantly, almost all of those "flawed" tests employed suitable negative controls. (*See e.g.*, RPFF ¶¶ 2197, 2223, 2226, 2246, 2249, 2265, 2269, 2290, 2294, 2309, 2327, 2351, 2368, 2424, 2426, 2459, 2461, 2465, 2480, 2486, 2509, 2526, 2536, 2552, 2561, 2583, 2587, 2595, 2605, 2618). ECM experts explained that the use of negative controls in those tests mitigated Complaint Counsel's perceived issues in the methodology, as explained below.[168]

[167] Tr. 1–3005; CCX 0–1108.

[168] Sahu, Tr. 1921; Barlaz, Tr. 2246; Complaint Counsel also refers to their own "well-documented studies" conducted by laboratories like O.W.S. and North Carolina State University. *See* CC Pretrial Br. at 37. However Complaint Counsel is unclear what they mean by "well-documented." Unlike many of ECM's studies, those studies to which Complaint Counsel referenced were not accompanied by raw data. Most of them included just final reports or results. Complaint Counsel apparently thinks that the conclusory data is of more quality despite the absence of methods simply because the reports were inconclusive.

For example, Complaint Counsel contends that tests did not maintain anaerobic conditions throughout the test. That is incorrect. In certain situations, laboratories (e.g., Northeast Labs) would "re-innoculate" the test vessel with fresh inoculum. The labs re-inoculated specifically to test the theory that a plateau effect indicated that the test article had finished degrading. NE Labs would flush the vessels with Nitrogen after adding inoculum, which effectively purges the system of oxygen and restores immediately the anaerobic environment. Dr. Sahu testified that the reinoculation process was not a concern in long term D5511 studies. (RPFF ¶ 2541).

Complaint Counsel's theories on "leakage" in the system are entirely theoretical. There is no evidence in the record that any of the ECM test vessels leaked. For instance, Alan Johnson at NE Labs testified that it would be immediately apparent if a leak arose in the system because the graduated cylinder would not be able to maintain proper pressure and the water levels would fall. (RPFF ¶ 2409). There is no evidence of that in any of the tests. Complaint Counsel also suggested that small leaks could factor in the testing results. That point is misleading for at least two reasons. First, the test vessels have a *positive* pressure, which is why they emit gas that can be collected.[169] If there was a "small" leak in the system, the leakage would be pushing gas out of the container and not permitting atmospheric gases into the container. Second, and relatedly, a "small" leak would only serve to diminish the results of a positive test because methane gas that would otherwise be collected and used to calculate the percentage of biodegradation would have been lost through the leak. If Complaint Counsel's point was to suggest that a leak introduces oxygen, than that point is also without merit because all experts agree that the presence of methane is exclusive to *anaerobic* systems, and oxygen would destroy anaerobic

[169] McCarthy, Tr. 300.

bacteria. (*See, e.g.*, RPFF ¶¶ 1718, 1810, 1840, 2059 In all of the positive anaerobic ECM tests, the labs and ECM's experts calculated the percentage of biodegradation largely through the *methane* content in the test samples. (RPFF ¶¶ 2180–2659).

For several tests where ECM received the raw datasets, Dr. Barlaz completed statistical analyses to determine standard deviations, t-tests, ratios, and other relevant calculations to test the sufficiency of the data. (RPFF ¶¶ 1967–70). Based on the raw data provided, Dr. Barlaz determined that the tests revealed that methane generation from the test materials was significantly ($p<0.05$) greater than what could be attributed to the inoculum. (RPFF ¶ 1967).[170] Moreover, based on calculations of the theoretical carbon yield from ECM's additive (by weight), the tests reveal that significantly more carbon would have come from the test article than what could reasonably have been supplied by the ECM additive. (RPFF ¶ 1969). In other words, the plastic substrate had biodegraded. (*See, e.g.*, RPFF ¶ 2469).

Complaint Counsel claims that tests were not run for periods of time validated under the methodology. Again, that criticism is invalid, considering that the methodologies are unsuited to measure slowly degrading substances. In addition, the method itself does not specify an actual time period for the test, and actually contemplates that the test will be run longer as necessary. (RPFF ¶ 2484).

Dr. Barlaz has visited Eden Laboratories and reviewed their testing operations. (RPFF ¶ 2211). He also reviewed NE Lab's protocols and testimony. (RPFF ¶¶ 2213, 2215, 2430). Dr. Barlaz found no reason to doubt the validity or reliability of the data from either laboratory. (RPFF ¶ 2216).

[170] *See* RX 853, at 14.

v. The Limited Number of Inconclusive Tests Do Not Rise to the Level of Evidence that ECM's Product Is Inefficacious

Complaint Counsel selectively relies on a lesser number of tests said to have shown no biodegradation of plastics infused with the ECM additive. Those tests are in the minority and are mischaracterized by Complaint Counsel to be negative. They are, in point of fact, inconclusive, because not in a single one has there been evaluative testing thereafter to establish the true cause of test failure and there are many potential reasons for failure. Either the actual cause must be proven or all other potential causes ruled out before one could conclude that the ECM additive did not render the plastic infused with it biodegradable. Among the many potential causes not ruled out in any of these tests are death of the bacteria in the inoculum, mis-manufacture of the plastic containing the ECM additive, and the presence of anti-bacterial additives in the plastic. (RPFF ¶¶ 760–66). Complaint Counsel's argument also reveals hypocrisy and inconsistency. First, the tests were conducted under largely the same conditions and protocols as the positive tests upon which ECM relies.[171] It is disingenuous to argue that ECM's favorable tests are worthless because they are flawed methodologically or do not simulate the landfill environment, but then embrace the inconclusive tests simply because the outcome better fits Complaint Counsel's theory of the case.

Second, those tests that reported *zero* or negative biodegradation totals are highly suspect. For context, Complaint Counsel has argued that favorable results in ECM testing are owed to something called the "priming effect." As used by Complaint Counsel, the "priming effect" allegedly occurs when the inoculum gears up to digest the ECM additive, which, as Complaint Counsel concedes, is composed of biodegradable material. We address the flaws in the priming

[171] Dr. Michel conducted his "peer-reviewed" study under a protocol similar to ASTM D5511. (RPFF ¶ 2917).

effect theory below. The crucial point, however, is that the ECM additive is biodegradable. Any legitimate test should therefore show a statistically higher rate of biodegradation in the test sample to account for the degradable nature of the ECM additive. If the test shows *zero* or event negative degradation, then questions immediately arise as to (1) the manufacturing quality of the test sample; (2) the inclusion of the additive in the test article uniformly (as ECM requires); or (3) the viability of the laboratory environment. For instance, on that latter point, several of the inconclusive tests Complaint Counsel rely upon showed that the positive control (cellulose) stopped degrading prematurely and plateaued. Cellulose is indisputably biodegradable, so the plateau is a true indication that the test was inadequate (the microbial life apparently ceased biological activity or died). Such is true of the Michel test, for example. (RPFF ¶ 2987). Closed systems have inherent limitations that might skew data. While those variables may not be to blame in every instance of inconclusive test data, evidence of improper testing conditions should be ascribed the proper weight.[172] Moreover, in systems dependent on a subset of microbial life to sustain them, the delicate nature of that life invites inconclusive tests because maintaining that life in a closed environment is difficult. (RPFF ¶¶ 2043, 2680–81).

One of the more considerable issues is the manufacture of the ECM product, which must be done correctly to keep the additive efficacious. The inconclusive tests do not include chain of custody data sufficient to prove that, indeed, the ECM additive was properly infused into the test plastic in strict accordance ECM manufacturing instructions. (*See, e.g.*, RPFF ¶¶ 2939–2944).

[172] For example, a fish tank is also a closed ecological system. Imagine a fish tank that was never cleaned or cared for. Over a short period of time, that closed system would develop feedback inhibition conditions (e.g., accumulation of waste bi-products) that would render certain processes or life untenable. Those similar limiting factors would not be expected in an environment open to the cleansing force of elements, like the ocean or a landfill in active use.

vi. The Priming Effect Is an Unproven Myth

Complaint Counsel's experts have tried to diminish ECM's positive test data by arguing that any reported biodegradation is owed to a supposed "priming effect." They argue, also, that the small amounts of biodegradation reported in ECM's studies are insignificant and should be disregarded. Although unclear from Complaint Counsel's presentation, their experts appear to argue that the degradation reported in ECM's favorable tests is a result of the inoculum increasing metabolic activity when exposed to the ECM additive. Dr. Barlaz has testified that the concept of "priming effect" has not been seen in anaerobic systems and is invalid in relation to tests on the ECM product. (RPFF ¶¶ 2020, 2024).

The major flaw in that theory is that it depends on the idea that the biodegradation recorded is solely attributed to the additive, or catalyzed by the additive. The test data upon which ECM relies show amounts of degradation far in excess of the amount of additive present in the test plastic. (RPFF ¶¶ 2180–2659). Thus, if the theory is that the inoculum is triggered by the ECM additive, then Complaint Counsel fail to explain why the amounts of degradation continue beyond the amount fairly attributed to the additive (e.g., 1% degradation). Moreover, Complaint Counsel's theory presupposes that all of the ECM additive is available to the biota at the start of the test, which is untrue. The ECM additive is uniformly mixed throughout the plastic and, so, only a small percentage of the additive is immediately available for consumption at the outset. (RPFF ¶¶ 745, 764, 1742–43). The biota may opportunistically find the additive or a defect in the plastic at or near the surface but must then consume the plastic substrate to reach new additive, a food source, which does occur and results in the biodegradation recorded. (RPFF ¶ 1724).

Dr. Barlaz testified that the priming effect theory is based on unsupported assumptions that when the ECM additive is degraded, it stimulates the inoculum and results in an increase in background methane. (RPFF ¶ 2018). Dr. Barlaz testified that the priming effect, as described by Complaint Counsel's witnesses, was "speculative" and "quite a stretch to dismiss … data on the basis of a priming effect." (RPFF ¶ 2019). Dr. Barlaz testified that the "priming effect" theory was first described in the peer reviewed literature in context with aerobic systems only, and then only with readily degradable substrates. (RPFF ¶ 2020). Dr. Barlaz explained that the priming effect theory described by Complaint Counsel's witnesses has not been reported in the peer-reviewed literature with respect to anaerobic systems and slowly degradable substrates like the ECM additive. (RPFF ¶ 2021). Dr. Barlaz explained that, per Dr. McCarthy's report, the ECM additive was mostly polycaprolactone (PCL), and in Dr. Barlaz's own research, the amount of degradation solely from PCL was not that significant to stimulate background methane. (RPFF ¶ 2022). Dr. Barlaz explained that, in the absence of any peer reviewed literature or evidentiary support, which Complaint Counsel's experts did not provide, the priming effect theory was "quite speculative as a way to shoot down a test." (RPFF ¶ 2023). Comparing a potential priming effect from a readily degradable substrate in an aerobic environment to a slowly degradable substrate in an anaerobic environment is not an appropriate comparison scientifically. (RPFF ¶ 2024). Dr. Barlaz also explained that the amount of biodegradation observed in the ECM tests is much higher than anything that can be attributed to a priming effect and, so, the so-called "priming effect" would need to be massive to swallow the test results. (RPFF ¶ 2025). According to Dr. Barlaz, given the amount of biodegradation observed, "if someone is going to use [the priming effect] to throw out data, I'd like to see something more

than this, what to me is this is [a] theoretical possibility without supporting data." (RPFF ¶ 2026).

Dr. Sahu testified in a complementary manner that the theory of a "priming effect" presented by Complaint Counsel's witnesses was unsupported. (RPFF ¶ 2027). Dr. Sahu testified, as did Dr. Barlaz, that the amount of methane and carbon dioxide gas emitted from the test vessels far exceeded that which could have been sourced by the inoculum and the ECM additive. (RPFF ¶ 2028). Dr. Sahu testified that the amount of gas generated in the tests had to come from the test plastic. (RPFF ¶ 2029).

Furthermore, as a way to check against the priming effect, Dr. McCarthy suggested that the laboratories test the ECM additive by itself to determine how much, if any, methane would be sourced from the additive alone. (RPFF ¶ 2030). Unbeknownst to McCarthy that was actually done. In one of his BMP tests, Dr. Barlaz actually did test the ECM additive by itself and did discover the amount of methane produced. (RPFF ¶ 2031).

In that test (CCX 951), Dr. Barlaz reported that the amount of methane produced from the ECM additive alone, under BMP testing conditions that favor biodegradation, was 151.2 mL CH4/g. (RPFF ¶ 2032). Thus, the additive, when tested by itself, did not produce a priming effect equivalent to that which Complaint Counsel ascribes to other positive ECM tests. (RPFF ¶ 2033). Moreover, the additive produced methane within the range that Dr. Barlaz had calculated based on his Buswell equation memorialized in RX 968. (RPFF ¶ 2034). Based on Dr. McCarthy's own suggestion, therefore, the data in CCX 951 contradicts Dr. McCarthy's (and Complaint Counsel's) priming effect theory. (RPFF ¶ 2035).

Put differently, even assuming a priming effect existing in these systems, there is no evidence that the effect is quantifiable, consistent, or sufficient to account for the amount of

methane generated. There is no evidence that any of the test standards developed for the testing of plastics biodegradation ever included controls to address the so-called priming effect. There is no evidence that Complaint Counsel's own witnesses factored or controlled for the priming effect when they performed their own biodegradation gas evolution tests.

Finally, Complaint Counsel's dismissal of ECM tests that reported single digit biodegradation is erroneous. Tests must be compared to negative controls, or untreated plastics without the ECM additive. For instance, a 2011 test of ECM's additive in a Low Density Polyethylene plastic bag revealed 5.94% biodegradation in 30 days. (RPFF ¶ 2504). The product contained 1.5% of the ECM additive. (RPFF ¶ 2493). When compared to the cellulose positive control the rates seem low (the cellulose had degraded to more than 86% in the same time period).[173] However, in that same 30-day period, and under so-called "optimal" conditions, the negative control had degraded just 0.09%.[174] Therefore, 5.94% biodegradation in a short term lab test is powerful validation for a product that is not otherwise biodegradable. In fact, in this test, the laboratory extended the duration to one calendar year, and recorded total degradation of the test plastic of about 17%. (RPFF ¶ 2504). The rate of biodegradation slowed, but continued consistently well beyond the amount that could fairly be attributable to ECM's additive.[175]

[173] RX 838.
[174] RX 838.
[175] RX 838.

6. Complaint Counsel's Scientific Experts Tolaymet, McCarthy, and Michel Are Not Credible

a. Dr. Thabet Tolaymat's "Expert" Opinion Is Not Credible or Reliable

When fashioning his expert opinion in this case, Complaint Counsel's witness Dr. Tolaymat rejected dozens of scientific tests (including gas evolution tests) outright because he deemed them to be unreliable or methodologically flawed. (Tolaymat, Tr. 296; CCX 893 (Tolaymat, Rep. at 39–46)).

He took positions that were in conflict with the EPA's statements concerning landfills, including, for example, his position on "dry tomb" landfills. (RX 967). Dr. Tolaymat never bothered to consult with colleagues at the EPA, even though he was aware that there were others in EPA with substantially more experience with landfills and landfill gases. (Tolaymat, Tr. 216–17). Furthermore, Dr. Tolaymat is an agent of a sister government agency. (Tolaymat, Tr. 216–17). Far from an objective witness, Dr. Tolaymat represents the U.S. Government, the same entity prosecuting ECM for false or misleading claims.

Complaint Counsel retained Dr. Tolaymat back in 2010. (Tolaymat, Tr. 214). Although he guided Complaint Counsel as a consultant, and now a testifying witness, Dr. Tolaymat performed no research of the major issues in this case. (Tolaymat, Tr. 214). He spent a total of 80 hours on the case in almost four years of work, and much of that was spent drafting portions of his expert report. (Tolaymat, Tr. 214).

Dr. Tolaymat's efforts to shape testimony in Complaint Counsel's favor are obvious and unsupported by facts or science. For example, he testified repeatedly that ECM's gas evolution testing was wholly inadequate to substantiate biodegradable claims because those tests did not "replicate" the landfill environment. (Tolaymat, Tr. 235–37). In fact, he admitted that his *sole* reason for rejecting most those studies was because they did not "simulate" the landfill.

(Tolaymat, Tr. 243). He explained that he would have rejected those studies even if they were perfectly run—which he cannot know, because he did not perform any analysis of the study data. (Tolaymat, Tr. 296, 314–15). Dr. Tolaymat never performed any statistics, and ignored the statistical calculations in Dr. Barlaz's work. (Tolaymat, Tr. 314–17).

Then, in a *volte face*, Dr. Tolaymat later testified that he would accept a BMP gas evolution study as competent and reliable evidence of biodegradation in landfills. (Tolaymat, Tr. 220–21). He would accept that test despite it being *less* representative of the landfill environment than the D5511 tests which he rejected on the sole basis that they did not simulate the typical landfill. (RPFF ¶¶ 2751–59). He admitted at the hearing that the BMP test "does not simulate" a landfill and it differs "dramatically" from the typical U.S. landfill. (RPFF ¶¶ 2757–58). Yet, while the BMP test was somehow acceptable to Dr. Tolaymat, the D5511 test was not. Those two positions are impossibly conflicted, and reveal just how tortured Dr. Tolaymat's "expert" analysis had become.

Dr. Tolaymat could not abandon the BMP testing, because he himself (and many others) had used it to assess biodegradability of plastics, another contradiction in his testimony. (RPFF ¶ 2768). Instead, he argued that more evidence in addition to the gas evolution studies would be required. To get there, Dr. Tolaymat argued that field studies (*in-situ* landfill studies) or lysimeter studies were required. (RPFF ¶¶ 2723, 2729–42). But Dr. Tolaymat had never seen such a study conducted, and he was ill-prepared to advocate for same. (RPFF ¶¶ 2728–45). In fact, Dr. Tolaymat admitted that the field studies suffered from fatal design flaws and had more potential variables than tests he had rejected precisely for having too many variables (e.g., Environ PVC). (RPFF ¶¶ 2743). No other expert in the case advocated for *in situ* studies

because they were impractical and unnecessary. (Barlaz, Tr. 2236) (Dr. Barlaz "strongly disagree[d] with Dr. Tolaymat's theory on *in situ* landfill testing).

In advocating for *in situ* studies, Dr. Tolaymat testified that weight loss was a valid endpoint to measure biodegradation. (RPFF ¶ 2745). Dr. Tolaymat again contradicted himself, as he had argued originally that the Environ BioPVC testing was flawed precisely because it relied on gravimetric (weight loss) endpoints. (RPFF ¶¶ 2742–45). In order to support his *in situ* testing theory, Dr. Tolaymat completely reversed his opinion on weight loss endpoints without any reasoned basis. (RPFF ¶¶ 2742–45). He later conceded that weight loss was an acceptable end point; which was a complete contradiction to what he had stated under oath just hours earlier. (RPFF ¶¶ 2742–45).

Dr. Tolaymat had recommended to Complaint Counsel that he perform a BMP test of the ECM additive. (RPFF ¶ 2761). He testified at length during his deposition that he could run tests, and that he had recommended to Complaint Counsel that he should run a BMP (i.e., the gas evolution test which is *less* representative of a landfill than a D5511 reactor test) to assess the performance of the ECM additive. (RPFF ¶¶ 2761–65). Then, in another contradiction, Dr. Tolaymat testified during re-direct that he could not have tested the ECM additive because it was suddenly against the EPA's policy. (RPFF ¶¶ 2761–65).

Dr. Tolaymat set impossibly high standards for biodegradation testing that were not corroborated by any expert or peer reviewed literature. In fact, he admitted that, to meet his impossibly high standards, a company seeking to market a "biodegradable" plastic would likely need to test their product for 20 years. (RPFF ¶ 2778). Although he agreed that biodegradation tests are ordinarily "accelerated" to show an effect within reasonable time constraints, he also testified that a test must precisely mirror the landfill environment. (RPFF ¶¶ 2778–80).

Otherwise, if tests did not mirror the landfill environment, he would outright reject the tests as he did with all 30 ECM gas evolution tests. That point notwithstanding, Dr. Tolaymat literally could not explain the contradictory positions in his testimony, to wit, how a test could *both* be accelerated to show biodegradation but also simulate the landfill precisely. (RPFF ¶¶ 2787–88). In response to questions concerning how a test can be a replication and accelerated at the same time, Dr. Tolaymat refused to answer, and simply stated that his explanation would "take more than this court has time to allow." (Tolaymat, Tr. 250). Indeed.

Following the many contradictions and untenable explanations, Dr. Tolaymat proved that his "expert" opinion is not reliable. (RPFF ¶¶ 2707–85). He either lacks the requisite expertise to offer a sound opinion, or he biased his opinions beyond repair to promote Complaint Counsel's case. Among the many other errors well-documented in ECM's Proposed Findings of Fact (RPFF ¶¶ 2707–85), consider the following:

- Dr. Tolaymat did not perform any research to familiarize himself with concepts relevant to the case. (RPFF ¶¶ 2720, 2789).
- He admitted to having no expertise or knowledge of the bacterial communities in landfills (even though he wrote about same in his report). (RPFF ¶¶ 2795–02).
- He admitted to having no expertise or knowledge of the enzymatic processes that occur in landfills (he could not even name the enzyme that degraded cellulose). (RPFF ¶¶ 2795–02).
- He did not consult with anyone at the EPA concerning the areas where he was lacking in knowledge. (RPFF ¶¶ 2711–16).
- He did not perform any statistical analyses of the tests or raw data relevant to the case. (RPFF ¶¶ 2853–57). He did not calculate or consider the theoretical gas yields

from the ECM additive and, so, he also did not consider whether the amount of methane recorded in the ECM tests would necessarily be attributed to the test plastic. (RPFF ¶¶ 2857–64). **Indeed, none of Complaint Counsel's experts reviewed the raw data or performed statistical analyses required to interpret same**. (McCarthy, Tr. 654; Michel, Tr. 2966).

- He could not reconcile his "dry tomb" landfill theory with the undisputed evidence of methane production in landfills nationwide, including the data that comes from EPA. (RPFF ¶¶ 2877–85; RX 967).
- He recommended the use of scientific tests that had never been used by the relevant scientific community (or industry) to show biodegradation of specific materials (e.g., *in situ* studies and lysimeter studies). (RPFF ¶¶ 2733–34).
- He rejected positive ECM tests because researchers took "weekly" gas measurements, when Dr. Tolaymat himself had performed gas evolution studies using weekly gas measurements (and sometimes less frequent measurements). (RPFF ¶¶ 2872–76).
- Repeatedly in his "expert" report, Dr. Tolaymat revealed that he did not understand how "half-lives" work. (RPFF ¶¶ 2776–77). He consistently calculated the lifespan of materials by doubling the half-lives, which he later admitted was erroneous at the hearing, but only after having been confronted with his mistake at his deposition. (RPFF ¶¶ 2776–77).
- He was unfamiliar with test standards at issue in this case. For instance, he entirely excluded D5511 studies when they exceeded 60 days, solely because he thought extended testing was not permitted by the D5511 test protocol, yet the D5511 test

method does not set a durational limit and actually encourages testing to continue. (RPFF ¶¶ 2784–86).

- He discounted the use of chloride ions in the Environ BioPVC study because he thought that the chloride ions came from the ECM additive (rather than the plastic). (RPFF ¶¶ 2821–25). He held to that position despite also testifying that the ECM additive "shouldn't" contain polyvinyl chloride. (RPFF ¶ 2823).

Those errors are only a subset of the errors apparent in his testimony. However, each of those errors is substantial and reveal Dr. Tolaymat not credible as an expert in this case. His testimony is unreliable, and his opinions should be devalued.

b. Dr. Steven McCarthy's "Expert" Opinion Is Not Credible or Reliable

i. Dr. McCarthy's Shifting Positions

Dr. McCarthy submitted an expert report in this case on June 4, 2014. (RPFF ¶ 266). In his report, without the benefit of citation to the scientific literature, he stated that "microorganisms do not produce enzymes that metabolize plastic."[176] He gave short shrift to the notion that naturally produced enzymes could metabolize conventional plastics, which, he argued, "remain resistant to microbial attack."[177] Dr. McCarthy also stated unequivocally that conventional plastics are not biodegradable, again without citation to the scientific literature. (RPFF ¶ 1487). He explained that the "evidence indicates that the minimal biodegradation observed in the tests ECM relies on is the result of the 'priming effect,' *i.e.*, biodegradation of the additive (which contains organic compounds highly susceptible to biodegradation) and the

[176] CCX 891 (McCarthy, Rep. at 29–30).
[177] *See id.*

organic materials of the test medium (the bacteria used for testing) rather than the plastic."[178] Dr. McCarthy offered those opinions without the benefit of a single supportive citation; indeed, he generally avoided citations throughout his report.[179]

ECM's experts countered with a large body of peer-reviewed literature showing that conventional plastics can be, and are in fact, enzymatically degraded. ECM's experts explained that the phenomena observed in ECM's tests were supported by the peer reviewed literature.[180] In response, Dr. McCarthy presented a rebuttal report on June 30, 2014, wherein he did not defend his original position but instead developed the argument that ECM's additive was not efficacious due to amorphous versus crystalline structures of plastic polymers.[181] Therein he did a *volte face* explaining that conventional plastics may be biodegradable after all, however, only amorphous sections of the plastic could biodegrade: "The material to biodegrade is the amorphous region of a polymer, which biodegrades at a fast rate. If the material were 50% crystalline, then the biodegradation rate would be very rapid until it reached 50% biodegradation."[182] Of course, Dr. McCarthy never posits or explains the percentage he actually thinks is "amorphous" in ECM's plastic products tested; nor does he rely on scientific literature to establish a foundation for his amorphous versus crystalline opinion. (RPFF ¶¶ 1553–54).[183] He likewise fails to explain what percentage of crystalline polymers are present in his patented "blends" of polyesters that are manufactured using blending techniques like ECM's technology

[178] CCX 891 at 36.

[179] *See generally, id.*

[180] *See* RX 855 (Sahu Rep. at 29–40 (collecting references demonstrating the enzymatic biodegradability of certain plastics)); RX 854 (Burnette, Rep. at 17–22).

[181] *See* 892 (McCarthy, Rebuttal Rep. at 10).

[182] *Id*.

[183] *See generally*, CCX 891 (McCarthy, Rep.); CCX 892 (McCarthy, Rebuttal Rep.); McCarthy, Tr. 359–690.

or the contradictory fact that he deemed the patented blends "biodegradable" in their entirety without regard to the percentage of amorphous and crystalline structures within them.[184]

Complaint Counsel also presented the rebuttal testimony of Dr. Frederick Michel. Complaint Counsel had negotiated stipulations concerning Dr. Michel's testimony as a fact witness, and held him out as a potential fact witness.[185] On June 30, 2014, Complaint Counsel suddenly added without prior notice Dr. Michel as a rebuttal expert witness, all within 24 hours of the expert discovery cutoff.[186]

In response, ECM moved to add a surrebuttal witness, Dr. Steven Grossman.[187] Dr. Grossman is a professor of plastics engineering and a colleague of Dr. McCarthy, Complaint Counsel's scientific expert.[188] Dr. Grossman works in the same department as Dr. McCarthy.[189] The court denied leave to allow Dr. Grossman's surrebuttal.[190] Dr. Grossman would have provided crucial concerning false or misleading statements in Dr. McCarthy's expert report and testimony as revealed in an offer of proof supplied to the Court. (RPFF ¶ 3004).

[184] RX 928.

[185] *See* Resp.'s Mot. For Sanctions, to Exclude Complaint Counsel's Concealed Expert Rebuttal Witness, and For Leave to Include Surrebuttal Expert (July 9, 2014).

[186] *See id.*

[187] *See id.*

[188] *See id.*

[189] *See id.*

[190] Order on Resp.'s Combined Mot. For Sanctions, to Exclude Expert Witness, and for Leave (July 23, 2014).

ii. Dr. McCarthy's Hypocritically Demands that ECM Rely on Experimental Testing Methods and Standards that Dr. McCarthy Neither Uses Nor Requires for His Own Claims of Biodegradability in Plastics

Dr. McCarthy's expert report stated that any deviation from the protocol prescribed in ASTM D5511 invalidates biodegradation testing, but he himself does not use ASTM testing in his own biodegradation tests at UMass-Lowell or in his scientific publications, using instead a different gas evolution test he designed, referred to as UML-7645 in his '199 patent. (RPFF ¶ 1467).[191] Moreover, Dr. McCarthy testified that carbon 14 radiological testing is the only test that can definitively prove plastic biodegradation, but he himself has never used carbon 14 radiological testing and has instead relied on extrapolation and other tests (that neither adhere to an ASTM standard nor involve radiological markers) to prove biodegradation, such as one he used at UMass., UML-7645; he also uses measures of weight loss to prove biodegradability of polymer products. (RPFF ¶¶ 1449–1453, 145–60, 1503, 1508). Dr. McCarthy also claims, again without any support in the peer-reviewed literature, that in order to prove biodegradation "[t]he study must last long enough for the sample to reach at least 60% biodegradation."[192] Dr. McCarthy makes that assertion after authoring peer-reviewed literature and a patent wherein he concludes that polymers are biodegradable when they have biodegraded only 14% in 45 days. (RPFF ¶ 1542).

Dr. McCarthy broadly asserts that extrapolation is prohibited, thus substantively condemning his own published work and patent, deeming here for the first time 100% biodegradation in the laboratory to be required. (RPFF ¶¶ 1540, 1542). Similarly, Dr. McCarthy believes that "one of the most serious flaws in the conclusion of [ECM's] experts is that once

[191] CCX 891 (McCarthy, Rep. at 34).
[192] *Id.* at 15.

biodegradation is established, it will continue to completion." (RPFF ¶ 1556). However, Dr. McCarthy's '199 patent made biodegradable claims even though the rate of biodegradation was lower than 60%, reaching only 14% in 45 days, and where he did not use a negative control. (RPFF ¶¶ 1542, 1557). Further, much of Dr. McCarthy's prior research on biodegradable plastics did not meet the same 60% threshold that he states in his report is required of ECM's additive. (RPFF ¶ 1543).

Dr. McCarthy authored the scientific content of patent number 5,883,199. (RPFF ¶ 1397). In that patent, Dr. McCarthy tested the biodegradation rates of five different polymer blends and claimed that those and various additional polymer blends are biodegradable. (RPFF ¶ 1449). In order to do so, Dr. McCarthy used not an ASTM standard method, but a gas evolution test method he developed at UMass-Lowell, known as UML-7645. (RPFF ¶¶ 1467, 1541). Dr. McCarthy ran UML-7645 for only 45 days and on only five polymer blends. (RPFF ¶¶ 1459, 1467). Despite running the test for only 45 days, Dr. McCarthy extrapolated the results to conclude that all five blends and additional blends are biodegradable. (RPFF ¶ 1459). UML-7645 does not require radiolabeling. (RPFF ¶ 1453). UML-7645 is not even an ASTM test method. (RPFF ¶ 1451). UML-7645, like ASTM D5511, is simply a gas evolution test.[193] During the 45 day test, some of the polymer blends biodegraded by more than 60% and others did not.[194] For example, the polylactic acid blend degraded by about 14% in 45 days. (RPFF ¶ 1463). Patent '199 contains no requirement that polymer blends fully biodegrade in order to be considered biodegradable. (RPFF ¶ 1454).[195] Patent '199 contains no requirement that polymer

[193] RX 928.
[194] *Id.*, at fig. 11.
[195] RX 928.

blends biodegrade by 60% in order to be considered biodegradable.[196] Nowhere in the patent does Dr. McCarthy establish that any of the five polymer blends decompose into elements found in nature within one year after customary disposal. (RPFF ¶ 1456). Nevertheless, Dr. McCarthy concluded that all five of the blends, and additional blends, are biodegradable. (RPFF ¶ 1461).[197]

Dr. McCarthy does not consider PET to be biodegradable. (RPFF ¶ 1469). In the '199 patent, however, Dr. McCarthy claims that PET blended with PLA is biodegradable. (RPFF ¶ 1468).[198] Similarly, Dr. McCarthy considers PET to be a homopolymer. (RPFF ¶ 1530). Nevertheless, patent '199 deems a blend of a homopolymer to be biodegradable. (RPFF ¶ 1531). Dr. McCarthy also asserts in his expert report that a study used to determine whether something is biodegradable must include a negative control, (RPFF ¶ 1472) , yet patent '199 does not include a negative control in the underlying tests despite the patent representation that the blends are biodegradable. (RPFF ¶¶ 1472–1474).[199]

Dr. McCarthy authored an article entitled "Advances in Properties and Biodegradability of Co-Continuous, Immiscible, Biodegradable, Polymer Blends." (RPFF ¶ 1496; RX 940). In that article, Dr. McCarthy measured the biodegradability with proteinase K in soil and composting for the blends which are the basis for the '199 patent. (RPFF ¶¶ 1496–1501). In measuring biodegradability of polymer blends in that article, Dr. McCarthy did not use carbon 14 radiolabeling testing. (RPFF ¶¶ 1496–1501). In measuring biodegradability of polymer blends in that article, Dr. McCarthy did not rely on an ASTM standard testing method. (RPFF ¶¶ 1496–1501). Like in patent '199, Dr. McCarthy used his university's own testing method to determine

[196] *Id.*

[197] *Id.*.

[198] One must wonder why, then, Dr. McCarthy is so quick to dismiss data evidencing that a blend of PET and ECM Additive renders a biodegradable plastic. (RPFF ¶ 1966).

[199] RX 928.

biodegradability of polymers. (RPFF ¶¶ 1496–1501; RX 940). In that article, Dr. McCarthy concluded that certain test samples were biodegradable without proving that they completely biodegraded within one year after customary disposal. (RPFF ¶ 1501; RX 940).

Dr. McCarthy also authored an article entitled "Biodegradable Polymer Blends of Poly(lactic acid) and Poly(ethylene glycol)." (RPFF ¶ 1502). In that article, Dr. McCarthy measured enzymatic degradation based solely on a weight loss calculation. (RPFF ¶ 1503). Like in his patents and other articles, and contrary to his positions in this case, Dr. McCarthy measured enzymatic biodegradation without using an ASTM standard and without using any radiolabeling testing. (RPFF ¶¶ 1504–05).

Dr. McCarthy co-authored an article entitled "Degradation Ranking of Plastics in a Landfill Environment." (RPFF ¶ 1506). Once again, in that article, Dr. McCarthy measured degradation rates. (RPFF ¶¶ 1507–09). This time, like Dr. Barber, Dr. McCarthy used weight loss to measure degradability. (RPFF ¶ 1508). Dr. McCarthy used qualitative measurements, such as looking at the samples to evaluate whether the samples looked weathered, in order to determine the samples' degradability. (RPFF ¶ 1510). Once again, in that article, Dr. McCarthy did not use any ASTM method or any radiolabeling to determine degradation. (RPFF ¶¶ 1507, 1509).

Dr. McCarthy authored an article entitled "Biodegradable Blends of Bacterial Polyesters with Polyethylene and Polystyrene." (RPFF ¶ 1511). No author of Biodegradable Blends of Bacterial Polyesters with Polyethylene and Polystyrene established that the polyethylene and polystyrene blends tested completely break down and return to nature within one year after

customary disposal. (RPFF ¶ 1512). Nevertheless, the authors concluded that the polyethylene and polystyrene blends were biodegradable.[200]

Dr. McCarthy co-authored an article entitled "The Effect of Hyperbranched Polymers on Processing and Thermal Stability of Biodegradable Polyesters." (RPFF ¶ 1513). In that article, Dr. McCarthy characterized polyhydroxybutyrate as wholly biodegradable. (RPFF ¶ 1514). At his deposition, Dr. McCarthy testified that the authors of that article did not determine that existence of biodegradation predicated upon establishment that the polyhydroxybutyrate completely broke down and returned to nature decomposing into elements found in nature within one year after customary disposal. (RPFF ¶ 1516). Dr. McCarthy contradicted himself at trial, stating that the authors of that article established that polyhydroxybutyrate completely decomposed into elements found in nature within one year after customary disposal. (RPFF ¶¶ 1514–16). Nothing in the article so states. (RPFF ¶ 1515).

Dr. McCarthy co-authored an article entitled "Microwave-Assisted Solvent-Free or Aqueous-Based Synthesis of Biodegradable Polymers." (RPFF ¶ 1517). At his deposition, Dr. McCarthy testified that this article did not establish that the polymers would biodegrade such that they would break down and return to nature decomposing into elements found in nature within one year after customary disposal. (RPFF ¶ 1519). However, once again, Dr. McCarthy contradicted himself at trial, testifying that the article established that the polymers would biodegrade such that they would break down and return to nature, decomposing into elements found in nature within one year after customary disposal. (RPFF ¶ 1518). Nothing in the article so states.[201]

[200] RX 945.
[201] RX 948.

Dr. McCarthy believes that a biodegradation study must last long enough for the same to reach at least 60 percent biodegradation. (RPFF ¶ 1539). Dr. McCarthy also agrees that ordinarily 60 percent biodegradation of a sample is not something that can occur in a just a few minutes. (RPFF ¶ 1561). Dr. McCarthy also co-authored an article entitled "The Influence of Injection Molding Conditions on Biodegradable Polymers." (RPFF ¶ 1558). In that article, Dr. McCarthy analyzed certain polymers for their rates of biodegradation. (RPFF ¶ 1562). Remarkably, Dr. McCarthy measures rates of degradation in that study by conducting a test that lasted only five minutes. (RPFF ¶ 1562). Yet, Dr. McCarthy relied on those five minute tests to draw conclusions about the biodegradability of polymers. (RPFF ¶ 1562). The five minute tests failed to demonstrate 60 percent biodegradation. (RPFF ¶ 1562).

iii. Dr. McCarthy's Failure to Consider Scientific Data

In his expert report, Dr. McCarthy makes sweeping conclusions regarding the ECM additive, such as that "after blending the ECM additive with conventional plastic, the conventional plastic remains non-biodegradable."[202] However, Dr. McCarthy does not base that specific conclusion, or any of his sweeping conclusions, on either product testing or reference to any peer-reviewed scientific article.[203] Furthermore, unlike Dr. Barlaz, Dr. McCarthy conducted no statistical analyses of any tests measuring the biodegradation of plastics infused with the ECM additive. (RPFF ¶ 1568).

[202] CCX 891 (McCarthy, Rep. at 250).
[203] *Id.*

iv. Dr. McCarthy's Adoption of a Litigation Definition for "Biodegradable" that Is Not Supported by Science

For purposes of this litigation, Dr. McCarthy decided to define biodegradable to mean precisely what the Green Guides defines biodegradation to mean: "that the entire treated plastic will completely break down and return to nature (*i.e.*, decompose into elements found in nature) within one year after customary disposal (i.e., incinerator, landfill or recycling)." (RPFF ¶ 1361). Dr. McCarthy further stated that this definition of "biodegradable" is "interchangeable" with the scientific definition of "biodegradable." (RPFF ¶ 272).

No published peer-reviewed scientific definition of "biodegradable" includes either a one year time limit or a requirement that the treated plastic completely break down and return to nature (i.e., decompose into elements found in nature). (RPFF ¶¶ 798–800). In fact, Dr. McCarthy in his own scientific publications on biodegradation of plastics has never defined biodegradable in the same way he defines biodegradable for purposes of this litigation. (RPFF ¶ 1372). Consistent with the scientific definition, Dr. McCarthy has previously written that the "the definition of biodegradable polymer varies greatly among scientists, manufacturers, and consumers." (RPFF ¶ 1375). At trial, Dr. McCarthy admitted that "[m]any different definitions [of biodegradation] have officially been adopted, depending on the background of the defining standard organizations and their particular interests." (RPFF ¶ 786). Dr. McCarthy's own writings, outside of this litigation, defining biodegradation do not include the qualifier that an item must completely breakdown within a period of one year. (RPFF ¶ 787). Under cross examination, when pressed for any evidence that the definition he uses "for purposes of this litigation" was replicated anywhere in the scientific literature, Dr. McCarthy stated, "actually, I believe I would like to change that." (RPFF ¶ 1368).

Unlike Dr. McCarthy's and Complaint Counsel's arbitrary definitions, scientific literature defines the term "biodegradable" as *an on-going process*: "the chemical dissolution of materials by bacteria or by other biological means." (RPFF ¶ 774). "Biodegradation takes place by the action of enzymes, chemical degradation with living organisms." (RPFF ¶ 775). Biodegradation has been described as a "two step" process. ((RPFF ¶ 776). "The first step is the fragmentation of the polymers into lower molecular mass species by means of abiotic reactions, like oxidation, photodegradation or hydrolysis, or biotic reactions, like degradations by microorganisms." (RPFF ¶ 777). The second step is "the bioassimilation of polymer fragments by the microorganisms and their mineralization." (RPFF ¶ 778). Degradation results "from the action of naturally occurring microorganisms such as bacteria, fungi, and algae." (RPFF ¶ 779).

Similarly, the Merriam-Webster dictionary defines "biodegradable" as something "capable of being **slowly** destroyed and broken down into very small parts by natural processes, bacteria, etc." or "capable of being broken down especially into innocuous products by the action of living things (as microorganisms)." (RPFF ¶ 780). Other sources have defined "biodegradable" to mean "capable of being decomposed by bacteria or other biological means." (RPFF ¶ 781).

Some standards have been put in place by various organizations that attempt to define a time span for this process, but biodegradation is not subject to a time span limitation because it is an ongoing process. (RPFF ¶ 810). Still, the ASTM definition of "degradable plastics" mirrors the accurate scientific definition which is that a degradable plastic is a plastic that will break down into different chemical materials. (RPFF ¶ 811). Slightly different, the ASTM definition of "biodegradable plastics" is a plastic which breaks down by natural biota. (RPFF ¶ 812). The ASTM definition of "biodegradation" contains no requirement that the test plastic completely

break down into elements found in nature within one year of customary disposal. (RPFF ¶ 813). Indeed, the ASTM has never defined biodegradation as the test plastic completely breaking down into elements found in nature within one year of customary disposal. (RPFF ¶ 796). Further, the plastics industry has never adopted a definition of biodegradation that requires a plastic product to completely decompose and break down into elements found in nature within one year after customary disposal in a landfill. (RPFF ¶ 814).

Likewise, fact witnesses and expert witnesses for both parties in this litigation have defined biodegradable to be unrelated to any temporal restraint. (RPFF PP 782 –814). Complaint Counsel's expert witness Dr. Tolaymat testified that "[b]iodegradation is the conversion of organic matter through the action of bacteria and fungi into more elementary components or elements." (RPFF ¶ 782). Dr. Tolaymat's definition of biodegradation includes no time limit or time constraint. (RPFF ¶ 783). Contrary to Dr. McCarthy's time restricted definition of biodegradation, Complaint Counsel's expert witness Dr. Michel testified that "biodegradation is the mineralization of materials as a result of the action of naturally-occurring microorganisms such as bacteria and fungi." (RPFF ¶ 788).

Dr. Timothy Barber, a neutral fact witness, testified that biodegradation is a process by which microbial organisms sustain their life by eating and metabolizing a material. (RPFF ¶ 792). He also testified that whether something is "biodegradable" requires the determination of whether biological organisms, microbial organisms, sustain their life functions and eat and metabolize this material. (RPFF ¶ 809).

Dr. Sahu testified that the common scientific definition of biodegradation is degradation by biological means and that "biodegradation means different things to different researchers … or in different contexts." (RPFF ¶¶ 790–91). Dr. Sahu also testified that "in all contexts

[biodegradation] simply means the breakdown of whatever is the object of interest using biological means, using essentially biota such as bacteria or fungi or other type of naturally occurring or evolving biota in the environment." (RPFF ¶ 794). Dr. Burnette testified that "from a microbiological standpoint [biodegradation] really is [] the conversion of … one substance to another substance as the result of biological activity." (RPFF ¶ 793).

Despite his definition of "biodegradable" used "for purposes of this litigation," Dr. McCarthy readily admits that not even tree trunks, orange peels, or banana peels, all generally accepted to be biodegradable in the environment, can reliably break down into elements found in nature within one year after customary disposal. (RPFF ¶ 805).

v. Dr. McCarthy Is a Biased Witness with Financial Interests in the Outcome of This Litigation, and His Testimony Reflected That Bias

Complaint Counsel retained Dr. Steven McCarthy approximately two years ago as a consultant, and eventually as a testifying witness against ECM in this case. (CCX 891) Dr. McCarthy's scientific positions were apparent in Complaint Counsel's pre-complaint decisions. Email correspondence from Complaint Counsel to ECM in July 2013 mirrored the content in Dr. McCarthy's expert report. (RPFF ¶ 1534; *Compare e.g.*, RX 593 *with* CCX 891). Dr. McCarthy is a professor at UMass Lowell in Massachusetts ("UMass"). (RPFF ¶ 1428; RX 841 (McCarthy, Dep. at 15)). He is not a reliable expert witness. (RPFF ¶ 1353–80). He has accepted on behalf of UMass millions of dollars in funding from ECM competitors that offer bioplastics and compostable products. (RPFF ¶ 1396; CCX 891, at 42–44 (McCarthy's CV)). Dr. McCarthy has directly profited from research he performed for ECM competitors. (RPFF ¶ 1398–05, 1408–11). UMass-Lowell has boasted of Dr. McCarthy's income earning potential,

noting in 2012 that Dr. McCarthy "has obtained nearly $9 million in externally sponsored research grant and contracts, plus nearly $33 million in intellectual property donations to UMass Lowell." (RPFF ¶ 1407). Dr. McCarthy's success at UMass appears directly linked with his ability to generate income through IP "donations" and grant money.

For instance, Dr. McCarthy directly profits from compostable plastic resin patent royalties paid to UMass. (RPFF ¶¶ 1403–04). Under an agreement with the University and in accordance with UMass policy, Dr. McCarthy assigned his patent rights in a compostable plastic resin he invented to UMass. (RPFF ¶ 1408; RX 841 (McCarthy, Dep. at 57). In exchange, he receives a profit share of the royalty stream. (RPFF ¶ 1409; RX 841 (McCarthy, Dep. at 59). One of Dr. McCarthy's patents was purchased, and has been used, by an ECM competitor, Metabolix Inc. (RPFF ¶ 1401; RX 362 (U.S. Patent No. 5,883,199 (issued Mar. 16, 1999)). To the extent Metabolix's sales increase based on incursions into ECM's market, royalties from the patent will increase and Dr. McCarthy's income from those royalties will increase as well. (RPFF ¶ 1405; RX 841 (McCarthy, Dep. at 51–52, 55–61). Once again, UMass is the patent's assignee. (RPFF ¶ 1399; RX 761; RX 757 (Metabolix Website Article)). Metabolix is the exclusive licensee of the technology. (RPFF ¶ 1401; RX 209). Metabolix's potential royalties from licensing UMass patents exceed $100,000 per year. (RPFF ¶ 1402; RX 209). Dr. McCarthy testified that he receives money directly from the '199 patent, which is licensed by Metabolix. (RPFF ¶¶ 1403–04, 1409; RX 841 (McCarthy, Dep. at 59–60). He acknowledged that Metabolix's products compete directly with ECM's technology for market share.[204] (RPFF ¶ 1412). To date, Dr. McCarthy has received about $28,000 in royalties from the patent. (RPFF ¶

[204] RX 841 (McCarthy, Dep. at 64–66) (acknowledging that it is a competitive marketplace and that products based on the '199 patent are in competition with other products marketed as biodegradable, compostable, and recyclable).

1404). Metabolix has paid more than any other funder to the UMass Lowell Bioplastics and Medical Plastics Center. (RPFF ¶ 1434). Overall, Metabolix has paid approximately one and a half million dollars in grants to UMass Lowell. (RPFF ¶ 1435). Metabolix has also reimbursed UMass Lowell for equipment the university purchased. (RPFF ¶ 1436).

Ignoring conflicts of interest concerns, Metabolix employees have worked directly alongside both Dr. McCarthy and his students. (RPFF ¶ 1437). Dr. McCarthy's students are available to work for Metabolix whenever Metabolix requests. (RPFF ¶ 1438). Metabolix employees actually oversee the work of Dr. McCarthy's students to ensure that the conditions are those that Metabolix wants. (RPFF ¶¶ 1439–40). Metabolix then pays the university for the students' time, and the university subsequently pays the students with the money paid by Metabolix. (RPFF ¶ 1441; McCarthy, Tr. 533–34). In essence, Metabolix pays Dr. McCarthy's students to perform work for Metabolix. (RPFF ¶ 1441). Metabolix has paid up to $200,000 per year as part of this "fee for service" agreement between UMass Lowell and Metabolix. (RPFF ¶ 1433). UMass Lowell and Metabolix's relationship is such that Metabolix essentially leased storage space from the university and has donated items, such as air compressors, to the university. (RPFF ¶ 1430). In sum, one of ECM's competitors is paying Dr. McCarthy's students through the fee for service agreement, Dr. McCarthy's employer through grants, leases, and royalties, and Dr. McCarthy himself through royalties. If the Commission is successful against ECM in this matter (and by extension against similar additive products), Metabolix's market share increases along with the return to Dr. McCarthy from his royalty payments. Although this patent reveals a direct financial interest by Dr. McCarthy in the outcome of the litigation, it is not the only evidence revealing such an interest.

Dr. McCarthy collects a share of research grant money that he secures for UMass Lowell from compostable product competitors of ECM, such as Metabolix and other compostable product manufacturers.[205]

Metabolix supplied grants to UMass of approximately $2.5 million, sponsored more than 50 students for their master's and doctorate degrees, and has made substantial equipment donations (over $500,000). (RPFF ¶ 1427; RX 210). Since 2008, Metabolix has also lobbied the FTC to act against ECM. (RPFF ¶ 1414; RX 211 (requesting FTC to investigate Good Earth and ECM for alleged deceptive environmental claims)). Natureworks, one of the companies Metabolix sublicenses the patent to, is ECM's competitor. (RPFF ¶¶ 323, 1411). Dr. McCarthy has worked with BPI, and collected substantial revenue (approximately $40,000), performing BPI "certifications" for trade customers in the compostable industry which compete with ECM. (RPFF ¶¶ 1421–22; RX 841 (McCarthy, Dep. at 92). Metabolix is also a member of the Biodegradable Products Institute ("BPI"), a primary ECM competitor, and sells approximately a dozen products that are "BPI certified" in direct competition with ECM. (RPFF ¶ 1415; RX 171; RX 172). BPI is a vocal opponent of ECM, and has lobbied the FTC repeatedly since at least 2005 to act against ECM and ECM's customers. (RPFF ¶ 1417–19; RX 744 (BPI Correspondence to FTC of April 25, 2005)).

Dr. McCarthy's personal affiliations and financial interest in ECM's competitors makes his scientific opinions unreliable because he has well established financial interests in opposition to those of ECM. He is an agent of ECM's competitors, profiting directly from their success either by the receipt of royalties, payment for services (such as his service for years as a certifier

[205] RX 841 (McCarthy, Dep. at 52–55) (explaining that a project account receives forty-six percent (46%) of the research grants Dr. McCarthy secures, and that he is in control of that account when he is the principal investigator).

for BPI, or grants to UMass-Lowell in support of his research). A successful prosecution of ECM and the additive market would bestow a substantial windfall on Metabolix, BPI and related compostable product manufacturers, who would immediately stand to gain market advantage. Dr. McCarthy is compensated $100/hour for his work in this matter (except deposition and trial testimony). (CCX 891). The idea that he would enter an opinion in a high profile FTC case that cut against the businesses that support him financially defies credulity. Indeed, the evidence suggests that he tailored his opinion to meet Complaint Counsel's needs, even accepting the fundamental definition of what "biodegradation" means from Complaint Counsel, despite contrary representations in his own scientific articles and in his own patent. (RPFF ¶¶ 269–74, 1360–71).

Dr. McCarthy has adopted positions that contradict prior work he performed for ECM's competitors. For example, his expert report stated that carbon 14 radiolabeling testing is the only testing that can dispositively prove that ECM's additive causes biodegradation of plastics, but he himself has relied on extrapolation and other tests (that neither adhere to an ASTM standard nor involve radiological markers), such as one he created himself, UML-7645, and measures of weight loss, to prove biodegradability of polymer products. (RPFF ¶¶ 1449–80, 1539–64; RX 841 (McCarthy, Dep. at 74–75, 148–149, 165–172). In his published works outside of this litigation, Dr. McCarthy has never mentioned the need for a product to biodegrade within a year to be deemed biodegradable, and yet, for ECM's additive, Dr. McCarthy is adhering to the one year rule contained in FTC's Revised Green Guides in collaboration with Complaint Counsel. (RPFF ¶¶ 1538–64).[206]

[206] RX 841 (McCarthy, Dep. at 19, 20–42, 69–76 (explaining that the '199 patent used the term "biodegradability" without requiring complete biodegradation within a year), 185–187

Moreover, Dr. McCarthy's report stated that "evidence that a substance is biodegradable is not 'competent and reliable' unless the tested sample reaches 'at least 60% biodegradation,' and there is both a 'negative control' and a 'positive control,'" but Dr. McCarthy's '199 patent made biodegradable claims even though the rate of biodegradation was far less than 60%. (RPFF ¶¶ 1539–64; RX 756, at Figure 11).

Dr. McCarthy himself has used the very same test methods ECM has used to demonstrate a "biodegradable" product before the U.S. Patent and Trademark Office. Dr. McCarthy's prior research on biodegradable plastics did not meet the same 60% threshold that he now requires of ECM's additive. (RPFF ¶¶ 1539–64, 1611; RX 756, at Figure 11). Dr. McCarthy's insistence on carbon 14 testing is not the consensus in the relevant scientific community. (RPFF ¶¶ 1608–17).

Perhaps caught on the science, Dr. McCarthy's June 30, 2014 rebuttal report eventually presented new theories in response to ECM's expert testimony that had not before been presented by Complaint Counsel. For instance, Dr. McCarthy had previously contended that the "priming effect" would have accounted for the positive results in ECM's testing. (RPFF ¶ 267). When the priming effect was eventually debunked by ECM's experts, Dr. McCarthy developed a new theory, that it was the split between amorphous and crystalline properties of plastic polymers that prevented complete biodegradation. (RPFF ¶¶ 1551–54; CCX 892, at ¶ 22). He also posited that polyethylene polymer chains could only be reduced through the use of pro-oxidants, which ECM's technology did not involve. (CCX 892, at ¶ 11) Truth be told, ECM's additive falls within the types of alternative technologies that have been shown to facilitate polyethylene degradation, (RPFF ¶¶ 2131, 2180–2706), and, contrary to Dr. McCarthy's testimony, amorphous and crystalline structures are not separate and distinct in plastics but

---

(explaining that a banana peel, tree trunk, and orange peel are biodegradable even if they do not biodegrade within a year of customary disposal).

overlap and are inextricably intertwined, (RPFF ¶¶ 1749–53). While crystalline structures may slow down biodegradation, it is a false assertion that they stop or prevent it. (RPFF ¶¶ 1757–62).

Consequently, the evidence reveals that Dr. McCarthy has fashioned his scientific opinion to suit Complaint Counsel's purposes and further Dr. McCarthy's financial interests. Dr. McCarthy is not an objective expert in this case, and his opinion should be rejected as biased, impeached through inconsistency, and lacking a foundation in supportive peer reviewed scientific evidence.

F. Complaint Counsel Has Failed to Prove that Claims Concerning Biodegradation Rate Are Material to Purchasing Decisions

"To establish that an act or practice is deceptive under Section 5, the FTC must demonstrate that '(1) there was a representation; (2) the representation was likely to mislead customers acting reasonably under the circumstances; and (3) the representation was material.'" *F.T.C. v. NHS Syss., Inc.*, 936 F. Supp. 2d 520, 531 (E.D. Pa. 2013) (citations omitted). In order to determine whether an advertisement is material, "[t]he basic question is whether the act or practice is likely to affect the consumer's conduct or decision with regard to a product or service." *Cliffdale Assocs., Inc.*, 103 F.T.C. 110, at *45 (1984)). "In other words, [information that is material] is information that is important to consumers." *Id*. at *49. As the Seventh Circuit stated, "[a] claim is considered material if it involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding, a product." *Kraft, Inc. v. F.T.C.*, 970 F.2d 311, 322 (7th Cir. 1992) (internal quotations and citations omitted); *see also F.T.C. v. Colgate-Palmolive Co.*, 380 U.S. 374, 391 (1965) (citing *F.T.C. v. Raladam Co.*, 316 U.S. 149, 152 (1942)) ("when the Commission finds deception it is also authorized, within

the bounds of reason, to infer that the deception will constitute a material factor in a purchaser's decision to buy").

The FTC applies a presumption of materiality to "(1) express claims; (2) implied claims where there is evidence that the seller intended to make the claim; and (3) claims that significantly involve health, safety, or other areas with which reasonable consumers would be concerned." *Id.* The first situation applies "[w]here the seller knew, or should have known, that an ordinary consumer would need omitted information to evaluate the product or service, or that the claim was false," and, in such a circumstance, "materiality will be presumed because the manufacturer intended the information or omission to have an effect." *Matter of Cliffdale*, 103 F.T.C. 110 (1984). The third situation can apply when the advertisement concerns information that "pertains to the central characteristics of the product or service." *Id*.

"A representation is material if likely relied upon by a reasonable prospective purchaser." *F.T.C. v. Wash Data Ress.*, 856 F. Supp. 2d 1247, 1272 (M.D. Fla. 2010). Importantly, "[r]ather than an isolated word, phrase, or sentence, the representations net impression controls." *Id.* at 1272 (citations omitted). "What is important in determining whether a statement is misleading is the over-all impression it tends to create on the public." *Country Tweeds, Inc. v. F.T.C.*, 326 F.2d 144, 148 (2d Cir. 1964) (citing *Murray Space Shoe Corp. v. F.T.C.*, 304 F.2d 270 (2d Cir. 1956)).

A respondent can counter a presumption of materiality with extrinsic evidence. *See In the Matter of Pom Wonderful LLC*, 2012 WL 2340406 (F.T.C. May 17, 2012). As explained in *POM Wonderful* and *Novartis*:

> Respondent can present evidence that tends to disprove the predicate fact from which the presumption springs (*e.g.*, that the claim did *not* involve a health issue) or evidence directly contradicting the initial presumption of materiality. This is not a high hurdle. Unless the rebuttal evidence is so strong that the fact

> finder could not reasonably find materiality, the fact finder next proceeds to weigh all of the evidence presented by the parties on the issue. *See id.* at 516 (noting that after the presumption drops out, "the inquiry ... turns from the few generalized factors that establish [the presumption] to the specific proofs and rebuttals ... the parties have introduced").

Id. at *235. "Materiality turns upon whether those consumers who have drawn the claim from the advertisement and have been misled by it are also **likely to have their conduct affected by the misrepresentation**." *In re Novartis Corp.*, 127 F.T.C. 580, 691 (1999) (emphasis added).

ECM's claims concerning the *rate* of biodegradation are not material because (1) ECM and its customers made those claims ostensibly for regulatory compliance purposes, and not as performance claims; (2) the claims largely were not passed along in commerce, and rarely to end users and, in any event, consumer survey evidence proves that consumers did not regard rate claims as material; (3) ECM's customers were only concerned with having the ability to market a "biodegradable" product and not with the rate of biodegradation; and (4) the specific rate of degradation is not scientifically or environmentally material.

First, ECM identified a specific rate of biodegradation not as a comparative or performance claim in the market. The testimony revealed that ECM began using its "5 year" claim as a means to differentiate its technology from *more rapidly degrading* compostable products and predicated on testing results obtained by additive inventor and former ECM owner Patrick Riley and those of ECM President Robert Sinclair and Chief Financial Officer Ken Sullivan. (RPFF ¶¶ 45–54, 308).[207] In those tests in 50 gallon drums, the ECM infused plastics broke down within 9 months to 5 years. (RPFF ¶ 53–54). ECM wanted to be clear that its products would not perform like the compostable products, which were expected to fully degrade in aerobic conditions in under 6 months (180 days). (RPFF ¶ 308). ECM chose a period of 9

[207] *See* CCX 818 (Sinclair, Dep. at 77–79, 85–88).

months to 5 years at a time when the scientific understanding of landfills and biodegradation was evolving, thinking that the 5 year qualification would provide an adequate buffer. In 2012, when the FTC revised the Green Guides, ECM changed its claim language (permanently discontinuing the "9 month to 5 year claim," added more qualifications, and informed customers that biodegradation claims should only be made if the specific customer had evidence sufficient to meet the Green Guide recommendations. (RPFF ¶ 309).[208]

ECM customers therefore considered ECM's "rate" claims only with respect to regulatory compliance. The record reveals that ECM customers did not consider rate claims material but instead sought to discern if the additive enabled plastics to become more biodegradable than plastics without the additive. (RPFF ¶¶ 321, 329, 330, 359).

There is literally no evidence that the actual rate of biodegradation was ever important to ECM customers or their subsequent customers. (RPFF ¶ 729).[209] One customer, BER Plastics, was asked about whether the ECM additive "would make plastic biodegrade in nine months to five years" and, tellingly, the witness replied: "Never really thought about the – how long it would take to biodegrade." (RPFF ¶ 605).[210] Still more customers testified that rate of biodegradation was only significant to the extent it showed the products were "biodegradable"

[208] *See* RX 195, at 121 n.409 (noting that studies supporting the "one year" rule "may be faulted for lacking control groups and presenting the timeframe questions with closed-ended, rather than open-ended, answers, but they nevertheless are the only studies in the record").

[209] Island Plastic Bag's customer, Down to Earth, testified through its agent only that the rate claims was a significant part of the reason for purchasing ECM's product, but also noted that "price" was a major factor. *See* CCX 803 (Santana, Dep. at 39–40). Complaint Counsel never asked "why" the rate claim was important to the customer.

[210] *See* CCX 800 (Ringley, Dep. at 32). Another customer, Kappus Plastics, was asked whether they considered the "nine months to five years" claim a "rigid standard," and the witness responded apathetically: "Again, we're not really saying anything. We took information that was provided and moved it from one piece of paper to the other. It says it on the piece of paper." *See* CCX 812 (Kappus, Dep. at 50) (noting that the rate claim was not perceived by the witness as "rigid").

generally or "green." (*See generally*, RPFF ¶¶ 605–725). [211] Similarly, another customer, Quest Plastics, was generally uninterested in the "rate" of degradation. When asked about ECM's five year claim, the witness testified:

> Q: So your assumption, when you read the claims on the website, was that if it stated it was fully biodegradable in nine months to five years, that it would fully biodegrade in nine months to five years?
>
> A: I didn't know, and I left it up to my customer to decide whether this is what he wanted to use.[212]

(RPFF ¶ 707).

According to the witness, his customer was simply "looking for an additive to make the biodegradable – the gold tee biodegradable." (RPFF ¶ 705).[213]

That lack of interest in the rate claim is reflected in the advertising before the Court. Throughout the hundreds of thousands of pages of advertising and correspondence in Complaint Counsel's possession, the so-called "rate" claim for biodegradation has appeared relatively infrequently, and rarely when compared to the more general "biodegradation" claim. If the rate claim was material and important to purchasing decisions, then ECM's customers would pass that information along in commerce routinely, but they didn't. Indeed, doing so, was the rare exception. The claim was unimportant.[214] In fact, Complaint Counsel has recorded pictures and samples of many ECM goods that actually reached the end consumer, and, with very few

---

[211] *See* CCX 882, at 12–13.

[212] *See* CCX 817 (Bean, Dep. at 32).

[213] *Id.* at 33.

[214] The majority of advertisements do not mention rates of biodegradation: RX 00, RX 02, RX 03, RX 14, RX 15 (focus on cost), RX 16 (logo only), RX 17 (general biodegradable claim), RX 22, RX 26, RX 28, RX 29, RX 30, RX 315 (cost the focus), CCX 30 (general focus on biodegradability); CCX 31 (same), CCX 32, CCX 36 (labeling instructions to downstream customers without including rate); CCX 39, CCX 43, CCX 46, CCX 47, CCX 49, CCX 50, CCX 52, CCX 59 (focus on shelf life), CCX 60 (same), CCX 63, CCX 64, CCX 65 (focus on "green), CCX 66, CCX 79.

exceptions, every product includes only a generalized "biodegradable" claim without reference to, or reliance on, the rate of biodegradation.[215] Complaint Counsel acknowledges that, more than selling just an additive, ECM really "sells the purported ability to make a 'biodegradable' advertising claim."[216] Exactly—which is indicative of the fact that ECM's customers are unconcerned about the rate of biodegradation, except to the extent it would influence their ability to make a "biodegradable" claim broadly. (RPFF ¶¶ 605–725). That means ECM's customers did not base their purchasing decisions on ECM's rate claims, but on the fact of biodegradation without regard to the precise rate. Customers were primarily concerned just with the "biodegradable" claims, and testified as such. (RPFF ¶¶ 605–725).[217] More importantly, however, the customers were interested in a "biodegradable" product that could work with their manufacturing systems, because the plastic had to serve a function foremost. (RPFF ¶ 340). Small companies particularly devoted substantial test resources to that inquiry, as Island Plastic Bags explained:

> Q: And in the email David Hong is stating that he was experimenting with ECM plastic for over a year.
>
> A: So what we—what I believe he was doing was—and we didn't, like, test it or anything, what we were doing is seeing if we could actually run it through our machines, because it could—you know, ECM at that time said it's biodegradable, but it doesn't do us any good if we can't use it through our machines. So what we were doing was putting the additive

[215] All of the following exhibits represent photos of the actual consumer goods that are eventually labeled "biodegradable," but without reference or focus on the rate of biodegradation: CCX 97, CCX 98, CCX 99, CCX 100, CCX 10, CCX 103, CCX 104, CCX 107, CCX 109, CCX 110, CCX 111, CCX 112, CCX 113, CCX 114, CCX 115, CCX 116, CCX 117, CCX 118, CCX 119, CCX 120, CCX 121, CCX 122, CCX 123, CCX 124, CCX 125, CCX 126, CCX 127, CCX 128, CCX 129, CCX 130 (specifically says time "will vary due to local conditions"), CCX 131, CCX 132, CCX 133, CCX 135, CCX 136, CCX 138, CCX 139, CCX 140, CCX 142, CCX 143, CCX 144, CCX 145, CCX 146, CCX 147, CCX 148, CCX 149, CCX 150, CCX 151.

[216] *See, e.g.,* CC Pretrial Br. at 15.

[217] *See, e.g.,* CCX 811 (Hong, Dep.).

> inside of our plastics to see if it could actually run through our extruders and then be cut and sealed as plastic bags.[218]

(RPFF ¶ 340).

The lack of materiality is also confirmed through expert testimony. Dr. Stewart testified that, based on several surveys of high methodological value, end users or consumers have no uniform understanding of "how long" it should take an item to decompose in landfills. (RPFF ¶¶ 1315–16).[219] There is also an understanding among many consumers that the length of time required for an item to degrade is dependent on a variety of factors including the material from which it is made and the conditions under which degrading occurs. (RPFF ¶ 1311).[220] Consumers also expressed considerable skepticism over rate claims that were presented to them in relation to plastic products. (RPFF ¶ 1337).[221] Thus, according to Dr. Stewart, the results of his survey evidence make clear that consumers are highly unlikely to be misled by ECM's product claims because "(1) there is no shared understanding among consumers of the length of time required for an item to decompose and (2) the lack of understanding and skepticism of the claims make it highly unlikely that the claims will have a material influence on the consumer."[222] Put simply, if the consumer has no reasonable or accurate knowledge of how long a plastic *should* take to biodegrade in the environment, then they cannot adequately or reasonably interpret whether ECM's rate claim is good or bad.[223] The rate claim is very different from other familiar rate claims, for example miles-per-gallon (MPG), where consumers can correlate a rate

---

[218] CCX 811 at 44.
[219] RX 856, at 15 (Stewart Rep.).
[220] RX 856.
[221] *Id.*
[222] *Id.*
[223] Assuming, *arguendo*, that consumers really do expect a product to biodegrade within one year, then ECM's 5-year claim would have a negative influence on purchasing decisions. Those customers would think the product did not meet their expectations.

with performance. Furthermore, there is no evidence in this case that ECM's competitors have offered rate claims that differ from ECM's, such that a consumer would be drawn to an ECM product through comparative advertising.

In deposition testimony, Dr. Barlaz described his attempts to calculate rates of degradation in landfill environments.[224] He testified that his work was experimental, and that the precision of his rates fluctuated sometime by a factor of two.[225] Complaint Counsel questioned whether the fluctuations would be considered significant, and Dr. Barlaz explained that it was not all that important:

> Q: Is a factor of two large or small? I really don't know.
>
> A: Sure. My opinion would be that, for a landfill, a factor of two is fine, because the retention time is infinite. If I were in an engineered tank where I were putting stuff in, I needed it to biodegrade at a certain rate so I knew when to take it out so I could put more in, then the rate affects the size of the tank, and the size of the tank affects the cost of the tank. Then people would be interested in something better than a factor of two.
>
> Q: So can you just give me an example—I work better with hard numbers, so just an example of how—and I understand that you don't recall the specific results were, but the difference between inocula coming from an anaerobic digester versus inocula coming from a sewage treatment plant, if those were two different types of inocula that you were looking at?
>
> A: They were.
>
> Q: Did you understand my question?
>
> A: Let me—you are asking me, as I understand it, for an example of the difference in laboratory scale decay rate as calculated for a substrate, for example, copy paper, on two different inocula, for example, anaerobic sewage sludge and leachate?
>
> Q: Yes.

[224] *See* RX 864 (Barlaz, Dep. at 106–108).
[225] RX 864 at 107.

…

Q: Okay. You said your testimony was a factor of two is fine for landfills because their retention time is infinite. So meaning it could take longer than whatever the average is?

A: What I mean is that, if I estimate a half-life of three years and the actual half-life is six years or one-and-a-half years, it's inconsequential for the performance of the landfill. Either way, there is biodegradation occurring because the material is in the landfill, in essence, forever. That's what I mean by infinite retention time. Whether we are off a few years in either direction, it doesn't really seem to matter.[226]

The salient point made by Dr. Barlaz is that there is no material benefit to a product that biodegrades in a landfill in, say, 15 years versus another that degrades in 30 years. The more rapidly degrading product offers no material environmental benefit, and indeed, a plastic product that completely biodegrades in a landfill within one year after customary disposal actually harms the environment as a net contributor to global methane emissions. (RPFF ¶¶ 1604–05). Landfill operators do not change waste management techniques based on the biodegradable speed of plastics and, in turn, plastics manufacturers are not motivated by a need to somehow ensure any particular rate of biodegradation. What, then, is the materiality of a rate claim other than to satisfy the FTC's flawed and unscientific standards in 16 C.F.R. § 260.8?

Finally, ECM permanently discontinued use of the "9 months to 5 years" rate claim at the center of Complaint Counsel's case in 2012 when the FTC revised its Green Guides. (RPFF ¶¶ 315–15).[227]

[226] RX 864 at 109–110; RPFF ¶¶ 1604–05).

[227] Complaint Counsel has identified several limited instances where ECM distributed the 9 month–5 year rate claim accidentally by releasing outdated brochures or flyers to customers, but those have not been shown to have been intentional or material to the ECM customer and were against the direction of Robert Sinclair, ECM's President.

1. To Determine Whether A Claim is False or Misleading, the Trier of Fact Must View the Claim from the Perspective of the Target Audience

"In reviewing allegedly false and misleading statements, courts are to read the statements in their entirety and in context to determine whether they are actionable." *Schering-Plough Healthcare Prods., Inc. v. Schwartz Pharma, Inc.*, 547 F. Supp. 2d 939, 943 (E.D. Wisc. 2008) (citing *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir 1997) ("When evaluating whether an advertising claim is literally false, the claim must always be analyzed in its full context")); *Castrol, Inc. v. Pennzoil Co.*, 987 F.2d 939, 946 (3d Cir. 1993) ("in assessing whether an advertisement is literally false, a court must analyze the message conveyed in full context"); *Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc.*, 388 F.Supp.2d 967, 976 (E.D. Wis. 2005) ("To determine whether a particular representation is literally false, it must be analyzed with its full context")). "In addition, the specific audience is part of the context that must be considered in deciding whether a statement is literally false." *Id.* "Context can often be important in discerning the message conveyed and **this is particularly true where, as here, the target of the advertising is not the consuming public but a more well informed and sophisticated audience.**" *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 229 (3d Cir. 1990) (emphasis added) (citation and internal quotation marks omitted); *see also DeSena v. Beekley Corp.*, 729 F. Supp. 2d 375, 393 (D. Me. 2010) ("A target audience's special knowledge of a class of products is highly relevant to any claim that it was misled by an advertisement for such a product").

Similarly, under state anti-competition laws, "[w]hen the practice [at issue] is targeted to a sophisticated purchaser, the question of whether it is misleading to the public will be viewed from the vantage point of members of the targeted group, not others to whom it is not primarily

directed." *Ariz. Cartridge Remanufacturers Assoc., Inc. v. Lexmark Int'l, Inc.*, 290 F. Supp. 2d 1034, 1041 (N.D. Cal. 2003).

2. ECM's Target Audience and Actual Customers Were Sophisticated Purchasers That Studied the Product and Engaged in Sophisticated Transactions

In business transactions, when the selling company provides the purchasing company with specifications or data, such transactions are "classified as sophisticated." *John Crane Prod. Solutions, Inc. v. R2R and D, LLC*, 861 F. Supp. 2d 792, 799 (N.D. Tex. 2012). In addition, there is less likelihood of confusion when the parties to a business transaction "have a close working relationship." *Id.* at 801. In fact, "[c]ourts have found that the sophistication of the potential purchasers alone is enough to find that there is no likelihood of confusion even when all of the other digits [in the trademark context] weigh in favor of such a finding. *See, e.g., Perini Corp. v. Perini Constr.*, 915 F.2d 121, 128 (4th Cir.1990) (reversing summary judgment because district court did not consider how sophistication of purchasers of construction services affected analysis, even though all other digits weighed in favor of finding likelihood of confusion)." *Id.* at n. 16.

Courts have classified transactions and purchasers as sophisticated in a number of contexts. *See, e.g., Checkpoint Sys., Inc. v. Check Point Software Tech.*, 269 F.3d 270, 285 (3d Cir.2001) (holding that purchasers of retail store security equipment and computer security software were sophisticated); *Rust Env't & Infrastructure, Inc. v. Teunissen*, 131 F.3d 1210, 1217 (7th Cir. 1997) (holding that purchasers of services from engineering consulting firms were sophisticated); *Oreck v. U.S. Floor Sys., Inc.*, 803 F.2d 166, 173 (5th Cir. 1986) ("Because these persons are buying [vacuums and extraction machines] for professional and institutional

purposes at a cost in the thousands of dollars, they are virtually certain to be informed, deliberative buyers."); *Armstrong Cork Co. v. World Carpets, Inc.*, 597 F.2d 496, 504 n. 10 (5th Cir. 1979) ("[A] person buying a 'big ticket' item such as carpeting would ordinarily be expected to be a more careful buyer than the impulse purchaser or the purchaser of a relatively inexpensive item").

ECM customers are sophisticated manufacturers often several layers removed from end-consumers.[228] Moreover, Complaint Counsel has not identified precisely who the "end-consumer" might be here. ECM sells its additive to plastics manufacturers.[229] Most (if not all) of ECM's customers extensively test the ECM product before determining whether to incorporate ECM's technology into their plastics.[230] All 30+ of the gas evolution tests used in this case are not sponsored by ECM but by customers critically evaluating whether the product effected biodegradation of their own plastics before deigning to make a purchase. (RPFF ¶¶ 35, 477, 1606, 2133, 2145, 2150, 2155, 2162, 2169, 2176, 2218, 2242, 2260, 2285, 2304, 2323, 2347, 2364, 2457, 2478, 2507, 2524, 2534, 2550, 2559, 2581, 2603, 2616, 2627, 2640, 2650.) Those manufacturers generally sell to sub-manufacturers or distributors as bulk plastic products.[231] The mid-level distributors market and sell items like plastic bags or packaging cushions to corporations (e.g., grocery stores or common carriers).[232] A so-called "end consumer" thus never actually purchases an ECM plastic. They *receive* the ECM plastic either in the mail (for packaging products) or at the grocery store (for plastic grocery bags). Moreover,

---

[228] *See, e.g.*, RX 178, at 34 (page labeled as "BPI 004025").

[229] RX 875 (Sinclair, Tr. at 217:16–17) (ECM's "customer[s] [are] plastic product manufacturers").

[230] *See, e.g.*, CCX 802 (Leiti, Dep. at 92) (noting that Dispoz-o conducted its own tests).

[231] *See, e.g.*, RX 178, at 34 (page labeled as "BPI 004025").

[232] *See, e.g.*, CCX 811 (Hong, Dep. at 9–10) (explaining that Island Plastic Bags manufactures and sell plastic bags and plastic cutlery).

the ECM plastic is received by the end consumer *after* a sale in commerce. Thus, there is no evidence at all in this case that, for the bulk of the products ECM manufactures, a consumer ever makes a purchasing decision based on a single ECM claim or a single claim made by an ECM customer.

ECM's direct customers are ordinarily far larger than and equipped with more knowledge of plastics and degradation of their own plastics than ECM possesses.[233] ECM's customers, unlike ECM, are plastics manufacturing companies ordinarily with their own scientists, engineers, and lawyers. As plastics manufacturers, those companies are keenly aware of plastics chemistry. Moreover, the evidence suggests that most ECM competitors actively review competing products, and even test competing products to determine if ECM is the best fit from a performance and biodegradation perspective.[234]

Given that ECM has fully disclosed the nature of its products, there is transparency in ECM's advertising and a distinct lack of deception in the market. ECM customers are given samples to test and testing is encouraged. ECM's prospective customers often spend six months to two years evaluating the ECM product before deciding to infuse it into their plastics. Complaint Counsel argued in its Pretrial Brief that "[c]ustomers buy the ECM additive because they want biodegradable plastic—and they want to be able to advertise their plastic as biodegradable."[235] In fact, with the exception of several isolated instances, among what Complaint Counsel calls "millions" of customer contacts, claims concerning the *rate* of biodegradation have rarely appeared in the end-consumer market. Almost invariably, the end-

[233] RX 875 (Sinclair, Dep. at 258) (ECM's customer "have all the resources, ten times, hundred times the resources that [ECM] may have").

[234] *See, e.g.* RX 159.

[235] *See* CC Pretrial Br. at 14

customer is provided with no claim at all or a naked "biodegradable" claim, which is the only claim ECM has in its certificate of biodegradability.[236]

Second, ECM has routinely provided its scientific testing in full to corporations and customers. That information has included clearly favorable data, but also tests that Complaint Counsel has used to suggest that ECM's product is inefficacious. (RPFF ¶¶ 439, 465, 520, 683, 2707). ECM's willingness to share information in its negotiations with customers is evidence that ECM has in good faith attempted to explain the level of science supporting its product. It also reveals that ECM's customers have had the information necessary to evaluate ECM's claims and determine, just as ECM has, whether those claims are adequately supported. Unlike traditional retail sales where end-customers are often presented with little more than the product and a claim, in this case ECM's sales have been preceded (and followed) by substantial interaction with corporate customers, including critical scientific and engineering evaluations by company purchasers before making a purchase decision. Significantly, many of the claims conveyed in the stream of commerce are not ECM's claims but are those derived from company purchasers own experience with the product. Those claims are constructed by ECM's customers based on information generated and reviewed by corporate customers and based on their finished plastic products, not ECM's additive alone.[237]

ECM's customers were aware of the FTC's requirements in the Green Guides, and they tailored their advertising content according to those policies.[238] One of ECM's leading

[236] *See, e.g.*, RX 17.

[237] *See, e.g.*, CCX 48 (EcoSmart Plastic advertising that its products will "compost" in "9 months–7 years").

[238] *See, e.g.*, RX 871 (Blood, Dep. at 193:10–21) (explaining that one of the reasons FP International changed its claim was "The FTC's green guides [] even though [FP] didn't agree necessarily with the one-year time frame that the FTC decided was appropriate").

customers testified that they adapted advertising claims to fit their perception of the Green Guides:

> Q: How did FP come to the decision to transition its claims from the ones we discussed earlier to the claim that ECM plastic will biodegrade in landfills in one to five years or more?
>
> A: There were several contributing factors. One of them was the FTC's green guides. And even though we didn't agree necessarily with the one-year time frame that the FTC decided was appropriate, we decided that we would incorporate that to make it clear to our customers that it was not under a year. And so that was an element where we decided to go ahead and make that component of the claim, instead of the nine months.[239]

ECM customers have thus demonstrated that they understand the nature of ECM's advertising claims, and have been guided substantially in their decision to choose certain marketing language by the FTC's positions, which have skewed the claims in the market and effected a new national environmental policy.

Recognizing those facts, Complaint Counsel struggles to define ECM's purchasers misleadingly as "mom and pop"-type businesses that also apparently manufacture bulk plastic polymers, such as Island Plastic Bags. At sixteen (16) employees, Island Plastic Bags is more than twice the size of ECM, which has just six employees. That was the best example of a "mom and pop" manufacturer Complaint Counsel could marshal. In fact, Island Plastic Bags ("IPB") has a sophisticated operation whereby they manufacture high- and low-density polyethylene products through various manufacturing plants in Hawaii and China.[240] IPB learned of ECM's product not through website materials or marketing, but through conversations with ECM representatives at a trade show.[241] Although Island Plastic Bag testified (through extensive

[239] RX 871 (Blood, Dep.)
[240] *See* CCX 811 (Hong, Dep. at 10–11).
[241] *Id.*, at 11–12.

leading questions), that it did not have experience to review scientific literature concerning biodegradability, they could not deny that they were *provided* that literature over the course of detailed discussions with ECM.[242] And, certainly, they were able to test the ECM product for their intended uses.

3. The Bases for Purchase Among Sophisticated Customers Differ from Those of End Use Consumers

In order to succeed in a fraud action, a challenger must establish that he or she reasonably relied on the alleged material representation. *Terra Sec. Asa Konkursbo v. Citigroup, Inc.*, 740 F. Supp. 441, 448 (S.D.N.Y. 2010). "In assessing the reasonableness of a plaintiff's alleged reliance, [courts] consider the entire context of the transaction, including factors such as its complexity and magnitude, the sophistication of the parties, and the content of any agreements between them." *Emergent Capital Inv. Mgmt., LLC v. Stonepath Grp., Inc.*, 343 F.3d 189, 195 (2d Cir. 2003). For example, "[s]ophisticated investors must investigate the information available to them with the care and prudence expected from people with full access to information." *Terra*, 740 F. Supp. 2d at 448 (citing *Hirsch v. du Pont*, 553 F.2d 750, 763 (2d

[242] As in many of the customer depositions that occurred throughout the country, this one in Hawaii, ECM was unable to have counsel appear and instead offered a corporate representative. While that decision was ultimately ECM's, the lack of ECM's counsel should not excuse Complaint Counsel's objectionable examination throughout. Through leading questions, counsel essentially testified for the witness. *See, e.g.*, CCX 811 (Hong, Dep. at 35–39). The flawed examinations limit the credibility of witness testimony. Out of court testimony from a witness that could have been called, and thus not subject to cross-examination or to judicial assessment of the character of the witness on the stand, is discredited because having not undergone the rigors of cross and judicial scrutiny, it cannot be presumed credible or complete. *See, e.g.*, Fed. R. Evid. 804(b)(1) (deposition testimony is admissible as an exception to the evidentiary hearsay exclusion so long as the declarant is unavailable as a witness at the hearing , the deposition proceeded in compliance with law, and the party against whom the testimony is offered had an opportunity to develop the testimony by cross-examination).

Cir. 1977)); *see also Banque Franco–Hellenique de Commerce Int'l., et Maritime, S.A. v. Christophides*, 106 F.3d 22, 27 (2d Cir. 1997) (finding that analysis of reasonable reliance in fraud cases "has taken account of the degree to which the truth was accessible to the defrauded person"). The rationale is that the informed or sophisticated entity has the wherewithal to determine whether claims are supported and, so, the need to protect those sophisticated "consumers" is lessened.

Other courts outside of the Second Circuit have similar requirements to determine whether sophisticated purchasers reasonably relied on misrepresentations. *See, e,g,, Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 767–68 (7th Cir. 2010) (finding that the plaintiff's alleged reliance was unreasonable where "two sophisticated businesses negotiated an arms-length transaction of a period of several months"); *Tom Hughes Marine, Inc. v. Am. Honda Motor Co., Inc.*, 219 F.3d 321, 324 (4th Cir. 2000) (affirming decision that reasoned that the plaintiff was "a sophisticated businessman … and he [was] unable to establish that he had a right to rely on [the defendant's] representation or that he justifiably relied upon it"); *Gilchrist Timber Co. v. ITT Rayonier, Inc.*, 95 F.3d 1033, 1035 (11th Cir. 1996) (collecting cases supporting the proposition that a fraud claim is not actionable where "the parties are equally sophisticated, and have an equal opportunity to discover a defect"); *Cheney Bros., Inc. v Batesville Casket Co., Inc.*, 47 F.3d 111, 114 (4th Cir. 1995) (citation omitted) (holding that "there is no right to rely, as required to establish fraud, where there is no confidential or fiduciary relationship, and there is an arm's length transaction between mature, educated people"); *Kline v. First Western Gov't Sec., Inc.*, 24 F.3d 480, 497–98 (3d Cir. 1994) (holding that the "investor could not justifiably rely on representations" where the transaction "was on the cutting edge of strategic planning"); *Roberts v. United N. Mex. bank at Roswell*, 14 F.3d 1076, 1080 at n. 4 (5th Cir. 1994) (internal

quotations and citations omitted) ("If an investor is sufficiently sophisticated and experienced, that may be evidence that he did not rely on the seller's representations but on his own expertise."); *Davidson v. Wilson*, 973 F.2d 1391, 1399 (8th Cir. 1992) (noting that the "sophisticated investors should have been on notice not to rely upon those representations"); *Skeen v. C.I.R.*, 864 F.2d 93, 95 (9th Cir. 1989) (explaining that where the plaintiffs "are all sophisticated businessmen," the court "simply do[es] not believe that they would enter into profit-motivated transactions with an unknown party and rely solely on the representations of such part with respect to the most crucial aspect affecting the viability of the proposed venture").

4. Complaint Counsel Has Failed to Prove that Any Consumer Was Misled

An "advertisement is deceptive under the [FTCA] Act if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect." *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992). Courts have held that there is a reduced likelihood that a sophisticated party, as opposed to an unsophisticated party, will be influenced by a similar mark in an advertisement. *See, e.g.*, *Mead Data Dent., Inc. v. Toyota Motor Sales, U.S.A., Inc.*, 875 F.2d 1026, 1031–32 (2d Cir. 1989). "The degree of consumer care and sophistication can be proven by survey evidence, expert testimony, or inference." *Marketquest Grp., Inc. v. BIC Corp.*, 2011 WL 5360899, at *12 (S.D. Cal. Nov. 7, 2011) (citation omitted) (finding that the buyers were likely to be sophisticated because they were institutional buyers placing bulk orders and because the marketing materials "appear to be aimed at institutional purchasers").

The issue in *Mead* was whether the use of the term "Lexus" used by Toyota Motors would dilute the profitability of the term "Lexis" as used by Mead. *Mead*, 875 F.2d at 1027. The Second Circuit explicitly made clear that "the recognized sophistication of attorneys, the

principal users of [Lexis], has *substantial relevance*." *Id.* at 1031 (emphasis added). Given the fact that Lexis' users were principally sophisticated attorneys, the court concluded that there would not "be any significant amount of blurring between the LEXIS and LEXUS marks." *Id.* at 1032.

Numerous additional courts likewise find that purchasers are less likely to be confused when they are sophisticated, technical, experienced, retailers, or otherwise involved in the industry or have any relevant knowledge. *See, e.g.*, *In re Synthroid Mktg. Litig.*, 264 F.3d 712, 717 (7th Cir. 2001) (noting that "[u]nlike members of the consumers class, [third-party payers] are sophisticated purchasers"); *Interstellar Starship Servs., Ltd. v. Epix Inc.*, 184 F.3d 1107, 1110 (9th Cir. 1999) (citation omitted) (holding that confusion is less likely where the "customers are sophisticated industry and university researchers" and where the "goods cost in the range of several thousand to tens of thousands of dollars"); *Homeowners Grp., Inc. v. Home Mktg. Specialists, Inc.*, 931 F.2d 1100, 1111 (6th Cir. 1991) ("A sophisticated purchaser exercises a high degree of care and is less likely to be confused as to a product's origin."); *Pride Family Brands, Inc. v. Carl's Patio, Inc.*, -- F. Supp. 2d --, 2014 WL 186902, at *7 (S.D. Fla. Jan. 30, 2014) (noting that "[as] industry participants, retailers are a sophisticated customer base"); *Acxiom Corp. v. Axiom, Inc.*, 27 F. Supp. 2d 478, 497 (D. Del. 1998) (citations omitted) (explaining that "courts recognize that generally" when a seller "sell[s] relatively expensive products and services to sophisticated and knowledgeable purchasers that typically involve relatively long sales cycles . . . these factors indicate that great care, effort, and attention go into the purchase decision making which lessens likelihood of confusion."); *Giorgio Beverly Hills, Inc. v. Revlon Consumer Prods. Corp.*, 869 F. Supp. 176, 185 (S.D.N.Y. 1994) (citation omitted) (explaining that "[t]he more sophisticated the ordinary purchaser of a product is, the less likely it

is that the use of similar marks or trade dress will lead to confusion" and holding that "women tend to be sophisticated purchasers of perfume"); *Marketquest Group Inc. v. BIC Corporation, et al.*, No. 11-cv-618, 2011 WL5360899, at *11 (S.D. Cal. Nov. 7, 2011) (noting that "experienced industry distributors or agents [] are likely to be sophisticated consumers and investigate any potential confusion"); *In re Trans Union Corp. Privacy Litig.*, 2009 WL 4799954, at *11 (N.D. Ill. Dec. 9, 2009) (noting that insurance companies are sophisticated purchasers of legal services).

Like in the trademark context, parties are held to different levels of duty of disclosure when conducting business with sophisticated purchasers as opposed to the general public. For example, a purchaser is under no duty to disclose the financial conditions of its business when "the parties are represented by sophisticated businessmen, who are active and experienced in the area, and are dealing at arm's length without any fiduciary or confidential relationships or expectations." *Nationwide Book Indus., LLC v. A & S Booksellers, Inc.*, 950 F. Supp. 2d 264, 267 (D. Mass. 2013) (citations and quotations omitted). Similarly, in the securities context, securities issuers must disclose significantly more information when making public offering as opposed to selling the securities only to sophisticated qualified institutional buyers. *Gustafson v. Alloyd Co.*, 513 U.S. 561, 569 (1995) (citing 15 U.S.C. §§ 77b (11), 77d, 77e) ("By and large, only public offerings by an issuer of a security, or by controlling shareholders of an issuer, require the preparation and filing of registration statements."). This is because the sophisticated purchaser, capable of fending for itself and determining the benefits and costs of entering a business transaction, is held liable for his or her own decisions. *See, e.g., Miller v. Berman*, 289 F. Supp. 2d 1327, 1334 (M.D. Fla. 2003) ("Surely, as a sophisticated boat and sail maker, Mr.

Miller relied on his own expertise in deciding to enter into a contract for the purchase of a highly customized catamaran boat with Cougar Marine").

5. The Sophisticated Purchaser Defense Is Applicable in This Case

A manufacturer's duty to warn of dangers in the products liability context is "precluded in situations where the purchaser has particular knowledge of or experience with the inherent dangers in the use of a product or in instances when the purchaser has designed and requested a product for a particular application." *Byrd v. Hunt Tool Shipyards,* 650 F.2d 44, 47 at n. 1 (5th Cir. 1981); *see also O'Neal v. Celanese Corp.*, 10 F.3d 249, 252 (4th Cir. 1993) ("The [sophisticated purchaser] defense is available not only when the supplier actually warned the intermediary, but also when the supplier shows that it was reasonable to believe that a warning was unnecessary because the intermediary was already well aware of the danger"); *Goodbar v. Whitehead Bros.*, 591 F. Supp. 552, 561 (W.D. Va. 1984) ("Stated another way, when the supplier has reason to believe that the purchaser of the product will recognize the dangers associated with the product, no warnings are mandated."). This rule of law is known as the "sophisticated purchaser defense" which is "based upon the principles set forth in the Restatement (Second) of Torts." *Akin v. Ashland Chem. Co.*, 156 F.3d 1030, 1037 (10th Cir. 1998). "This exception absolves suppliers of the duty to warn purchasers who are already aware or should be aware of the potential dangers." *Id.* (citing *O'Neal*, 10 F.3d 249, 251–52 (4th Cir. 1993); *Davis v. Avondale Indus.*, 975 F.2d 169, 171 (5th Cir. 1992)).

Indeed, in certain situations, a "manufacturer [may] reasonably [] rely on an intermediary purchaser to warn ultimate users of dangers associated with the use of a product." *Baker v. Monsanto Co.*, 962 F. Supp. 1143, 1151 (S.D. Ind. 1997). Such a situation arises where "it

would be impossible for a manufacturer to access all ultimate users of a product because it had no control over the site of usage." *Id.*

In this context, the sophisticated purchase defense precludes a finding that ECM's representations to its plastic manufacturer customers were misleading. Assuming *arguendo* that harm results from making misleading advertisements to end consumers regarding a biodegradable claim (a difficult assumption given that there is no record evidence that an end consumer ever actually purchases a plastic infused with the ECM additive that bears an ECM claim), that harm is the harm of the target audience being misled. ECM's target audience, however, is not end consumers but wholly sophisticated manufacturers of plastics. Therefore, because ECM's customers were aware of the dangers associated with selling a "biodegradable" product, ECM had no duty to the end use consumer. *Akin*, 156 F.3d at 1037; *O'Neal*, 10 F.3d at 251–52; *Davis* 975 F.2d at 171. That is particularly true where, as here, ECM's customer performed independent testing on the products themselves, consulted with scientists, engineers, and legal counsel, and where ECM does not have access to all ultimate users of a product (or event knowledge of who they are) and has no control over the products made with its additive or the usage of the products made. *Baker*, 962 F. Supp. at 1151.

G. Complaint Counsel's Censorship of "Biodegradable" Claims Violates the First Amendment

First Amendment protections directly apply to FTC orders and limit the expansion of FTC advertising regulation. *See, e.g.*, *Standard Oil C. of California v. F.T.C.*, 577 F.2d 653, 662 (9th Cir. 1978) ("First Amendment considerations dictate that the Commission exercise restraint in formulating remedial orders which may amount to a prior restraint on protected commercial

speech"); *Sears, Roebuck and Co. v. F.T.C.*, 76 F2d 385, 399 n.31 (9th Cir. 1982); *Beneficial Corp v. FTC*, 542 F.2d 611 (3d Cir. 1976); *F.T.C. v. Simeon Management Corp.*, 532 F.2d 708, 713 (1976) ("[a]lthough commercial advertising may be subject to regulation serving an important public interest, it is not beyond the protection of the First Amendment").

In the context of communications between ECM and its sophisticated customers, the basis for a purchasing decision is not advertising but, instead, is a classic information exchange leading to a customer obtaining a small portion of the product for preliminary independent testing whereupon if itself convinced of the product's utility, it purchases and generally infuses its plastic with it. That scenario does not involve commercial speech ("speech that proposes a commercial transaction," *Bd. of Trustees of State Univ. of New York v. Fox*, 492 U.S. 469, 482 (1989)) but involves the exchange of fully protected technical and scientific information. As such, the material speech here in issue is appropriately entitled to full First Amendment protection and is not appropriately subjected to intermediate scrutiny that is the realm in which FTC speech regulation constitutionally occurs. *See, e.g., Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557, 562 n. 5 (1980) (explaining that lesser constitutional protection is warranted for statements "made only in the context of commercial transactions," because businesses "enjoy the full panoply of First Amendment protections for their direct comments on public issues"); *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 68(1983); *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 637-38 n. 7 (1985).

Fully protected speech may not be the subject of government constraint unless the government can prove a compelling state interest and that the regulatory means are narrowly tailored (that is, the least restrictive means) to achieve the interest. *See, e.g., Citizens United v.*

Fed. Election Comm'n, 558 U.S. 310, 340 (2010). In this case, any order that would forbid use of the term biodegradable in reference to ECM additive infused plastics or would compel a level of proof beyond the credible evidence supplied in support of biodegradability in this case would constitute an overbroad regulatory intervention suppressive of speech for which there is no proof of falsity. Thus the means would not be narrowly tailored to achieve a substantial state interest in avoidance of deception in advertising. Moreover, there are obvious, less speech restrictive alternatives, such as reliance on claim qualification to reveal that rates of biodegradation vary depending on ambient environmental circumstances, which qualification, if reasonable, would be fully acceptable to ECM (indeed, has long been in use by the company). *C.f. Am. Civil Liberties Union v. Mukasey*, 534 F.3d 181, 204 (3d Cir. 2008) (holding that the Child Online Protection Act (COPA), which criminalized transmission over the Internet, for commercial purposes, of material "harmful to minors," was not least restrictive alternative to advance government's compelling interest in protecting minors from exposure to sexually explicit material because available filtering technology, which Congress could promote and support in place of COPA, was more effective at blocking sexually explicit material, and unlike COPA, did not chill speech).

Although the speech here in issue fails to fall within either classic advertising or the context of commercial speech defined by the Supreme Court, if it is nevertheless deemed commercial because it, like a magazine, is loosely tethered to an ultimate purchase, any prospective order that would restrict future use of the claim of biodegradation on a demand for more proof than the credible evidence presented in this case would likewise offend the intermediate scrutiny standard applied in commercial speech cases. *See, e.g., Zauderer*, 471 U.S. at 637 ("The States and the Federal Government are free to prevent the dissemination of

commercial speech that is false, deceptive, or misleading, or that proposes an illegal transaction. Commercial speech that is not false or deceptive and does not concern unlawful activities, however, may be restricted only in the service of a substantial governmental interest, and only through means that directly advance that interest") (citing *Central Hudson*, 447 U.S. at 566) (other internal citations omitted).

ECM plastics are "biodegradable" under *scientific* definitions of the phrase in the peer-reviewed literature.[243] The addition of ECM's product to conventional plastic polymers results in an end-product that will "biodegrade." While rates of biodegradation vary, the evidence supporting biodegradation of ECM additive infused plastics is credible and, thus, protected commercial speech. *See, e.g.*, *Kiser v. Reitz*, 13-3956, 2014 WL 4211193 (6th Cir. Aug. 27, 2014) ("[C]ommercial speech is . . . constitutionally protected so long as it concerns lawful activity and is not misleading. . .") (internal quotations omitted).

Complaint Counsel contends that ECM's truthful description of its product is misleading because a small group of consumers allegedly think the word "biodegradable" should mean that a product disappears completely within one year, albeit no competent evidence of that small group exists. Never mind that those consumers have no reasonable understanding of the term biodegradable. Never mind that the concept of 100% biodegradation of a product within one year is nearly impossible for most materials known to be rapidly biodegradable. Complaint Counsel maintains that industry should aspire to that unscientific and implausible standard, simply because some unreasonable consumers thinks it so.

[243] The dictionary also defines "biodegradable" as that which is "capable of being decomposed by bacteria or other living organisms." ECM plastics have been shown capable of being decomposed and, so, the "biodegradable" claim is literally true.

Even assuming Complaint Counsel were correct, ECM's biodegradable claim would only then be potentially misleading, not inherently misleading, because the claim is literally true even if it could potentially be misunderstood by unreasonable consumers expecting a scientifically impossible result. The Constitution prohibits restriction of potentially misleading speech when there are obvious, less speech restrictive alternatives to imposing prospective speech burdens. *See, Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

A burden on speech need not be a complete prior restraint in order to compel constitutional assessment under the commercial speech standard. *See, e.g., Alliance for Natural Health U.S. v. Sebelius*, 786 F. Supp. 2d 1, 24 (D.D.C. 2011) ("the FDA cannot require a disclaimer that simply swallows the claim . . .").

Rather, a cease and desist order that either prohibited use of the term "biodegradable" unless more than the credible evidence in this record was prospectively produced or unless confined to the impossible (such as a set rate within one year, despite the impossibility of reliably achieving same, or such as a demand for 100% break down of the plastic into elements in nature, despite the fact that science proves biodegradation of plastics inevitably leaves residues that still contain elements of plastic) would violate both the "reasonable fit" prong of the commercial speech test and the "obvious, less speech restrictive alternative" prong. *See, e.g., City of Cincinnati v. Discovery Network, Inc*., 507 U.S. 410, 417 (1993) (holding that ban on news racks containing "commercial handbills," which did not apply to news racks containing "newspapers" was not a "reasonable fit" between city's legitimate interest in safety and esthetics and means chosen to serve interest); *Western States Medical Center*, 535 U.S. 357, 371 (2002) (explaining that the Court has "in previous cases addressing this final prong of the *Central*

Hudson test, . . . made clear that if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so").

In particular, a cease and desist order that prohibits commercial speech that is backed by credible evidence on the demand that more evidence exist before government will allow the claim is a burden on speech already held unconstitutional by our Court of Appeals in *Pearson v. Shalala* and its progeny (and that, in a public health context). *See, e.g., ANH*, 786 F. Supp. 2d at 24 ("Where the evidence supporting a [health] claim is inconclusive, the First Amendment permits the claim to be made . . ."). Moreover, there are obvious, less speech restrictive alternatives to satisfy government concerns that purchasers not be led to believe that claims of biodegradation imply either a rapid rate of disintegration or a complete return to elements in nature (no matter how absurd those assumptions may be in the present context) and that would be a claim qualification that advises purchasers that rates of biodegradation and the extent of biodegradation will vary depending on ambient environmental circumstances. A qualification of that kind would not be deemed objectionable by ECM but would be accepted (and is in fact akin to what ECM has long conveyed to its customers, RPFF ¶ 270).

In *Pearson I*, the D.C. Circuit held that perceived deficiencies in the scientific record must be proven incapable of being rendered non-misleading by resort to reasonable claim qualifications before the government may resort to a prospective speech ban. *See Pearson I*, 164 F.3d at 658 (holding that "[i]t is clear … that when government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness—government disregards a 'far less restrictive' means"); *see also Whitaker v. Thompson*, 248 F.Supp. 2d 1 (D.D.C. 2002); *Alliance for Natural Health U.S. v. Sebelius*, 714 F.Supp. 2d 48, 53 (D.D.C. 2010) ("*ANH I*"); *Alliance for Natural Health U.S. v. Sebelius*, 786

F.Supp. 2d 1, 8 (D.D.C. 2011) ("*ANH II*"). The same law and logic applies to FTC orders that restrain future speech through "fencing in" orders or other burdens.

Although the government may have an interest in protecting consumers from misleading claims, that interest cannot overcome the First Amendment's command for disclosure over suppression when claim qualification is a suitable, less speech-restrictive alternative. *See Whitaker*, 248 F.Supp. 2d at 10. As in this case, when "credible evidence supports a claim, that claim may not be absolutely prohibited." *See id.* (citing *Pearson I*, 164 F.3d at 659). Moreover, significantly, "[t]he mere absence of significant affirmative evidence in support of a particular claim … does not translate into negative evidence against it." *Pearson v. Shalala*, 130 F.Supp. 2d 105, 115 (D.D.C. 2001) ("*Pearson II*"); *Edenfield v. Fane*, 507 U.S. 761, 770 (1993) ("[I]t is well established that the party seeking to uphold a restriction on commercial speech carries the burden of justifying it"). Thus, in the penultimate case of ordering paragraphs, any cease and desist order requiring more proof than the credible evidence extant to permit prospective unmolested use of a biodegradable claim would be unconstitutional in light of the fact that the FTC has not, and cannot, meet its burden of proof under the First Amendment commercial speech standard.

A government mandated claim qualification is constitutional only if it is reasonable. *See, e.g. Whitaker v. Thompson*, 248 F. Supp. 2d 1, 2 (D.D.C. 2002) (enjoining FDA from taking any action that would prevent the use of the antioxidant vitamin health claim at issue as proffered or with reasonable disclaimers). A mandated claim qualification that requires an affirmative statement of a set time or rate for biodegradation or for the achievement of 100% elimination of the plastic is scientifically infeasible and, in light of the inherent variability of the environment,

entirely impracticable, and, so, it fails constitutional muster under apposite precedent because the mandate is unreasonable.

Unlike other FTC proceedings where the inherently misleading nature of speech overcomes the First Amendment analysis, the use of the "biodegradable" claim here is literally true and, at worst, only potentially misleading; thus the First Amendment trumps the attempt to prosecute the speaker and limit prospective speech. Accordingly, the complaint here in issue should be dismissed because no cease and desist and fencing in provisions may constitutionally be adopted.

H. Complaint Counsel's Enforcement Action Against ECM Is Not in the Public Interest

Requisite to enforcement action, the Commission must determine whether there is a reason to believe that an unfair method of competition is being used, that the proceeding would be in the public interest, and that such interest is specific and substantial. *See Federal Trade Commission v. Raladam Co.*, 283 U.S. 643 (1931). A proceeding by the Commission to prevent the use of unfair methods or unfair or deceptive acts or practices must appear to be in the interest of the public. *Thomas v. FTC*, 116 F.2d 347, 349 (10th Cir. 1940). In fact, the "commission is authorized to act only in the public interest, and to justify it in filing a complaint that public interest must be specific and substantial." *Arnold Stone Co. v. FTC*, 49 F.2d 1017, 1019 (5th Cir. 1931). The "mere misrepresentation and confusion or deception of purchasers" is insufficient for FTC action. *FTC v. Royal Milling Co.*, 288 U.S. 212, 216 (1933).

FTC precedent establishes that where a sophisticated entity, and not a consumer, makes the decision whether to purchase the product at issue, the respondent's claims regarding that product cannot have any influence on the consumers, and therefore the public interest is not

served by requiring corrective action. *In the Matter of Charles F. Harad*, 50 F.T.C. 300, 315–316 (1953). In *Harad*, the respondent claimed in a trade magazine that its product would be beneficial following patient surgery or after specific medical treatment. *Id.* at 315. Just as in this case, the experts in that case disagreed over whether or not the product was actually beneficial. *Id.* However, the hearing examiner found "it unnecessary to resolve th[at] difference of opinion." *Id.* The court first noted that because it was the physician's decision whether or not to purchase the device, the respondent's claim could not have "any significant influence on the[] patients." *Id.* In recommending dismissal of the complaint, the court then went on to state:

> In any event, since the representation made with respect to the … use of the device was concededly made in a publication intended for circulation among physicians only, who, it can be assumed, will not be misled by anything respondents might say regarding their product, and since there is no substantial evidence that the general consuming public would be misled thereby, it is the opinion of the undersigned that the public interest does not require the taking of any corrective action based on the alleged falsity of any representation that respondents' device may be used post-operation or post-injection.

Id. at 315–16 (*contrasting Irwin v. F.T.C.*, 143 F.2d 316 (8th Cir. 1944)) (where the respondent made claims regarding its product in "periodicals and by booklets, pamphlets, circulars, letters, and other advertising material").

Just like in *Harod*, here it is undisputed that ECM did not market its product directly to end use consumers. (RPFF ¶ 297). Rather, ECM, like the respondent in *Harod* made claims to entities interested in purchasing the product for commercial and not personal use, namely plastic manufactures. (RPFF ¶ 297). Whether or not to purchase the ECM additive is a decision left entirely to the plastic manufacturers that actually purchases the ECM additive. Like physicians determining whether to purchase a controversial medical device, plastic manufacturers are not misled by any marketing claims regarding additives used in the manufacture of plastics, which is

their specific profession and area of expertise. Therefore, "the public interest does not require the taking of any corrective action based on the alleged falsity of any representation that" that ECM made only to plastic manufacturers. *Harad*, 50 F.T.C. at 316.

In addition, consider the FTC's position that products which do not completely and totally biodegrade within one year cannot be labeled "biodegradable" without placing rate and extent qualifiers on the product that are likely infeasible to calculate with any accuracy. Because scientists cannot agree that there is a viable method to establishing the *rate* of biodegradation in a landfill (and Complaint Counsel has offered no such evidence), the FTC's position favors rapidly degrading substances. Furthermore, by placing an emphasis on the *speed* at which a product biodegrades, the FTC has prioritized rapidly degrading technologies. Those same rapidly degrading products, however, actually harm the environment when deposited in a landfill. The more rapidly a product biodegrades, the less likely the landfill operator will be able to capture the methane gas emissions. Therefore, the rapidly degrading material is a net contributor to atmospheric methane gas after disposal, whereas the landfill has a much better chance of capturing (and perhaps applying to beneficial use) the methane emitted from a slowly degrading material.

Yet despite those realities, Complaint Counsel is now enforcing through litigation a standard that favors rapidly degrading materials, in part, because the uniformed end-consumer erroneously believes that shorter is better when it comes to the disappearance of waste material.

Similarly, Complaint Counsel has predicated critical components of its case on faulty and unscientific "consumer impression," to wit, the existing of implied biodegradable *rate* claims. The consumer impression data is misleading and erroneous, having been obtained through flawed studies. The FTC lacked the opportunity to discover the varying understanding and belief

of consumers, which would have been essential in this area of complex scientific issues. (RPFF ¶¶ 1110-1132). Complaint Counsel effectively replaces good science and judgment with the opinions of end-consumers, almost all of whom have no practical understanding of the detailed scientific concepts and debates.

There can be no consumer deception in an area where consumers so lack foundational bases to fully understand the concepts involved as to have no common net impression from the advertising message. The public interest is not served by having the Federal Trade Commission wade into areas of unsettled and complex science where the debate within industry and academia has yet to be resolved. *See Koch v. FTC*, 206 F.2d 311 (6th Cir. 1953). ("A principal test as to whether a particular case affects the public interest is whether the misleading or deception of the public is shown"). Here, as discussed above, there is no evidence that the public has been misled.

In *Arnold Stone*, the Court held that action was not in the public interest or misleading because the FTC had failed to produce any evidence showing that a stone company's use of the word "stone" deceived any of their sophisticated customers, even though the "stone" products sold were actually made of composite materials like concrete. *Arnold Stone*, 49 F.2d at 1018-19. Significant to this case, the Court explained that "none of the words employed by the petitioner to describe any of its manufactured products or materials had the effect of misleading or deceiving architects, contractors, or builders who were the only classes of persons to whom petitioner sold or offered to sell any such products or materials." *Id.* The Court continued, "[t]he sum and substance of all the evidence was that the words 'cast stone' were understood by petitioner's prospective customers and by its competitors to mean just such a product as petitioner manufactured and sold." *Id.* So too, here, ECM's sophisticated plastics customers,

who are the only classes of persons to which ECM sells its additive, were seeking just "biodegradable" plastics, and that is exactly what they received. (RPFF ¶ 606–09, 620–25, 636–37, 647, 657–58, 661–62, 677–79, 694-95, 704, 706, 712–14). There is no evidence that ECM's customers desired any specific rate of biodegradation, or that biodegradation rate (even if changed) would have influenced their purchasing decisions. (RPFF ¶¶ 605–609, 613–16, 620–25, 633–35, 644–46, 653–56, 664–65, 673–76, 689–92, 700-03, 707, 710, 717–23). If ECM's customers cared at all about the "rate" of biodegradation, it was because they needed to be sure that the product would last long enough on the shelf, or because they were aware that the FTC demanded a rate. (RPFF ¶¶ 309–10, 724-–25). There is thus no evidentiary record in this case to show that action on ECM rate claims (or lack thereof) is at all in the public interest.

Having the FTC set environmental policy determinations within the context of a consumer deception/protection is not in the public interest, particularly when, as here, there are largely no actual commercial sales to end-consumers. That begs the question, if the FTC jurisdiction is limited to activity that affects commerce, who is the FTC protecting in this case? It is unclear if Complaint Counsel fully comprehends the answer to that question.

Underlying this entire discussion is the fact that a more slowly biodegrading product is actually *better* for the environment than a product that would disappear within, say, five years. (Barlaz, Tr. 2287–90). "[T]here must be a showing that the acts and practices sought to be proscribed are detrimental to the public interest in order to satisfy the statutory requirement that the proceeding be in the public interest." *S. Buchsbaum & Co. v. FTC*, 160 F. 2d 121, 123–24 (7th Cir. 1947). That fact was dispositive in the *Buchsbaum* case, as the Court explained:

> [T]he Commission made no finding that the deception, if any, had ever resulted in or had any tendency to result in detriment to the purchasing public. We find nothing in the findings to support the conclusion that the acts and practices are all to the prejudice and injury of the public.

Id. at 123-24. This ECM case is similar to the *Buchsman* case, where the FTC challenged a company making shatterproof "glass" products because, according to the FTC, the "glass" was actually made out of plastic. *Id.* at 123. The Court observed that, just like in this case where ECM can undercut the prices of the more expensive bioplastics:

> It is quite evident that [the] proceeding was actuated by the manufacturers of [competing] glass as contained in window panes, tumblers and the like. The trouble arises in trying to compete with petition in the sale of the same articles made of 'Elasti-Grass' by petition. Thus far, it appears from the record, the competition has not been successful for such manufacturers, because of the cheaper prices of petitioner's products.

Id. at 124. The ECM case is not substantially different from the *Buchsbaum* case. Complaint Counsel alleges that the word "biodegradable" has a specific meaning (just like "glass" had a meaning in *Buchsbaum*), and that customers will be misled into thinking the "biodegradable" plastic is of a specific kind, to wit, a kind that rapidly degrades. In *Buchsman* the Court rejected that very type of case for the same reasons this Court should deny Complaint Counsel relief: "We find in this record no evidence of any injury to any dissatisfied customer, indeed, there are no dissatisfied customers so far as this record discloses." *Id.* at 123. The Court also wisely acknowledged that any theorized injury could be alleviated through a more proactive consumer:

> It is intimated that the injury will occur to those who have been 'long accustomed to the worth and use of glass.' If this class of customers would consult their lexicons and inform the merchants as to the kind of glass they desire they will never be misled. Certainly they can not be misled or injured by petitioner's advertisements.

Id. at 123. As the precedent makes clear, Complaint Counsel is obliged to identify some tangible or palpable injury in the market in order to establish that this case is in the public interest. They have not done so, and they cannot do so with this record.

I. The FTC's Suggested Remedy Is Unlawful and Unsupported by the Facts

1. The FTC's Proposed Order Requires Proof of a "Rate" for Biodegradation When There Is No Competent and Reliable Evidence to Prove Any Set Rate

Logically, if Complaint Counsel would require a specific "rate" of biodegradation to qualify "biodegradable" claims, e.g., one year, Complaint Counsel must demonstrate what type of evidence, if any, ECM must rely on to prove satisfaction of that one year rule. (RPFF ¶¶ 1581–1605). Complaint Counsel has been unable to produce that evidence. (RPFF ¶¶ 1581–1605). In fact, no witness in this case (including Complaint Counsel's witnesses) has testified that it is possible to make a "rate" claim due to the variable environmental conditions that affect rate. (RPFF ¶¶ 1581–1605). Dr. Barlaz testified that there is no generally accepted method to calculate rate of biodegradation in landfills, in part, because the rates fluctuate so substantially based on the environmental conditions of disposal. (Barlaz, Tr. 2281–83).

The relief requested by Complaint Counsel, to wit, a specified "rate" of biodegradation in advertisements, is therefore not a scientific possibility. The lack of evidence showing how a company could potentially meet Complaint Counsel's requirement is therefore problematic and objectionable on at least two grounds. First, if there is no scientific consensus with respect to establishing a uniform "rate" of biodegradation, then ECM cannot logically comply with Complaint Counsel's proposed relief, and the relief is therefore a total bar to ECM's biodegradable claim. ECM would risk making a "rate" claim that is both deceptive and unsubstantiated, as Dr. Barlaz has explained that "it's very, very difficult to measure rates at either – at field scale either for individual components or for bulk waste…" (Barlaz, Tr. 2282). Moreover, even assuming that a "rate" of biodegradation could be established through evidence that would somehow satisfy Complaint Counsel, that "rate" would inherently mislead, because

the record is clear that the rate itself depends on many variables, and it will fluctuate drastically depending on the ambient environmental conditions even within a single landfill. (RPFF ¶¶ 1640–45, 1713, 1723, 2807–09). The rates of biodegradation also depend on the characteristics of each specific plastic, including the crystallinity of plastics (which is a characteristic developed through the manufacturing process and unique to each plastic batch, like a fingerprint). (RPFF ¶¶ 1640–45, 1713, 1723, 1749–65, 2807–09). Predicting even a conservative rate would be impossible or misleading, because there may be sterile areas within MSW landfills where even the most biodegradable materials will not biodegrade. (Sahu, Tr. 1769). Finally, Complaint Counsel has not explained how a laboratory test could "simulate" or "replicate" landfill environments such that the data gleaned from a laboratory test could be extrapolated into the landfill for the purpose of calculating "rate." (RPFF ¶ 1885). Complaint Counsel's witnesses struggled with that concept. (RPFF ¶¶ 2721–23, 2753–62, 2773–80).

Second, because Complaint Counsel's proposed qualifier is scientifically impossible, the relief will violate the First Amendment. The FTC's required disclaimer in its proposed order (¶ 4.B) is scientifically incompetent and also infeasible; thus, adoption of it would serve as a fully effective prior restraint on *all* future biodegradable claims in this market. That restriction would be overbroad and in violation of the *Pearson I* doctrine. 164 F.3d 650 (D.C. Cir. 1999). More particularly, the proposed relief precludes the truthful and obvious claim that the "rate" of biodegradation is uncertain and depends on many intrinsic and extrinsic factors, including the composition of the plastic and the environmental conditions following disposal. That latter statement, which is scientifically accurate and non-misleading, would be mutually exclusive to the qualification required under Complaint Counsel's proposed order.

2. Complaint Counsel has Failed to Prove That the "Extent" of Biodegradation is Relevant to a Consumer Claim

Complaint Counsel's proposed Order in Paragraph 4.B would alternatively require ECM to specify the "extent" to which a product is biodegraded within a certain period of time. As with the "rate" qualifiers suggested by Complaint Counsel, there is no evidence in the record to establish how a company could predict the "extent" of biodegradation given the many environmental variables that affect rate. It is decidedly the case that a biodegradable plastic will necessarily biodegrade at a different rate in one location than the next and even in different locations within the same landfill. (RPFF ¶¶ 1581–1605, 1640–45, 1713, 1723, 2807–09).

Moreover, all experts agree that even the most "biodegradable" substances, like cellulose or food waste, may not completely biodegrade under certain environmental conditions. (RPFF ¶¶ 2833–34, 2985, 2990; Sahu, Tr. 1767–69). Yet that does not affect whether the material is "biodegradable" from a scientific perspective. (Barlaz, Tr. 2217–19). Complaint Counsel's proposed relief would therefore apply an unscientific and infeasible standard to the "biodegradable" claim with respect to ECM plastics which is not logical or consistent with the scientific understanding of "biodegradability." In the scientific community, the "extent" and "rate" of biodegradation are not relevant because they are uncertain and unpredictable. (RPFF ¶¶ 1581–1605, 1593, 1640-45, 1713, 1723, 2807–09).

3. Complaint Counsel's Proposed Order Is Vague and Ambiguous, and It Would Impose Unworkable Standards

The two operative standards in Complaint Counsel's Proposed Order (¶ 4.B) require an advertiser to prove that a plastic product will "completely decompose into elements found in nature" within "stated timeframe," and the testing used to support those claims must "replicate"

or "simulate" the physical conditions found in the type of disposal facility or method stated in the representation." *Id.* This requirement is scientifically incompetent and entirely impracticable because, as stated above, there is no universal time frame provable for any biodegradable plastic and there is no biologically homogenous landfill environment; landfills are biologically heterogeneous by their very nature. (RPFF ¶¶ 1581–1605, 1593, 1640–45, 1713, 1723, 2807–09). As discussed *supra* at 198, Complaint Counsel has offered no evidence explaining what type and quality of evidence an advertiser could feasibly generate to support the rate and extent claims, while maintaining a perfectly "replicated" test environment. The Order would thus require more than Section 5 of the FTC Act requires to avoid deception and would substantively effect an absolute prior restraint or complete prospective speech ban on biodegradable claims. *See, e.g., In the Matter of Pom Wonderful LLC*, 9344, 2012 WL 2340406 (F.T.C. May 17, 2012) (at 324) (citing *Daniel Chapter One*, 2009 FTC LEXIS 259, at *70)).

First, Complaint Counsel has provided no evidence concerning how a product can be classified as having "completely decompose[d] into elements found in nature." The evidence suggests that the amount of a product that is converted through biodegradation to gas versus the smaller amounts converted to humus and other recalcitrant portions varies considerably. (RPFF ¶¶ 2989–90). In fact, Complaint Counsel's rebuttal witness, Dr. Michel, testified that even cellulose (a material generally accepted to be "biodegradable") can degrade anywhere between 44% to 100% and still be considered "fully" biodegraded at those respected amounts. (RPFF ¶¶ 2989–90). The point at which a material could be said to have "fully" biodegraded is therefore vague and ambiguous, and, so too, is the phrase "complete" biodegradation or decomposition. Complaint Counsel and their experts have not attempted to support paragraph 4.B of their

proposed order with any evidence showing how the scientific or consumer community would understand the terminology, which is complex and controversial.

Second, Complaint Counsel has not provided evidence to support the position that biodegradable testing can "simulate" or "replicate' the conditions found in a typical landfill, while remaining at all practical or feasible. In fact, Complaint Counsel's witnesses were unable to even define what constitutes "typical" landfill conditions, or explain how an "accelerated" biodegradation test (which is generally accepted) could similarly "simulate" the conditions in every landfill. However, Complaint Counsel's proposed order (Complaint, at 12) would require ECM to test under conditions that "simulate" the physical conditions "found in landfills." What are those conditions? If anything, the record shows that the conditions are highly variable and heterogeneous, making the characterization of a "typical" landfill nearly impossible. (RPFF ¶¶ 1581–05, 1593, 1640-45, 1713, 1723, 2807-09).

Thus, Complaint Counsel's theories with respect to testing that "simulates" landfills are unsupported by the evidence and the relevant science, which includes testimony given by Complaint Counsel's own witnesses. (RPFF ¶¶ 1581–1605, 1593, 1640–45, 1713, 1723, 2807–09).

J. Complaint Counsel's Case Against ECM Constitutes Ultra Vires Agency Action and Is an Assumption of Regulatory Power Vested Not in FTC, but in the EPA

Government action is *ultra vires* if the agency or other government entity "is not doing the business which the sovereign has empowered him to do or he is doing it in a way which the sovereign has forbidden." *Ancient Coin Collectors Guild v. U.S. Customs & Border Prot., Dep't of Homeland Sec.*, 698 F.3d 171, 179 (4th Cir. 2012) (quoting *Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682, 689 (1949)). Courts review *ultra vires* agency action when an

agency "patently misconstrues a statute, disregards a specific and unambiguous statutory directive, or violates a specific command of a statute." *Hunter v. F.E.R.C.*, 569 F. Supp. 12, 16–17 (D.D.C. 2008). Put differently, "[a]n *ultra vires* act is one performed without any authority to act…" *Sahaviriya Steel Industries Public Co. Ltd. v. U.S.*, 601 F. Supp. 2d 1355, 1366 (C.I.T. 2009). The Administrative Procedures Act (APA) further contemplates that agency action is void if found to be "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." *See* 5 U.S.C. § 706 (2)(C).

Complaints Counsel's definition of "biodegradable," which limits the naked term to products that completely degrade, returning to elements found in nature, within one year, is patently arbitrary and capricious and in conflict with environmental policies set by the federal Environmental Protection Agency. Because through an order prohibiting use of the term biodegradation on ECM's product for which there is credible scientific evidence of biodegradation, the FTC has effectively altered national environmental *policy*. Beyond adjudication of false or misleading advertising, the FTC has acted *ultra vires* and in excess of its statutory authority by establishing a market definition for biodegradation that differs fundamentally from what the scientific community and the EPA regard as biodegradable products that contribute to waste management. By effectively removing the market identifier "biodegradable" from slowly degrading landfillable products, the FTC necessarily alters national policy set by the EPA that, contrary to that FTC action, discourages promotion of rapidly degrading plastics, resulting in greater adverse environmental consequences through the production of more greenhouse gas emissions, as explained above. (RPFF ¶¶ 1596–1605).

The U.S. EPA has primary responsibility for enforcing the environmental statutes and regulations of the United States. 42 U.S.C. § 6901. Under the federal Resource Conservation

and Recovery Act (RCRA), Congress delegated to the EPA the task of managing solid waste disposal. *See, e.g.*, 42 U.S.C. § 6901. Congress passed the RCRA, in part, to address the "ever-mounting increase … of the mass material discarded by the purchaser of … products." 42 U.S.C. § 6901(a)(1). Moreover, concerning energy, Congress explained that "solid waste represents a potential source of solid fuel, oil, or gas that can be converted into energy." 42 U.S.C. § 6901(d)(1).

ECM experts testified that U.S. landfills have become a major source of harvestable natural gas in the form of methane emissions. (RPFF ¶¶ 1846–61). The major byproduct of biodegradation in landfills is methane and carbon dioxide gas. Methane is released as a result of the biodegradation process as microorganisms in the landfill disassemble carbon bonds from the solid waste, often through enzymatic digestion. Methane is formed with one carbon atom and four hydrogen atoms. As experts explained in this case, many modern landfills, operated under the auspices of the EPA and local regulations, are now designed to harvest gases emitted from landfills in conformity with national environmental regulations established by the EPA. (RPFF ¶¶ 1598–99). For instance, 1 million tons of waste within a landfill generally creates 550,000 cubic feet per day of landfill gas, or one megawatt of electricity, which is enough to power 700 homes for one year. (RX 967). Moreover, by collecting and using those methane emissions for beneficial use, the landfill operators remove methane gas from the atmosphere equal to taking about 8,800 cars off the road for a year. (RX 967).

Rapidly degrading waste is inconsistent with the ideals for the operation and maintenance of landfills. (RPFF ¶¶ 1593–1605). Landfills pass through several phases in their life cycle. In the first phase, the landfill is open and accepting waste into "cells." During that period there is both anaerobic and aerobic activity. However, the systems designed for landfill gas collection

are not active or functional during the open phase of landfill cells. Traditional landfill gas collection models are usually not equipped to collect gas emissions for two years. (RPFF ¶ 1599; RX 853, at 12). Thus, products that rapidly degraded within one year would cause methane gas to be released directly into the atmosphere, contributing to atmospheric greenhouse gases where they would otherwise be collected or flared. (RPFF ¶ 1600).

Dr. Morton Barlaz is one of the nation's leading experts in environmental sciences with respect to MSW landfills and biodegradation. (RPFF ¶¶ 182–200). Complaint Counsel's purported landfill expert, Dr. Tolaymat, recognized Dr. Barlaz as an authority in the field and would defer to Dr. Barlaz. (RPFF ¶¶ 2724–27). Dr. Barlaz testified that increasing the rates of biodegradation for landfilled products is antithetical to the EPA goals of gas collection and are detrimental to the environment. (RPFF ¶¶ 1593–1605). He testified that more rapidly degrading substances in landfills provide no appreciable environmental benefit, in part, because landfilled products are intended for nearly infinite storage, and landfill sites expect to provide same. He explained that plastic products that degrade in an MSW landfill within a matter of decades are preferable, and that decades would be a reasonably short period of time for degradation based on scientific principles. (RPFF ¶¶ 1593–1605).

It is decidedly within the enabling statute of the EPA for that agency, and not the FTC, to effect national environmental policy as it pertains to biodegradable plastics in landfills. Acts by the FTC to misidentify in the market products that effect biodegradation over periods greater than a year and instances where the products do not biodegrade 100% by returning to elements within nature before the passage of a year conflict directly with national environmental policy as set by the EPA which favors the gathering and conversion of greenhouse gas emissions from

slowly biodegrading products rather than rapidly biodegrading ones favored by the FTC's biodegradation and compostable product rules. (RX 967; RPFF ¶¶ 1593–1605).

Government action is *ultra vires* if the agency or other government entity "is not doing the business which the sovereign has empowered him to do or he is doing it in a way which the sovereign has forbidden." *Ancient Coin Collectors Guild v. U.S. Customs & Border Prot., Dep't of Homeland Sec.*, 698 F.3d 171, 179 (4th Cir. 2012) (quoting *Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682, 689 (1949)). "An *ultra vires* act is one performed without any authority to act…" *Sahaviriya Steel Industries Public Co. Ltd. v. U.S.*, 601 F. Supp. 2d 1355, 1366 (C.I.T. 2009). The Administrative Procedures Act (APA) further contemplates that agency action is void if found to be "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." *See* 5 U.S.C. § 706 (2)(C). When agencies of the government adopt rules that trench upon a regulatory province delegated to a sister agency, the action is considered unlawful because it is ultra vires.

K. The "One-Year" Rule Is An Unlawful Industry-Wide Trade Regulation Rule

The "One-Year" Rule promulgated in the 2012 revision of the Green Guides is not an interpretative, non-binding statement of policy, but an industry-wide rule that redefines scope of products that can be marketed. The rule favors short-term degradable products to the prejudice of those products that would biodegrade slowly in a landfill, but still within a reasonably short period of time compared to conventional plastics. Furthermore, because Complaint Counsel has explained through this proceeding that no test can accurately substantiate the time for disposal in an MSW landfill, and the rule expressly states that it is "deceptive to make an unqualified degradable claim for items entering the solid waste stream if the items do not completely

decompose within one year after customary disposal," the Green Guides prohibit technologies that do not, in fact, disappear in landfills within one year. *See* 16 C.F.R. § 260.8(c). In other words, the Commission has condemned the use of *landfill-able* technologies *in toto*. That is an environmental policy that says landfill-able products are not desirable—not a position with respect to consumer deception. The FTC has thus enacted a new industry-wide rule equivalent to the FDA's prior restraint the United States Court of Appeals condemned as unconstitutional in *Pearson I*. *See Pearson I*, 164 F.3d at 655–60.

15 U.S.C. § 57 requires that FTC proceed through Magnuson-Moss rulemaking when promulgating rules defining practices which are unfair or deceptive. *See* 15 U.S.C. § 57a (requiring heightened procedural safeguards in FTC rulemaking proceedings); *see also* 5 U.S.C. § 553 (requiring federal agencies, with limited exceptions, to follow notice-and-comment rulemaking procedures when promulgating a new rule, regulation, or interpretation of a regulation). Because the Commission has not complied with all of the requirements of Section 57a (in particular, Section 57a(b)(2)), the trade regulation rule implemented and now enforced against ECM is unlawful and should be given no weight in this proceeding.[244]

[244] For example, because the FTC did not properly characterize the industry rule as a Trade Regulation Rule under Section 57a, the Commission did not apparently notify and seek input from the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Energy and Commerce of the House of Representatives. *See* 15 U.S.C. § 57a(b)(2).

L. Complaint Counsel's Case Against ECM Violates Due Process

1. The FTC Proceedings Violate the Separation of Functions Doctrine

Due Process is required in administrative proceedings. *See Withrow v. Larkin*, 421 U.S. 35, 46 (1975); *Utica Packing Co. v. Block*, 781 F.2d 71, 76 (6th Cir. 1986). Under 5 U.S.C. § 556 of the Administrative Procedures Act, Congress requires administrative agencies to conduct hearings mandatory under §§ 553 and 554 "in an impartial manner." 5 U.S.C. § 556. "A fair trial in a fair tribunal is a basic requirement of due process. Fairness of course requires an absence of actual bias in the trial of cases. But our system of law has always endeavored to prevent even the probability of unfairness." *In re Murchison*, 349 U.S. 133 (1955). As the D.C. Circuit has stated: "With regard to judicial decision making, whether by court or agency, the appearance of bias or pressure may be no less objectionable than the reality." *D.C. Federation of Civic Ass'ns v. Volpe*, 459 F.2d 1231, 1246–47 (D.C. Cir. 1971), *cert. denied*, 405 U.S. 1030 (1972).

"When governmental agencies adjudicate or make binding determinations which directly affect the legal rights of individuals, it is imperative that those agencies use the procedures which have traditionally been associated with the judicial process." *Utica Packing*, 781 F.2d at 78. In administrative proceedings, "the requirement of a fair trial before a fair tribunal has not been eliminated. This concept requires the appearance of fairness and the absence of a probability of outside influences on the adjudicator; it does not require proof of actual partiality." *Id.* at 76 (*citing Withrow*, 421 U.S. at 35).

In order to enforce this separation of functions and impartiality in administrative hearings, Congress included 5 U.S.C. § 554(d) in the APA. That statute restricts the investigator/prosecutor from being involved in the decision making process. "The clear purpose

of [5 U.S.C. § 554(d)] is to separate the investigative and prosecutorial functions from the adjudicative function" in administrative hearings. *Utica Packing*, 781 F.2d at 76 (*citing Wong Yang Sung v. McGrath*, 339 U.S. 33, 41 (1950)). Section 556(d) (5 U.S.C. § 556(d)) cannot be read narrowly. *Id.*

In this case, ECM is in danger of losing an important legal right without traditional judicial process. Indeed, unlike other companies prosecuted by the FTC for alleged violations of the Green Guides, ECM is at risk of losing its right to effectively market the only product it sells—the ECM additive. (RPFF ¶ 41). Complaint Counsel, through the Green Guides and through this litigation, intends to prohibit ECM from making any unqualified "biodegradable" claim. *See In re ECM Biofilms,* Complaint, at 12. Without the ability to effectively market its only product, ECM will, of course, go out of business. ECM is willing to make reasonable qualifications of its biodegradable claim. (RPFF ¶¶ 314–15). However, the qualifications Complaint Counsel demands—namely that ECM state how long each plastic product containing the ECM additive will take to biodegrade—is simply impossible. (RPFF ¶¶ 1581–1605, 1593, 1640-45, 1713, 1723, 2807-09). ECM does not know and cannot not know all of the plastic products that are manufactured with the ECM additive. Further, the rates of biodegradation of plastics containing the ECM additive vary greatly depending on the environment in which the product ultimately comes to rest. (RPFF ¶¶ 1581–1605, 1593, 1640–45, 1713, 1723, 2807–09).

The FTC is the judge, jury, and executioner in this case. The only "trial" available is before the ALJ—an adjudicatory body with no authority to issue a final decision. After a decision is reached by the ALJ, the decision is submitted to the FTC commissioners for *de novo* review, yet the Commission is the charging party because it has approved the staff's Complaint for issuance to the respondent. 16 C.F.R. § 3.11(a). If the Commission does not agree with the

ALJ, the Commission is free to overturn the decision and create a ruling as it so chooses. This system does not give individuals sufficient due process in situations, where, as here, entire companies and livelihoods are wholly at risk. ECM was afforded the right to argue its position before a neutral referee, but the ultimate decision maker—the Commission—was not present to evaluate the arguments or the testimony offered by the parties and is in fact the ultimate charging party. While the Commission is obligated to acknowledge the ALJ's findings, there is no requirement that the Commission give those findings any weight. The Commission brought the allegations against ECM and will be the ultimate adjudicator against ECM. Thus, the Commission necessarily has an interest in the outcome sufficient to violate the doctrine of separation of functions. *See Leer Elec., Inc. v. Penn. Dep't of Labor and Indus.*, 597 F. Supp. 2d 470, 481 (M.D. Pa. 2009) (noting that the officials' multiple roles as investigators, prosecutors, and adjudicators were sufficient to present a risk of actual bias).

2. Complaint Counsel's Abusive Discovery Practices

In this proceeding, Complaint Counsel failed to produce documents responsive to ECM's requests of considerable import in this action.[245] This Court Sanctioned Complaint Counsel for failing to disclose information to ECM that was later used against ECM's principles in depositions through a planned "gotcha" moment.[246] That document was Dr. Michel's analysis of several competing biodegradable technologies. Although Dr. Michel has been an FTC consulting witness since 2012, Complaint Counsel feigned any knowledge of his work, but when ECM subpoenaed Dr. Michel for information concerning his study, Complaint Counsel

[245] *See In re ECM Biofilms*, Order Granting in Part and Denying in Part Respondent's Motion for Sanctions, Dkt. No. 9358 (Mar. 21, 2014).

[246] *Id.* at 6.

intervened and instructed him not to timely respond to ECM's non-party subpoena.[247] Those acts are illegal, as they deprived ECM of the documents in question and thereby violated ECM's basic right to Due Process.[248] Courts have long held far less subtle attempts by party opponents to dissuade subpoena response to be sanctionable conduct in violation of the Due Process rights of the movant. *See, e.g., Price v. Trans Union, LLC*, 847 F.Supp. 2d 788, 794 (E.D. Pa. 2012).

Complaint Counsel has also escalated costs in an effort to limit ECM's defense. The cost of Complaint Counsel's erratic, meandering and ill-timed discovery practice has been considerable.[249] Complaint Counsel has performed **twenty (20)** fact depositions of testing laboratories and ECM customers all over the country, in Hawaii, California, New York, Ohio, and the District of Columbia, to name a few.[250] Those depositions included the following persons and entities:

- Northeast Labs (May 9, 2014) (in New Haven, CT)
- BER Plastics (May 8, 2014) (in New York, NY)
- D&W Fine Pack, LLC (May 5, 2014) (in Washington, DC)
- Down to Earth (Apr. 29, 2014) (in Honolulu, HI)
- Eagle File Extruders (May 14, 2014) (in Grand Rapids, MI)
- Eden Labs (May 19, 2014) (in Albuquerque, NM)

[247] *See In re ECM Biofilms*, Order Denying Respondent's Motion for Sanctions for Unauthorized Dissuasion of Response to Subpoena *Duces Tecum*, Dkt. No. 9358 (Apr. 9, 2014).

[248] *See Chambers v. Mississippi*, 410 U.S. 284 (1973) (due process affords parties the right to introduce certain evidence); *Epstein v. MCA , Inc.*, 54 F.3d 1422 (9th Cir. 1995) (the federal rules ordinarily contemplate a "broad right of discovery"); *Berger v. United States*, 295 U.S. 78, 88 (1935) ("[The Government] is the representative *not* of an ordinary party … but of a sovereignty … whose interest is not that it shall win cases, but that justice be done") (emphasis original).

[249] The transcripts alone in this case cost over $1,000 per document. Other costs include attorney fees, costs of travel and lodging, and document costs.

[250] By contrast, to eliminate extraordinary burden, the Federal Rules of Civil Procedure generally prohibit a party from seeking more than ten (10) depositions. *See* Fed. R. Civ. Pro 30(a)(2)(A)(i). Parties seeking to expand that number must justify the *necessity* of each deposition. *See, e.g., Archer Daniels Midland Co. v. Aon Risk Services, Inc. of Minnesota*, 187 F.R.D. 578, 586 (D.Minn. 1999) (collecting cases).

- Elsevier (May 30, 2014) (telephonic)
- Flexible Plastics (May 15, 2014) (in St. Paul, MN)
- Island Plastic Bags (April 28, 2014) (in Honolulu, HI)
- Kappus Plastic Company (May 6, 2014) (in New York, NY)
- Quest Plastics (May 7, 2014) (in New Haven, CT)
- 3M Corporation (May 16, 2014) (in St. Paul, MN)
- ANS Plastic (May 5, 2014) (New York, NY)
- FP International (May 1, 2014) (in San Francisco, CA)
- Timothy Barber, Ph.D. (May 7, 2014) (in Cleveland, OH)
- Thomas Nealis, ECM Employee (March 5, 2014) (in Painesville, OH)
- Alan Poje, former ECM Employee (March 6, 2014) (in Painesville, OH)
- Robert Sinclair, ECM President (February 18, 2014) (in Painesville, OH)
- ECM Biofilms (February 19, 2014) (in Painesville, OH)
- Kenneth Sullivan, ECM Officer (February 20, 2014) (in Painesville, OH)

Each of the foregoing depositions were noticed and conducted by Complaint Counsel. Also, Complaint Counsel noticed and took five additional expert depositions, bringing their total for the case to twenty four (25) total depositions in its case against ECM, which has just six total employees and two officers:

- Dr. Ron Sahu (June 30, 2014) (in Los Angeles, CA)
- Dr. David Stewart (July 1, 2014) (in Los Angeles, CA)
- Dr. Ryan Burnette (July 2, 2014) (in Washington, DC)
- Dr. Morton Barlaz (July 14, 2014) (in Raleigh, NC)
- Dr. Sasha Volokh (July 15, 2014) (in Atlanta, GA)

The burdens and costs associated with the many fact depositions forced ECM to appear unrepresented, or have counsel appear telephonically at a distinct disadvantage. Knowing that ECM could not appear at the depositions themselves, or entered limited telephone appearances, Complaint Counsel relies exclusively on the transcripts from those very depositions in lieu of

live witness testimony, thus ensuring that ECM lacks an opportunity to perform any meaningful cross-examination of witnesses Complaint Counsel will rely upon at trial.

Complaint Counsel's many fact depositions also created an *in terrorem* effect in the market as ECM's customers fear FTC enforcement. On October 29, 2013 the FTC announced six enforcement actions against companies, including ECM, for violating the revised Green Guides and the One Year Rule.[251] The FTC has already secured two consent orders from ECM former customers. Parties participating in depositions have been forced to disclose their business records to the FTC. Those customers now reasonably fear FTC action, which renders them more willing to please the FTC and offer testimony unfavorable to ECM and less willing to do business with ECM.

Knowing that ECM was unable to provide live counsel during depositions of ECM customers, Complaint Counsel lead witnesses excessively, effectively testifying for those witnesses through counsel's questions.[252]

Complaint Counsel now presents that testimony in written form only, where ECM lacked the ability to cross-examine the witnesses, and the Court cannot make assessments of witness credibility, or determine (crucially) whether the manner and format of Complaint Counsel's questions influenced the witnesses' testimony. Complaint Counsel essentially asks the Court to take these witnesses' statements at face value.

It is axiomatic to basic notions of Due Process that at trial all fact witnesses whose testimony may be relied upon if available to testify be called at hearing, be subjected not only to direct but also cross examination, and be witnessed in their demeanor by the presiding judge who

[251] http://www.ftc.gov/news-events/press-releases/2013/10/ftc-cracks-down-misleading-unsubstantiated-environmental

[252] *See, e.g.*, CCX 811 (Hong, Dep. at 33–38).

may, on that basis, evaluate the character and credibility of the testifying witness. Out of court statements thus lack the reliability and completeness required to be credited at trial because they are not subjected to the crucible of cross or the direct examination of the fact finder.[253]

Accordingly, this Court should give no dispositive weight to any content in the transcripts of fact witnesses relied upon by Complaint Counsel who did not appear as witnesses at trial. Moreover, this Court should find that ECM's due process rights have been violated by Complaint Counsel's interference with subpoenas in this case and establish a clear precedent to prohibit similar conduct in future.

3. Unfair Surprise

Although having been aware of Dr. Michel's study of ECM plastic (and other commercial plastics since Complaint Counsel contracted with Dr. Michel in 2012, in this case Complaint Counsel elected not to list Dr. Michel as a witness on any of their proposed witness lists. Despite having five (5) distinct opportunities in the case to list Dr. Michel as a witness, Complaint Counsel never suggested he would testify in any capacity. Complaint Counsel even secured a stipulated agreement with ECM's counsel to preclude Dr. Michel's deposition testimony on the basis that he would not be called as a fact witness. Meanwhile, Complaint Counsel took a number of actions to bolster Dr. Michel's anticipated testimony, including taking the deposition of Elsevier, the company that staffed the reviewer for Dr. Michel's article.

[253] *See, e.g., Prebble v. Brodrick*, 535 F.2d 605, 616 (10th Cir. 1976) (where information from persons not present at hearing concerns an important issue in dispute, a due process objection may well be valid).

Complaint Counsel eventually listed Dr. Michel as a rebuttal witness only, and the testimony offered in Dr. Michel's "rebuttal" report was information that could have, and should have, been presented in Complaint Counsel's affirmative case.

That strategy violated the meaning of Rule 3.31A, as well as principles of due process and fairness. The Rules prohibited Complaint Counsel from calling any expert witness to testify at the hearing that it failed to list on its expert witness list. Parties to an FTC administrative action are required to "serve each other with a list of experts they intend to call as witnesses at the hearing not later than 1 day after the close of fact discovery, meaning the close of discovery except for depositions and other discovery permitted under §3.24(a)(4), and discovery for purposes of authenticity and admissibility of exhibits." 16 C.F.R. § 3.31A(a). Therefore, any expert not designated in the expert witness list is not permitted to testify at the evidentiary hearing, and cannot be later designated a rebuttal expert. *See In the Matter of POM Wonderful*, 2011 WL 1429882, at n. 1 (F.T.C. Apr. 5, 2011) (Chappell, A.L.J.) ("*an expert must first be designated* and provide an expert report in order to be allowed to testify") (emphasis added, citing Rule 3.31A(b)); 16 C.F.R. § 3.31A(b) ('No party may call an expert witness at the hearing unless he or she has been *listed* ...'").

Application of the rules in a way that permits surprise rebuttal witnesses (who have not previously been identified) is erroneous and leads to fundamental fairness issues for at least two reasons. First, Respondent is not entitled to file surreply reports as a matter of course, *and* Respondent's expert testimony is limited at the hearing to what experts wrote in their original expert reports. Accordingly, the prospect of a "new" witness leaves Respondent incapable of addressing the material raised by that new witness prospectively. Second, even assuming that Respondent's experts could testify beyond the four corners of their original report to address

material raised by a surprise rebuttal witness, that concept is inconsistent with judicial efficiency and logic because Complaint Counsel is not required actually present the testimony of their rebuttal experts. Respondents may therefore be addressing information that will never be presented into evidence. In fact, Dr. Michel's testimony was not fair rebuttal, because it was not limited to "that which is precisely directed to rebutting *new matter or new theories* presented by the defendant's case-in-chief." *Bowman v. Gen. Motros Co.*, 427 F.Supp. 234, 240 (E.D. Pa. 1977) (emphasis added). Literally all of Dr. Michel's testimony covered areas of scientific dispute that Complaint Counsel knew of before expert witness lists were due months before trial, because all of the issues he testified to either bolstered Complaint Counsel's initial expert testimony, or addressed factual issues (e.g., scientific studies) that should have been part of Complaint Counsel's affirmative case.

Similarly, ECM was denied an opportunity to present a surrebuttal expert, Dr. Steven Grossman, who would have responded to false and scientifically incorrect statements made by Dr. McCarthy during his hearing testimony. This case concerned the credibility of expert opinion and, yet, ECM was not afforded the same benefits that Complaint Counsel were given concerning the presentation of expert testimony. Dr. Grossman's proffered testimony involved an exceptional situation. Dr. Grossman is a colleague of Dr. McCarthy's. Dr. Grossman is a polymer engineer and teaches in the same department as Dr. McCarthy at UMass Lowell. Dr. Grossman, if permitted to testify, would have explained that Dr. McCarthy's scientific positions are entirely without merit, in conflict with Dr. McCarthy's own research, and incompetent with respect to basic scientific issues. The relative importance of that crucial testimony renders the

denial of same a considerable violation of rights, as this case may now be determined on an incomplete scientific record.[254]

IV. CONCLUSION

For the foregoing reasons, ECM respectfully requests that this Court deny each of Complaint Counsel's requests for relief, dismiss the Complaint, and enter judgment in ECM's favor.

Respectfully submitted,

/s/ Jonathan W. Emord
Jonathan W. Emord
Peter A. Arhangelsky
Bethany R. Kennedy
Eric J. Awerbuch
EMORD & ASSOCIATES, P.C.
Telephone: 202-466-6937
Fax: 202-466-6938
Email: jemord@emord.com

DATED: September 25, 2014

[254] Outright disqualification of an expert is rare and should involve an assessment of the public interest in permitting the expert to testify. *Koch Refining Co. v. Jennifer L. Boudreau M/V*, 85 F.3d 1178, 1181-82 (5th Cir. 1996).

CERTIFICATE OF SERVICE

I hereby certify that on September 25, 2014, I caused a true and correct copy of the foregoing to be served as follows:

One electronic copy to the **Office of the Secretary** through the e-filing system:

Donald S. Clark, Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Room H-113
Washington, DC 20580
Email: secretary@ftc.gov

One electronic courtesy copy to the **Office of the Administrative Law Judge**:

The Honorable D. Michael Chappell
Administrative Law Judge
600 Pennsylvania Ave., NW, Room H-110
Washington, DC 20580

One electronic copy to **Counsel for Complainant**:

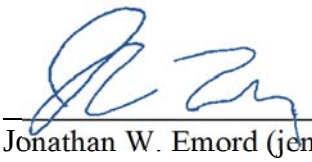
Katherine Johnson
Division of Enforcement
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
Mail stop M-8102B
Washington, D.C. 20580
Email: kjohnson3@ftc.gov

Arturo Decastro
Division of Enfoncement
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
Mail stop M-8102B
Washington, D.C. 20580
Email: adecastro@ftc.gov

Jonathan Cohen
Division of Enforcement
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
Mail stop M-8102B
Washington, D.C. 20580
Email: jcohen2@ftc.gov

I certify that I retain a paper copy of the signed original of the foregoing document that is available for review by the parties and adjudicator consistent with the Commission's Rules.

Respectfully submitted,



Jonathan W. Emord (jemord@emord.com)
EMORD & ASSOCIATES, P.C.
11808 Wolf Run Lane
Clifton, VA 20124
Telephone: 202-466-6937
Facsimile: 202-466-6938

DATED: September 25, 2014

RESPONDENT'S WEBSITE APPENDIX

Exhibit	Document Description	Where Cited
1	"Biodegradable." *Merriam-Webster.com*. Merriam-Webster, n.d. Web. 22 July 2014, *available at* http://www.merriam-webster.com/dictionary/biodegradable	Post-Trial Brief, p. 62
2	"Biodegradable." *Collins English Dictionary*, 10th Ed. 2009 (July 22, 2014), *available at* http://dictionary.reference.com/browse/biodegradation	Post-Trial Brief, p. 62
3	Frequently Asked Questions, The University of Arizona Cancer Center, m azcc.arizona.edu ("[m]any standard treatments used today are the result of past clinical trials, which involve a strict and rigorous, multi-step process that takes eight years on average to complete."), *at* http://azcc.arizona.edu/patients/clinical-trials/faq (last visited Sep. 25, 2014)	Post-Trial Brief, p. 113
4	"FTC Cracks Down on Misleading and Unsubstantiated Environmental Marketing Claims."*FTC.gov*, (October 29, 2013). Web. 25 September 2014, *available at* http://www.ftc.gov/news-events/press-releases/2013/10/ftc-cracks-down-misleading-unsubstantiated-environmental	Post-Trial Brief, p. 215
5	Aguirre, "Plastics Engineering Educator Praised for Research, Service" (Sep. 21, 2012), *available at* http://www.uml.edu/News/stories/2011-12/University-Professor-reception.aspx	RPPF ¶ 1407
6	"FTC's winning streak is over." *The Hill* (February 11, 2014), *available at* https://thehill.com/blogs/congress-blog/economy-budget/197969-ftcs-winning-streak-is-over	Post-trial Brief, p. 73

EXHIBIT 1

biodegradable

bio·de·grad·able *adjective* \-di-'grā-də-bəl\

: capable of being slowly destroyed and broken down into very small parts by natural processes, bacteria, etc.

Full Definition of BIODEGRADABLE

: capable of being broken down especially into innocuous products by the action of living things (as microorganisms) <*biodegradable* trash bags>

— **bio·de·grad·abil·i·ty** *noun*
— **biodegradable** *noun*
— **bio·deg·ra·da·tion** *noun*
— **bio·de·grade** *verb*

See biodegradable defined for English-language learners »
See biodegradable defined for kids »

First Known Use of BIODEGRADABLE

1961

Other Biochemistry Terms

bile, capsaicin, keratin, metabolism

Rhymes with BIODEGRADABLE

photodegradable

bio·de·grad·able *adjective* \-di-'grād-ə-bəl\ ***(Medical Dictionary)***

Medical Definition of BIODEGRADABLE

: capable of being broken down especially into innocuous products by the action of living things (as microorganisms)

—**bio·de·grad·abil·i·ty** *noun*, *plural* **bio·de·grad·abil·i·ties**
—**bio·deg·ra·da·tion** *noun*
—**bio·de·grade** *verb*, **bio·de·grad·ed** **bio·de·grad·ing**

Learn More About BIODEGRADABLE

Spanish Central Translation: "biodegradable" in Spanish

Browse

- Next Word in the Dictionary: biodemography
- Previous Word in the Dictionary: biodefense
- All Words Near: biodegradable

Seen & Heard

What made you want to look up *biodegradable*? Please tell us where you read or heard it (including the quote, if possible).

Join Us

Merriam-Webster on Twitter »
Merriam-Webster on Facebook »

Bookstore: Digital and Print

Merriam-Webster references for Mobile, Kindle, print, and more. See all »

Other Merriam-Webster Dictionaries

Spanish Central »
Learner's ESL Dictionary »
WordCentral for Kids »
Visual Dictionary »
SCRABBLE® Word Finder »
Webster's Unabridged Dictionary »
Britannica English – Arabic Translation »

EXHIBIT 2

biodegrade (http://static.sfdict.com/staticrep/dictaudio/B03/B0345100.mp3)

[bahy-oh-di-**greyd**]

Word Origin

verb (used without object), **biodegraded, biodegrading.**

1. to decay and become absorbed by the environment:
   "toys that will biodegrade when they're discarded."

Origin

1970-1975

1970-75; back formation from biodegradable
(http://dictionary.reference.com/browse/biodegradable)

Related forms

biodegradation (http://static.sfdict.com/staticrep/dictaudio/B03/B0345200.mp3) [bahy-oh-deg-ruh-**dey**-shuh n] (Show IPA) noun

biodegrade in Medicine

biodegradation bi·o·deg·ra·da·tion (bī'ō-dĕg'rə-dā'shən)
n.
See biotransformation (/search?q=biotransformation).

The American Heritage® Stedman's Medical Dictionary

EXHIBIT 3

Patient Care

- Make an Appointment
- Find a Physician
- Find a Clinical Trial
- For New Patients
- Multidisciplinary Clinics & Treatment
- Supportive Care for Healing
- Learn About Cancer Research Studies
  - Additonal Resources: Screening and Prevention
  - Frequently Asked Questions
- Cancer Prevention
- Glossary of Terms
- Patient Stories

Act Against Cancer

Quick Links

- What We Treat
- Find a Physician
- Make an Appointment
- Locations
- UACC Blog
- Find a Clinical Trial
- Cancer Prevention
- Calendar of Events
- Ways To Give
- En Español
- Info by Disease

Frequently Asked Questions

The University of Arizona Cancer Center, a National Cancer Institute-designated Comprehensive Cancer Center, is one of the leading sites in the country for the treatment of cancer. In addition to receiving state-of-the-art, evidence-based multidisciplinary cancer care, our patients have access to novel targeted therapy medications and innovative treatments through clinical trials.

Clinical trials are scientific studies in which people volunteer to participate under the supervision of physicians and research professionals. In the realm of cancer, therapeutic clinical trials examine new medications, new combinations of drugs or new approaches to surgery or radiation therapy. However, clinical trials may also study new diagnostic and screening methods as well as prevention and quality of life strategies.

In therapeutic trials, new treatments, which on average have at least six years of research behind them, are tried in a small number of patients in order to determine safety and effectiveness before they can be made widely available. Many standard treatments used today are the result of past clinical trials, which involve a strict and rigorous, multi-step process that takes eight years on average to complete. Clinical trials are monitored by the National Institutes of Health and the U.S. Food and Drug Administration as well as by local oversight boards that ensure volunteers' rights are preserved.

Inclusion and exclusion criteria, such as age, disease type, medical history and current medical condition, are used to identify appropriate participants for a clinical trial and help researchers ensure they can answer the questions they plan to study. Before patients decide to enroll in a trial, they learn about a study's treatments and tests, and possible benefits and risks, but participants can also withdraw from a study at any time.

Choosing to participate in a clinical trial is an important personal decision. Patients interested in clinical trials should read these frequently asked questions and talk to their physician. For more information about clinical trials at the University of Arizona Cancer Center, please call (866) 278-1554.

How does a clinical trial work?

A volunteer is usually assigned a specific study group. Volunteers in one study group may receive an investigational treatment or drug while other volunteers may receive a standard treatment, sometimes a placebo, an inactive product, is used with a standard treatment to assess the effectiveness of the experimental treatment. The group in which a volunteer is placed may not be known to those involved in the study, which allows researchers to objectively observe and evaluate the volunteers. Regardless of which treatment volunteers receive, the level of medical attention and care received is the same.

What are the different types of clinical trials?

- Treatment trials – test experimental treatments, new combinations of drugs or new approaches to surgery or radiation therapy.
- Prevention trials – look for better ways using medicines, vaccines, vitamins, minerals or lifestyle changes to prevent a disease from occurring or returning.
- Diagnostic trials – look for better tests or procedures for diagnosing a disease or condition.
- Screening trials – look for better methods to detect diseases or health conditions.
- Quality of Life trials (or Supportive Care trials) – look for ways to improve comfort and the quality of life for individuals with chronic illnesses.

What are clinical trial phases?

Each phase of the clinical trial process has a different purpose and is treated as a separate study. After completion of a phase, investigators must submit data for approval from the FDA before continuing to the next phase.

- Phase I - researchers test an experimental drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range and identify side effects.
- Phase II - the experimental drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.
- Phase III - the experimental drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments and collect information that will allow it to be used safely.
- Phase IV – studies occur after an approved drug is on the market to delineate additional information including the drug's risks, benefits and optimal use.

Who can participate in a clinical trial?

Eligible participants are determined by a clinical trial's inclusion and exclusion criteria, which are based on factors such as age, disease type, medical history and current medical condition. Some studies seek volunteers with a particular illness to be studied, while other trials recruit healthy volunteers. The criteria are used to identify appropriate participants and help researchers ensure they can answer the questions they plan to study.

What protections exist for clinical trial participants?

An Institutional Review Board comprised of scientists and non-scientists of varied backgrounds, genders and ethnicities review all human subject research conducted at the Arizona Cancer Center to ensure that studies are ethical and participants are not likely to be harmed. The IRB can stop a study if it appears to be causing unexpected harm to participants or if it is clear that the new treatment is effective and should be made more widely available.

What is informed consent?

Doctors and nurses involved in a trial explain the details of a study to interested candidates using terms the potential participants will understand. Candidates receive an informed consent document that includes a detailed description of what's expected of a volunteer as well as details such as the trial's purpose, duration, required procedures, risks, potential benefits and key contacts. Candidates then decide whether to sign the document and agree to participate in the trial. A participant can withdraw from a study at any time without penalty.

What questions should be asked before choosing to participate?

- How long will the trial last?
- Where is the trial being conducted?
- What treatments will be used and how?
- What is the main purpose of the trial?
- How will patient safety be monitored?
- Are there any risks involved?
- What are the possible benefits?
- What are the alternative treatments besides the one being tested in the trial?
- Who is sponsoring the trial?
- Do I have to pay for any part of the trial?
- What happens if I am harmed by the trial?
- Can I opt to remain on this treatment, even after termination of the trial?

What are the possible benefits of joining a trial?

- Access to promising new interventions that are generally not yet available to the public and may be more effective than standard therapy.
- Receive highly specialized and monitored medical care and attention.
- Help others by contributing to medical research.

What are the possible risks of joining a trial?

- Experimental treatment may not be more effective than standard treatment or may have unexpected side effects.
- May require more trips to the study site or more treatments.

What happens after the trial?

The data collected from the study is used to determine the therapy's effectiveness, safety and side effects. Researchers then determine whether to move on to the next phase of study. After Phase III of a study is complete, data may be submitted to the FDA for approval. If a drug is approved, pharmaceutical companies may continue to conduct studies that compare the new drug to other drugs already on the market or assess a drug's long-term effectiveness and impact on the quality of a person's life.

How can I find out more?

Choosing to participate in a clinical trial is an important personal decision. Patients interested in clinical trials should talk to their physician. Search a list of open therapeutic trials at the University of Arizona Cancer Center. A searchable registry of clinical trials around the world is available at www.clinicaltrials.gov.

E-mail this page

NCI Designation
En Español
Salmon Awards

Patient Care
Make an Appointment
Find a Physician
Find a Clinical Trial
For New Patients
Multidisciplinary Clinics & Treatment
Supportive Care for Healing
Learn About Cancer Research Studies
Cancer Prevention
Glossary of Terms
Patient Stories

Pilot Project Funding
Shared Resources
Common Equipment List
Preceptorship Program
Scientific Review Committee
Find a Clinical Trial
Find a Researcher
Biorepository
Research Grant Support and Resources

Academic Programs
Cancer Biology Graduate Interdisciplinary Program
Cancer Prevention and Control Postdoctoral Training Fellowship
Hematology and Medical Oncology Fellowship Training Program

Ways to Give
Act Against Cancer Fund
Director's Circle
Naming Opportunities
Phoenix Friends
Highlights in Giving
Support UACC Through Amazon.com
Volunteer
Hold an Event
Contact Us

Employee Access Log In • UAConnect Mail

For information about receiving treatment at The University of Arizona Cancer Center, please call (520) 694-CURE (2873).

THE UNIVERSITY OF ARIZONA HEALTH NETWORK

Please contact us with any questions or problems you have with this website.

EXHIBIT 4

FTC Cracks Down on Misleading and Unsubstantiated Environmental Marketing Claims

Actions Challenge Deceptive Biodegradable Plastics Claims for the First Time

FOR RELEASE

October 29, 2013

TAGS: restrictions on advertising | Retail | Merchandise & Clothing | Bureau of Consumer Protection | Consumer Protection | Advertising and Marketing | Environmental Marketing

The Federal Trade Commission today announced six enforcement actions, including one that imposes a $450,000 civil penalty and five that for the first time address biodegradable plastic claims, as part of the agency's ongoing crackdown on false and misleading environmental claims.

The plastic cases include a complaint against a company that markets an additive it claims makes plastic products biodegradable and four complaints and proposed consent orders against companies that marketed various plastics with allegedly false and unsupported claims that their products were biodegradable. In the civil penalty case, the FTC filed a complaint and consent order against a company for violating a 1994 FTC order that prohibited it from making unsupported green claims for its paper plates and bags.

All of these cases are part of the FTC's program to ensure compliance with the agency's recently revised Green Guides. The Commission publishes the Guides to help businesses market their products accurately, providing guidance as to what constitutes deceptive and non-deceptive environmental claims.

"It's no secret that consumers want products that are environmentally friendly, and that companies are trying to meet that need," said Jessica Rich, Director of the Federal Trade Commission's Bureau of Consumer Protection. "But companies that don't have evidence to support the environmental claims they make about their products erode consumer confidence and undermine those companies that are playing by the rules."

Each of the FTC's plastics matters and, where appropriate, the proposed consent order, and the paper products civil penalty settlement are detailed below.

ECM Biofilms, Inc. is based in Ohio and markets its additives (which allegedly make plastic products biodegradable) under the trade name MasterBatch Pellets. It advertises its additives on its website and through marketing materials, such as fliers and brochures that are available to distributors and manufacturers

that incorporate ECM additives into their products. According to the complaint, ECM also issues its own "Certificates of Biodegradability of Plastic Products," which ECM allegedly uses to convince its customers and end-use consumers that its additive makes plastic products biodegradable.

ECM allegedly claimed, for example, that "plastic products made with [its] additives will break down in approximately nine months to five years in nearly all landfills or wherever else they may end up." The complaint alleges that these purportedly biodegradable plastics do not in fact biodegrade within a reasonably short period of time after disposal in a landfill. Moreover, the complaint alleges that ECM has no substantiation to support its claims that its additive makes plastic biodegradable.

The Commission complaint charges ECM with violating the FTC Act by misrepresenting that: 1) ECM plastics (plastics made with ECM additives) are biodegradable and will completely break down within a reasonably short period of time after customary disposal; 2) ECM plastics are biodegradable in a landfill; 3) ECM plastics are biodegradable in a stated qualified timeframe; and 4) that various scientific tests prove ECM's biodegradability claims. Finally, the complaint charges ECM with providing its customer and independent distributors – through the distribution of its promotional materials – with the means to deceive consumers. The notice order attached to the complaint would, among other things, prohibit ECM from engaging in each violation alleged in the complaint.

The FTC's complaints against the following companies charge them with misrepresenting that plastics treated with additives are biodegradable, biodegradable in a landfill, biodegradable in a certain timeframe, or shown to be biodegradable in a landfill or that various scientific tests prove their biodegradability claims. The FTC also alleges that the companies lacked reliable scientific tests to back up these claims.

American Plastic Manufacturing is based in Seattle, Washington, and was an ECM customer until at least December 2012. The FTC alleges that APM advertised its plastic shopping bags on its website as biodegradable, and sold them to distributors nationwide. APM's marketing materials claimed that its products were biodegradable based on the use of the additives sold by ECM.

CHAMP, located in Marlborough, Massachusetts, also was an ECM customer, and advertised on its website that its plastic golf tees were biodegradable. CHAMP sold the tees both online and in brick and mortar stores throughout the United States. The company's marketing materials claimed that the ECM additive made its products biodegradable.

Clear Choice Housewares, Inc. based in Leominster, Massachusetts, was a customer of an additive manufacturer called Bio-Tec Environmental. Clear Choice sold what it claims are biodegradable, reusable plastic food storage containers on its website, as well as in retail stores nationwide. Clear Choice's marketing materials claimed its products were biodegradable based on the application of a Bio-Tec product called Eco Pure. The FTC alleges that Clear Choice made false and unsubstantiated claims that Eco Pure made its products "quickly biodegradable in landfills."

Carnie Cap, Inc., based in East Moline, Illinois, incorporated Eco-One, an additive manufactured and marketed by Ecologic, into its plastic rebar cap covers. Carnie Cap advertised the caps on its website and sold them through various distributors nationwide. It claimed, with no qualification, that the Eco-One product makes it plastic rebar cap covers "100 % biodegradable."

The proposed consent orders settling the FTC's complaints are essentially the same. They prohibit the four companies from making biodegradability claims unless the representations are true and supported by competent and reliable scientific evidence. Consistent with the Green Guides, the companies must have

evidence that the entire plastic product will completely decompose into elements found in nature within one year after customary disposal (defined as disposal in a landfill, incinerator, or recycling facility) before making any unqualified biodegradable claim.

For qualified claims, the companies must state the time required for compete biodegradation in a landfill or the time to degrade in a disposal environment near where consumers who buy the product live. Alternatively, the companies may state the rate and extent of degradation in a landfill or other disposal facility accompanied by an additional disclosure that the stated rate and extent do not mean that the product will continue to decompose.

The proposed consent orders also make it clear that ASTM D5511 (a test standard commonly used in the additive industry) cannot substantiate unqualified biodegradable claims or claims beyond the results and parameters of the test, and that any testing protocol used to substantiate degradable claims must simulate the conditions found in the stated disposal environment.

AJM Packaging Corporation. AJM manufactures paper products, including paper plates, cups, bowls, napkins, and bags, for sale throughout the United States. Based in Bloomfield Hills, Michigan, the company touts itself as a "leading manufacturer of these products," and refers to its lunch bags and Green Label paper plates as national brand leaders.

According to the FTC, through its recent marketing practices, AJM violated a July 19, 1994, Commission consent order that barred it from representing that any product or package is degradable, biodegradable, or photodegradable unless it had competent and reliable scientific evidence to substantiate the claims. The order defines the terms "competent and reliable scientific evidence," as well as what constitutes a "product or package," including plates and bags.

Despite the terms of the order, AJM began making new environmental claims for a number of its papers products, including claims that they were "biodegradable," "compostable" or both. AJM made these claims for some of its most popular products, including: Nature's Own Green Label and Gold Label papers plates, AJM lunch bags, AJM grocery bags, and Bio-Save Lawn & Leaf Bags. The packaging for AJM's paper plates also prominently stated that they are "recyclable."

Based on this conduct, the FTC's complaint charges AJM with violating the 1994 order by failing to have competent and reliable evidence to substantiate claims that: its products will biodegrade within one year when disposed in a landfill; its products will compost in a safe and timely manner in a home composting pile; and its paper plates are recyclable.

In settling the FTC's current complaint, AJM agrees to vacate the prior Commission order and enter into a new order that contains new language and definitions that reflect updates to the Green Guides that were finalized last year. Specifically, the updated order bars AJM from making unsubstantiated claims that a product or package is biodegradable, compostable, recyclable, or offers an environmental benefit and requires AJM to disclose information needed to qualify certain green claims to avoid deception.

The court order also requires AJM to pay a $450,000 civil penalty for violating the 1994 order and enjoins AJM from violating the new order. The FTC can seek additional penalties if AJM violates the new order in the future.

Green Marketing Consumer and Business Education

The FTC recently released several business and consumer education resources designed to help users understand its Green Guides and environmental marketing in general. These include: 1) "Environmental Claims – Summary of Green Guides," a four-page summary of the changes in the Guides; 2) "The Green Guides," a video explaining highlights of the changes; 3) a new page on the FTC Business Center, with links to legal documents, the Guides and other "green" content; 4) a Business Center blog post; and 5) related consumer information.

In addition, the FTC today posted a new blog for consumers to help them understand the issues surrounding biodegradable plastics claims in order to make informed purchasing decisions. The post, "Green" Claim Check," can be found on the FTC's website. The Commission also has new information for businesses, "Grading your degradability claims: The latest for green marketers."

The Commission Votes

The Commission vote to issue the administrative complaint against ECM Biofilms was 4-0. The case will be heard before an administrative law judge at the FTC, with the proceeding scheduled to begin on June 18, 2014.

The Commission vote to accept the consent agreement packages containing the proposed consent orders for public comment in each of the four biodegradable plastics cases was 4-0. The FTC will publish a description of the consent agreement packages in the Federal Register shortly. The agreements will be subject to public comment for 30 days, beginning today and continuing through November 29, 2013, after which the Commission will decide whether to make the proposed consent orders final.

Interested parties can submit written comments electronically or in paper form by following the instructions in the "Invitation to Comment" part of the "Supplementary Information" section. Comments in paper form should be mailed or delivered to: Federal Trade Commission, Office of the Secretary, Room H-11, and 600 Pennsylvania Avenue, N.W., Washington, DC 20580. Comments also can be filed electronically:

Comment on the APM matter.

Comment on the CHAMP case.

Comment on the Clear Choice case.

Comment on the Carnie Cap case.

The Commission vote approving the complaint against AJM was 5-0, with former Chairman Jon Leibowitz and former Commissioner J. Thomas Rosh participating. The vote to approve the stipulated final order was 4-0. The complaint was referred to the Department of Justice and then back to the FTC. The FTC filed the complaint and stipulated order in the U.S. District Court for the District of Columbia on October 1, 2013.

NOTE: The Commission authorizes the filing of a complaint when it has "reason to believe" that the law has been or is being violated, and it appears to the Commission that a proceeding is in the public interest.

NOTE: The Commission refers a complaint to the DOJ for filing when it has "reason to believe" that the law has been or is being violated and it appears to the Commission that a proceeding is in the public interest. The order has the force of law when approved and signed by the district court judge.

The Federal Trade Commission works for consumers to prevent fraudulent, deceptive, and unfair business practices and to provide information to help spot, stop, and avoid them. To file a complaint in English or Spanish, visit the FTC's online Complaint Assistant or call 1-877-FTC-HELP (1-877-382-4357). The FTC enters complaints into Consumer Sentinel, a secure, online database available to more than 2,000 civil and criminal law enforcement agencies in the U.S. and abroad. The FTC's website provides free information on a variety of consumer topics. Like the FTC on Facebook, follow us on Twitter, and subscribe to press releases for the latest FTC news and resources.

CONTACT INFORMATION

MEDIA CONTACT:
Mitchell J. Katz
Office of Public Affairs
202-326-2161

STAFF CONTACTS:
Megan Bartley
Bureau of Consumer Protection
202-326-3424
(AJM Packaging Corporation)

Katherine Johnson
Bureau of Consumer Protection
202-326-2185

Related Cases

MacNeill Engineering Company, Inc., d/b/a CHAMP, In the Matter of

Carnie Cap, Inc., In the Matter of

Clear Choice Housewares, Inc., also d/b/a FARBERWARE® EcoFresh, In the Matter of

AJM Packaging Corporation

American Plastic Manufacturing, Inc., In the Matter of

ECM BioFilms, Inc., also d/b/a Enviroplastics International, In the Matter of

For Consumers

Blog -"Green" Claim Check

Going Green

For Businesses

Blog - Grading your degradability claims: The latest for green marketers

Environmental Marketing

Video - Green Guides

Media Resources

Our Media Resources library provides one-stop collections of materials on numerous issues in which the FTC has been actively engaged. These pages are especially useful for members of the media.

Events Calendar

Speeches

Audio/Video

Social Media

Blogs

ENFORCEMENT

Cases and Proceedings

Premerger Notification Program

Merger Review

Anticompetitive Practices

Rules

Statutes

Consumer Sentinel Network

Criminal Liaison Unit

POLICY

Advocacy

Advisory Opinions

Cooperation Agreements

Federal Register Notices

Reports

Studies

Testimony

Public Comments

Policy Statements

International

TIPS & ADVICE

For Consumers

Business Center

Competition Guidance

I WOULD LIKE TO...

Submit a Consumer Complaint to the FTC

File a Comment

Get a Free Copy of My Credit Report

List a Number on the National Do Not Call Registry

Report An Antitrust Violation

File Documents in Adjudicative Proceedings

SITE INFORMATION

Privacy Policy

Website Policy

No FEAR Act

USA.gov

Accessibility

Digital Government Strategy

Open Government

FEDERAL TRADE COMMISSION

Headquarters:
600 Pennsylvania Avenue, NW
Washington, DC 20580
Contact Us

Stay Connected with the FTC

EXHIBIT 5

McCarthy Honored as Newest University Professor

Plastics Engineering Educator Praised for Research, Service

Prof. Stephen McCarthy, second from right, is shown with, from left, Provost Ahmed Abdelal, Chancellor Marty Meehan and Prof. Robert Parkin.

09/21/2012
By Edwin L. Aguirre

Chancellor Marty Meehan joined University administrators, faculty and staff as well as friends and family members in honoring plastics engineering Prof. Stephen McCarthy, who was named this year's University Professor, during a reception held at the UMass Lowell Inn & Conference Center on Sept. 20.

Meehan lauded McCarthy for his "exemplary teaching, outstanding research and extraordinary service to UMass Lowell for nearly three decades."

"It's a great honor to receive this award," said McCarthy. "I'm very grateful to Chancellor Meehan, Provost Ahmed Abdelal, Dean John Ting and Prof. Bob Parkin, who nominated me for this prestigious title. I also want to thank my family for their support and understanding, especially for putting up with the long hours I spend working in the University."

A resident of Tyngsboro, McCarthy joined the UMass Lowell faculty in 1984. Among his many accomplishments as an innovative educator, he has graduated 25 doctoral students in plastics engineering and biomedical engineering as well as several times this number of master's students.

As a world-class researcher, he has obtained nearly $9 million in externally sponsored research grants and contracts, plus nearly $33 million in intellectual property donations to UMass Lowell. He also founded the Massachusetts Medical Device Development Center (M2D2), a signature program for the campus. To date, he has published more than 100 peer-reviewed papers and holds eight U.S. and two international patents. He is also instrumental in establishing global partnerships with institutions in Ireland, Northern Ireland, Israel and Egypt.

McCarthy's three-year term will run from September 2012 through August 2015. Previous University Professors include Susan Braunhut (biology), 2008–11; Ken Geiser (work environment), 2009–12; Robert Giles (physics), 2010–13; and Regina Panasuk (education), 2011–14.

McCarthy will deliver an annual University Professor lecture next spring about his work on biodegradable plastics and medical devices.

To see photos from the reception, visit UMass Lowell's Photo Gallery.

University Relations - Cumnock Hall, 31 University Ave., Lowell, MA 01854
Phone: 978-934-3224 Fax: 978-934-3033 Contact Us

EXHIBIT 6

THE HILL

February 11, 2014, 04:00 pm

FTC's winning streak is over

Six months ago in **Can the FTC be a fair umpire?** I wrote in the The Hill's Congress blog about the concerns arising from the Federal Trade Commission's dual role as prosecutor and final decision maker in its administrative litigation. I noted that for 19 years in every case brought by the Commission it had found an antitrust violation. I observed "One must wonder about fairness when the pitcher is also the umpire - - and is always calling strikes." This winning streak did not mean a perfect record – indeed in the cases appealed to Courts of Appeal the FTC was reversed 20 percent of the time (compared to a 5 percent reversal rate for federal court judges).

Congress noticed. In two antitrust oversight hearings last fall the FTC was questioned about their "perfect" record. As the Chairman of the House Judiciary antitrust subcommittee Spencer Bachus (R-Ala.) said "With this kind of record and an unbeaten streak that Perry Mason would envy, a company might wonder whether it is worth putting up a defense at all in a system in which the FTC brings a complaint, the case is tried before an administrative law judge at the FTC, and the FTC holds the authority to overturn a decision adverse to the agency."

Last week, that winning streak ended. In a case involving McWane, a firm that manufactures ductile iron pipe fittings, the Commission dismissed all of the complaint counts alleging collusion and all but one of the counts alleging monopolization. (The Commission deadlocked 2-2 on party lines on two conspiracy counts).

The Commission did find that exclusive dealing by McWane violated the antitrust laws. On that count, the Commission divided 3-1, with a blistering exhaustive 52-page dissent by Commissioner Joshua Wright.

What is the significance of the Commission's decision?

First, this is an example of good government and common sense. The FTC's generation long winning streak was indefensible and undermined the credibility of the Commission. Courts were increasingly skeptical of the FTC's administrative process. This decision begins to restore a sense of procedural fairness and substantive rationality.

Second, the dissent is the main course. The most compelling jurisprudence is in Commissioner Wright's dissent. He marshaled the case law, economic theory, antitrust policy and a copious recitation of the facts to demonstrate there was no illegal monopolization. His dissent demonstrates that the basics of any antitrust case – higher prices, less output or choice, or greater barriers to entry are simply missing. Indeed, the most probative evidence – the successful entry of a rival – suggested there was no harm to the market.

Third, don't bet on the FTC on appeal. As mentioned earlier, when the FTC finds a violation they are often reversed by the appellate courts (at a much higher rate than other agencies of district courts). In this case the Commission not only has to overcome the increasing skepticism of the courts about fairness in FTC administrative litigation but also Commissioner Wright's dissent which provides a detailed roadmap to reversal. Commissioner Wright's dissent will be even more compelling because he was one of the leading authorities on the new learning on exclusive dealing before he went to the Commission.

Fourth, reforms matter. Probably no one noticed when in the last month of the Bush II Administration the FTC implemented procedural reforms to streamline administrative litigation under the leadership of former Chairman Bill Kovacic. One of the reforms was to require the Commission to issue decisions in 180 days after the ALJ initial decision. But for the time limit the Democratic Commissioners could have delayed the decision in this case until the fifth Commissioner (a Democrat) took office and they had a majority on the collusion counts. That might have been expedient but it would have been poor public policy and further diminished the credibility of the agency.

Finally, Congress matters. The FTC turns 100 years old this year. When its creation was proposed Louis Brandeis, one of the authors of the Federal Trade Commission Act said "sunlight is said to be the best of disinfectants." In this case Congressional sunlight on the FTC administrative process helped set the Commission on a more prudent course. That's a valuable lesson for everyone.

Balto is an antitrust attorney and former policy director at the Federal Trade Commission.

The Hill 1625 K Street, NW Suite 900 Washington DC 20006 | 202-628-8500 tel | 202-628-8503 fax

2005 WL 4227194
United States District Court,
C.D. California.

FEDERAL TRADE COMMISSION, Plaintiff,
v.
A. Glenn BRASWELL, et al., Defendants.

No. CV 03-3700 DT (PJWX). | Sept. 27, 2005.

Attorneys and Law Firms

Alysa S. Bernstein, Christine Jean Lee, David P. Frankel, David K. Koehler, James A. Trilling, Lawrence Demille-Wagman, Mamie Kresses, Marilyn E. Kerst, Richard L. Cleland, Rosemary Rosso, Theodore H. Hoppock, William E. Kovacic, Federal Trade Comission, Washington, DC, Kenneth H. Abbe, Federal Trade Commission, Los Angeles, CA, for Plaintiff.

Andrew B. Lustigman, Sheldon S. Lustigman, Lustigman Law Offices, New York, NY, Casey Cooper, Michael L. Calhoon, Baker Botts, Washington, DC, D. Jay Ritt, Kerry R. Bensinger, Bensinger Ritt & Botterud, Pasadena, CA, Bryan D. Daly, Charles L. Kreindler, Edward E. Alon, Beck De Corso Daly Kreindler & Harris, G. Cresswell Templeton, III, Hill Farrer & Burrill, Eugenie L. Warner, Michael L. Mallow, Kirkpatrick and Lockhart, Peter Morris, Altman and Morris, Los Angeles, CA, for Defendants.

ORDER DENYING DEFENDANT CHASE REVEL'S MOTION FOR SUMMARY JUDGMENT OR PARTIAL SUMMARY JUDGMENT

TEVRIZIAN, J.

I. *BACKGROUND*

A. *Factual Summary*

***1** Plaintiff, the Federal Trade Commission ("FTC" or "Commission"), is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. It brings this action against Defendants A. Glenn Braswell ("Braswell"), JOL Management Co. ("JOL"), G.B. Data Systems, Inc. ("G.B.Data"), Gero Vita International, Inc. ("Gero Vita"), Theraceuticals, Inc. ("Theraceuticals"), Halsey Holdings LLC ("Halsey"), Health Quest Publications, Inc. ("Health Quest"), G.B. Data Systems, Inc. (Canada), Ron Tepper ("Tepper"), Ronald M. Lawrence, M.D., Ph.D. ("Lawrence"), Hans Kugler, Ph.D. ("Kugler"), Chase Revel a/k/a Marcus Welbourne, John Wellburn, James Wellburn, Martin Wellner, John Meggenhorn, and John Burke ("Revel").

The following facts are found to be undisputed: [1]

[1] The Court sets forth these facts based on its review of Revel's Statement of Uncontroverted Facts and Conclusions of Law, the FTC's Statement of Genuine Issues and Revel's Reply Statement. While many facts were set forth in Revel's Separate Statement in support of his Motion for Summary Judgment, the Court sets forth only those undisputed facts relevant to the analysis set forth herein. Other disputed facts are discussed within the analysis portion or were not relevant based on the Court's determinations of the issues presented in this Motion.

On or about May 27, 2003, the FTC filed its original complaint against Defendants for violations of Sections 5 and 12 of the Federal Trade Commission Act ("FTC Act"). On or about March 30, 2004, the FTC sought leave to add

Revel as a defendant. On or about July 26, 2004, the FTC filed its Second Corrected First Amended Complaint for Permanent Injunction and Other Equitable Relief ("FAC").

The FTC alleges that Braswell, Tepper, JOL, G.B. Data, Canada, Gero Vita, Theraceuticals, Health Quest, and Halsey are part of the "Braswell Common Enterprise." The FTC does not allege that Revel is part of the Braswell Common Enterprise. It alleges that the Braswell Common Enterprise "advertised, labeled, offered for sale, sold, and distributed a variety of dietary supplements and other health-related products to the public, and that its total sales exceeded $798 million." Among the products that Defendants are alleged to have advertised, labeled, offered for sale, sold and distributed in recent years are: Lung Support Formula, Gero Vita G.H.3, and Testerex, all marketed since at least 1998; ChitoPlex, marketed since at least 1999; AntiBetic Pancreas Tonic, marketed since at least 2000; and Theraceuticals G.H.3 Romanian Youth Formula, marketed since at least 2001. The FTC has settled with all of the entities comprising the Braswell Common Enterprise with the exception of Braswell individually.

Revel drafted advertising copy for the Gero Vita companies pursuant to the contract between his company, Campaign Media Corporation ("CMC")[2] and Vita Industries ("Contract"). CMC agreed to create advertising material for direct mail or space advertising to promote Gero Vita's products. Under this Contract, CMC was to receive royalty payments based on a percentage of the sales generated by the advertising material created by CMC. Revel ceased working for the Gero Vita companies in early 2001.

[2] CMC later became Admax, Inc.

The FAC alleges three counts against Revel for the advertising he wrote for Lung Support Formula, AntiBetic Pancreas Tonic and Gero Vita GH3. Revel does not dispute that he wrote advertising for these products. The FAC alleges that Revel made claims that Gero Vita products will "cure, treat, or alleviate" certain conditions; and that they have been "scientifically tested and proven to be effective;" and that these representations violation Sections 5(a) and 12 of the FTC Act.

***2** More specifically, with respect to the three product claims at issue here, the FTC alleges the following in its FAC:
(1) Revel "represented, expressly or by implication, that Lung Support: a. Cures or significantly alleviates lung diseases and respiratory problems, including asthma, colds, influenza, bronchitis, chest congestion, emphysema, smoking damage, and shortness of breath; b. Reverses existing lung damage in persons with emphysema and significantly improves their breathing; c. Prevents breathing problems for many persons who do not have existing respiratory problems; and d. Is clinically proven to eliminate or cure allergies, asthma, colds, influenza, bronchitis, sinus problems, chest congestions, emphysema, smoking damage, and shortness of breath."

(2) Revel "represented, expressly or by implication, that AntiBetic: a. Can cure Type I and Type II diabetes; b. is an effective or superior alternative to insulin or other diabetes medications for the treatment of Type I and Type II diabetes; and c. is clinically proven to regenerate or repair the pancreatic cells that produce insulin and to lower blood sugar levels in persons with diabetes."

(3) Revel "represented, expressly or by implication, that: a. GH3 reverses and prevents age-related memory loss, dementia, and Alzheimer's disease; b. Persons who use GH3 or Theraceuticals GH3 can live 29% longer; and c. GH3 is clinically proven to prevent and reverse age-related memory loss, dementia and Alzheimer's disease."

The FTC alleges that the above-stated representations regarding Lung Support, Antibetic and the GH3 Products ("Representations") were made "expressly or by implication" and that they were "false or were not substantiated at the time [they] were made." The FTC contends that the "overall net impression" of Revel's advertisements convey such Representations.

B. *Procedural Summary*

The procedural history in this case is lengthy, as the original Complaint was filed on May 27, 2003, and it has been set out in previous orders of this Court. This Court hereby incorporates by reference the Procedural Histories set forth in prior Orders of this Court.

Currently before this Court is Defendant Chase Revel's Motion for Summary Judgment or Partial Summary Judgment, filed on August 29, 2005.

II. *DISCUSSION*

A. *Standard*

Under the Federal Rules of Civil Procedure, summary judgment is proper only where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). The moving party has the burden of demonstrating the absence of a genuine issue of fact for trial. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256, 106 S.Ct. 2505, 2514, 91 L.Ed.2d 202 (1986). If the moving party satisfies the burden, the party opposing the motion must set forth specific facts showing that there remains a genuine issue for trial. *See id.;* Fed.R.Civ.P. 56(e).

***3** A non-moving party who bears the burden of proof at trial to an element essential to its case must make a showing sufficient to establish a genuine dispute of fact with respect to the existence of that element of the case or be subject to summary judgment. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S.Ct. 2548, 2552, 91 L.Ed.2d 265 (1986). Such an issue of fact is a genuine issue if it reasonably can be resolved in favor of either party. *See Anderson*, 477 U.S. at 250-51, 106 S.Ct. at 2511. The non-movant's burden to demonstrate a genuine issue of material fact increases when the factual context renders her claim implausible. *See Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S.Ct. 1348, 1356, 89 L.Ed.2d 538 (1986). Thus, mere disagreement or the bald assertion that a genuine issue of material fact exists no longer precludes the use of summary judgment. *See Harper v. Wallingford*, 877 F.2d 728 (9th Cir.1989); *California Architectural Building Prods., Inc. v. Franciscan Ceramics, Inc.*, 818 F.2d 1466, 1468 (9th Cir.1987).

If the moving party seeks summary judgment on a claim or defense on which it bears the burden of proof at trial, it must satisfy its burden by showing affirmative, admissible evidence.

Unauthenticated documents cannot be considered on a motion for summary judgment. *See Hal Roach Studios v. Richard Feiner and Co.*, 896 F.2d 1542, 1550 (9th Cir.1990).

On a motion for summary judgment, admissible declarations or affidavits must be based on personal knowledge, must set forth facts that would be admissible evidence at trial, and must show that the declarant or affiant is competent to testify as to the facts at issue. *See* Fed.R.Civ.P. 56(e). Declarations on "information and belief" are inappropriate to demonstrate a genuine issue of fact. *See Taylor v. List*, 880 F.2d 1040, 1045 (9th Cir.1989).

B. *Analysis*

Revel seeks judgment or partial judgment as a matter of law on the following bases:
(1) The FTC cannot meet its burden of proving that any advertisements drafted by Revel contained statements that were expressly false or deceptive or created a net impression that was false or deceptive;

(2) The FTC cannot meet its burden of proving that Revel lacked a reasonable basis for all statements made in advertising copy drafted by him regarding the products at issue in this case;

(3) The FTC cannot meet its burden of demonstrating the proper calculation of any restitution award against Revel regarding Lung Support Formula;

(4) The FTC cannot meet its burden of demonstrating that Revel should be subject to any injunctive relief;

(5) Revel has demonstrated that he acted in good faith in drafting the advertisements for Lung Support Formula, GH3 and AntiBetic.

1. Applicable standards for Sections 5 and 12 of the FTC Act

As set forth above, the FTC alleges that the advertisements drafted by Revel with respect to Lung Support Formula, GH3 and Antibetic contain representations which are false or were not substantiated at the time they were made, constituting a deceptive practice, and the making of false advertisements in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

***4** Section 5 of the FTC Act declares unlawful "unfair methods of competition in or affecting commerce, and unfair and deceptive acts or practices in or affecting commerce."

In support of his Motion, Revel argues that the FTC must meet its burden of demonstrating "substantial consumer injury" as set forth in 15 U.S.C. § 45(n).[3] However, the FTC responds that such a showing is the liability standard for "unfair practices," and it alleges "deceptive", not "unfair" practices. *See* Complaint at ¶¶ 36, 38, 40, 44 ("Therefore, the making of the representations ... constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.") This Court agrees with the FTC.

[3] Under § 45(n), an act or practice cannot be declared unlawful on the grounds that such act or practice is unfair unless the act or practice "causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition." 15 U.S.C. § 45(n).

"[T]he 'cardinal factor' in determining whether an act or practice is deceptive under § 5 is the likely effect the promoter's handiwork will have on the mind of the ordinary consumer." *Federal Trade Comm'n v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir.1963). Under Section 5, the FTC must show that the business entity made material representations likely to mislead ordinary consumers to their detriment. *F.T.C. v. Freecom Communications, Inc.*, 401 F.3d 1192, 1203 (10th Cir.2005); *see also Southwest Sunsites, Inc. v. Federal Trade Comm'n*, 785 F.2d 1431, 1436 (9th Cir.1986). Proof of consumer reliance or consumer injury is not necessary to establish a Section 5 violation. *Freecom*, 401 F.3d at 1203. As such, the FTC's burden of proof does not include "substantial consumer injury."[4]

[4] In his Reply, Revel admits that "the Commission is correct that it may establish a technical violation of the FTC Act without proof of consumer injury." However, he contends "the consequences of such a showing are virtually meaningless for the purposes of the FTC's case against Revel." He argues that because the only monetary relief that the FTC seeks from Revel is restitution based on injury to consumers, then the FTC still needs to prove "injury to consumers." However, as explained hereinbelow, triable issues of fact exist with respect to the issue of restitution.

Section 12 of the Act makes it unlawful "to disseminate, or cause to be disseminated, any false advertisement (1) by United States mails, in or having an effect upon commerce, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, devices, services, or cosmetics; or (2) by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce, of food, drugs, devices, services, or cosmetics." 15 U.S.C. § 52(a). A "false advertisement" is any advertisement that is misleading in a material respect. 15 U.S.C. § 55; *see also F.T.C. v. Pantron I Corp.*, 33 F.3d 1088, 1099 (9th Cir.1994)("Indeed, a 'false advertisement' need not be 'false'; it need only be 'misleading in a material respect.' "). In determining whether any advertisement is false or misleading, the Court must take "into account, among other things, not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations." 15 U.S.C. § 55.

2. Summary judgment is not warranted on the basis of the net impressions of the advertisements

The FTC's allegations against Revel are based on claims derived from the net impressions created by the challenged advertisements written by Revel for Defendant Braswell and his companies. Based on the FTC's allegations, then, the question is whether the net impression of the representation is such that the representation would be likely to mislead reasonable consumers. *FTC v. Gill*, 71 F.Supp.2d 1030, 1046 (C.D.Cal.1999).

***5** In seeking summary judgment, Revel argues that the FTC cannot meet its burden of proving that any advertisements drafted by him contained statements that created a net impression that was false or deceptive. He contends that his drafted advertisements contain appropriate qualifying language, and that the ads clearly describe the type of studies that are being relied on. In opposition, the FTC argues that there are genuine issues of fact regarding the falsity of the net impression claims conveyed by Revel's advertisements. This Court agrees with the FTC. In other words, a reasonable trier of fact could determine that the net impression of the representations in Revel's advertisements is such that the representations would be likely to mislead reasonable consumers.

At the outset, this Court notes that contrary to Revel's arguments, individual statements need not be false or misleading to render a net impression false or misleading. *See Sterling Drug*, 317 F.2d at 675 ("The courts are no longer content to insist simply upon the 'most literal truthfulness' for we have increasingly come to recognize that 'Advertisements as a whole may be completely misleading although every sentence separately considered is literally true.' " (citations omitted)); *FTC v. Arlington Press, Inc.*, 1999 WL 33562452 *9 (C.D.Cal.1999)("Even if literally true, a representation will be found to be deceptive and in violation of Section 5 of the FTCA is its net impression is likely to mislead consumers."). As such, this Court views the representations alleged to be made by the advertisements and determines whether the fact finder could determine that its net impression is likely to mislead consumers.

a. Lung Support Formula advertisement

The claims that the FTC alleges are made by this advertisement (*see* Koehler Decl., Exh. 1) are that Lung Support Formula: (1) cures or significantly alleviates lung diseases and respiratory problems, including asthma, colds, influenza, bronchitis, chest congestion, emphysema, smoking damage, and shortness of breath; (2) reverses existing lung damage in persons with emphysema and significantly improves their breathing; (3) prevents breathing problems for many persons who do not have existing respiratory problems; and (4) is clinically proven to eliminate or cure asthma, colds, influenza, bronchitis, and emphysema. (FAC at ¶¶ 35-36.)

A review of the ad shows that the fact finder could determine that these claims are conveyed, either expressly or impliedly. The ad claims on the cover page that "Scientists Find Amazing Remedy for: Asthma, Bronchitis, Emphysema and Smoking Damage." The word "remedy" can communicate a "significant alleviation" for those diseases. The majority of the ad concerns how individual ingredients have been proven to cure or alleviate

the symptoms of these conditions and others, including colds, flu and shortness of breath. The claims are reinforced by expert endorsements touting Lung Support as "scientifically proven to rejuvenate the important lung function" (Weissman) and "proven" to rejuvenate lungs (Kugler).

***6** Regarding the claim that Lung Support reverses existing lung damage in persons with emphysema and significantly improves their breathing, the ad reports on a study where researchers reported that they "were able to reverse ... damage to the alveoli of animals ...." and emphasizes that "They actually reversed emphysema!" In a conclusion, the ad claims: "It is obvious that asthma, bronchitis, and now, even emphysema, are reversible or avoidable, if you feed the body [Lung Support]."

Regarding the claim that Lung Support prevents breathing problems for many persons who do not have existing respiratory problems, the ad conveys this message through its discussion of the extreme dangers that air pollutants pose to the respiratory system, particularly the destruction of fibers in the lungs. According to the ad, the ingredients in Lung Support deter damage to the lung, thereby implying that Lung Support will prevent the development of breathing problems.

The ad represents that Lung Support is clinically proven to eliminate or cure asthma, colds, influenza, bronchitis, emphysema, and smoking damage. In addition to the express representations on the cover page and the expert endorsements, the ad develops this claim through the discussion of at least nine scientific or clinical tests that purportedly support the efficacy of the ingredients found in Lung Support.

Thus, this Court concludes that a fact finder could determine that the express statements and the reasonable inference therefrom, in the context of the advertisement as a whole, convey to reasonable consumers the claims regarding Lung Support alleged by the FTC.

b. AntiBetic Pancreas Tonic advertisement

The claims that the FTC alleges are made by this advertisement (*see* Koehler Decl., Exh. 2) are that AntiBetic Pancreas Tonic: (1) can cure Type I and Type II diabetes; (2) is an effective or superior alternative to insulin or other diabetes medications for the treatment of Type I and Type II diabetes; and (3) is clinically proven to regenerate or repair the pancreatic cells that produce insulin and to lower blood sugar levels in persons with diabetes. (FAC at ¶¶ 37-38.)

A review of the ad shows that the fact finder could determine that these claims are conveyed, either expressly or impliedly. The substance of the ad is that the various ingredients in AntiBetic have been demonstrated through purported scientific tests to be effective in the regeneration of pancreatic cells that produce insulin or regulation of blood sugar levels. Regarding the implication that AntiBetic cures Type I and Type II diabetes, the ad states "Formula Can Eliminate the Need for Drugs"; "treatment can be discontinued after between about four and twelve months, for type I and type II diabetes"; "the formula will cure diabetes"; "clinical tests show that we've finally found the answer" (expert endorsement); and "wipe one of the worst diseases off the list" (expert endorsement).

***7** Regarding the claim that AntiBetic is an effective or superior alternative to insulin or other diabetes medications for the treatment of Type I and Type II diabetes, the ad asserts that unlike AntiBetic, conventional treatments are dangerous and do not provide a cure for diabetes. The ad states:

> Whether you are type I or type II diabetic, you know the drugs your doctor gives you aren't curing the disease; they are only trying to keep your system in balance so you can function and live, {bold subline: you never get better on drugs} Unfortunately, you never get better using drugs. The longer you have the disease, the worse it gets because it is almost impossible to

> keep your blood sugar perfectly balanced with drugs.... Now, thanks to the wonders of nature and an ancient but very wise old doctor, you can stop the awful pillaging of your body ...

Regarding the claim that AntiBetic is clinically proven to regenerate or repair the pancreatic cells that produce insulin and to lower blood sugar levels in persons with diabetes, the ad references at least nine tests or studies relating to the regeneration or repair of pancreatic cells, the lowering of blood sugar levels, or the alleviation of the symptoms of diabetes. The express statement is made that "Clinical tests show that a minimum of four months is required for those with newly acquired adult-onset blood sugar problems and that it could take up to 15 months before those dependent on drugs can stop the need for injections."

Thus, this Court concludes that a fact finder could determine that the express statements and the reasonable inference therefrom, in the context of the advertisement as a whole, convey to reasonable consumers the claims regarding AntiBetic alleged by the FTC.

c. Gero Vita GH3 advertisement

The claims that the FTC alleges are made by this advertisement (see Koehler Decl., Exh. 3) are that: (1) GH3 reverses and prevents age-related memory loss, dementia, and Alzheimer's disease; (2) Persons who use GH3 can live 29 longer; and (3) GH3 is clinically proven to prevent and reverse age-related memory loss, dementia and Alzheimer's disease. (FAC at ¶¶ 39-40.)

A review of the ad shows that the fact finder could determine that these claims are conveyed, either expressly or impliedly. Revel's ad informs consumers that age-related memory loss, dementia, and Alzheimer's disease are the result of brown slime or lipofuscin (age spots) on brain neurons, which is caused by an excess of an enzyme called monoamine oxidase (MAO), among other things. The ad reveals that excessive MAO can be reduced significantly by paraminobenzoic acid (PABA) and dimethylaminoethanol (DMAE), ingredients contained in Gero Vita GH3.

Regarding the clinically proven claim, the ad states, on page one in bold: "IF YOU HAVE AGE SPOTS ... Don't Wait Until Your Memory Gets Worse! Clinical Tests Show The Condition Can Be Reversed!" In addition, throughout the ad there are references to scientific research linking age-related memory loss, dementia and Alzheimer's disease to excess lipofuscin and MAO levels and implying that the studies prove that PABA and DMAE reduce MAO levels.

***8** Regarding the claim that "persons who use G.H.3. can live 29% longer," the front page headlines proclaims "STOP THE CLOCK! Scientists Say: You Can Live 29% Longer". A bold subheadline in the text of the advertisement declares, "Patients Lived 29% Longer!" The text describes the results of a purported "test" of a procaine product reporting "that the test group lived an average of 29% longer than the normal life expectancy." In addition, the ad includes a discussion of a study involving DMAE (an ingredient in Gero Vita G.H.3) where mice fed DMAE "extended their life spans by 30% to 40%, even though they were very old when given [the] nutrient." The ad connects this test on mice to humans by stating that the report's apparent author "concluded that those results suggest that humans' life spans may also be increased by taking DMAE regularly."

Thus, this Court concludes that a fact finder could determine that the express statements and the reasonable inference therefrom, in the context of the advertisement as a whole, convey to reasonable consumers the claims regarding Gero Vita GH3 alleged by the FTC.

In light of the above, then, this Court concludes as a matter of law that the FTC has shown the existence of triable issues of fact. Therefore, summary judgment in favor of Revel is not warranted on the basis that Revel's advertisements do not create a net impression that was false or deceptive. [5]

[5] In his Reply, Revel urges this Court to make a determination as to the net impression claims upon this Motion for Summary Judgment since the Court will be the trier of fact at the bench trial. However, this Court declines to do so. Instead, the Court believes that the proper way to proceed it to allow the parties to establish a complete record on this issue at the time of trial and then render findings and conclusions at that time. In addition, Federal Rule of Civil Procedure 52(c) (Judgement on Partial Findings) provides:
If during a trial without a jury a party has been fully heard on an issue and the court finds against the party on that issue, the court may enter judgment as a matter of law against that party with respect to a claim or defense that cannot under the controlling law be maintained or defeated without a favorable finding on that issue, or the court may decline to render any judgment until the close of all the evidence.

3. Summary judgment is not warranted on the ground that Revel had a reasonable basis for the advertisements

Revel argues that the FTC cannot prove that Revel lacked a reasonable basis for his advertising copy. In response, the FTC argues that genuine issues of fact regarding whether Revel had a reasonable basis for his advertising copy preclude summary judgment. As explained below, this Court agrees with the FTC.

In Section 12 cases involving objective product claims, the FTC can rely on a "reasonable basis" theory. *FTC v. Garvey*, 383 F.3d 891, 901 (9th Cir.2004)(quoting *Pantron I*, 33 F.3d at 1096). Under the reasonable basis theory, the FTC must show that the advertiser lacked a reasonable basis for asserting that the message was true. *Id.* (quoting *Pantron I*, 33 F.3d at 1096). "In determining whether an advertiser has satisfied the reasonable basis requirement, the Commission or court must first determine what level of substantiation the advertiser is required to have for his advertising claims. Then, the adjudicator must determine whether the advertiser possessed that level of substantiation." *Pantron I*, 33 F.3d at 1096.

With respect to determining the level of substantiation required, at issue are objective product claims. Objective product claims contain affirmative information about a product's attributes, performance or efficacy and require some level of substantiation in support. *In re Removatron*, 111 F.T.C. 206 (1988). In other words, objective product claims imply support by a reasonable basis. *In the Matter of Thompson Medical Co.*, 104 F.T.C. 648, 813 (1984), aff'd, 791 F.2d 189 (D.C.Cir.1986), cert. denied, 479 U.S. 1086, 107 S.Ct. 1289, 94 L.Ed.2d 146 (1987). If the ad contains express representations regarding the particular level of support that the advertiser has for the claim or implies a particular level of substantiation to reasonable consumers, then the reasonable basis consists of the amount and type of substantiation the advertiser claimed to have. *Id.* Typically, advertising that expressly or impliedly represents support by a scientific level of substantiation contains such words as "tested," "established," "here's proof" or "medically proven." *Removatron*, 111 F.T.C. 206. If such advertisement represents that a particular claim has been scientifically established, then the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claim's truth. *Thompson*, 104 F.T.C. at 821-22 n. 59.

***9** In this case, this Court concludes that the Revel ads expressly or impliedly represent support by a scientific level of substantiation. For example:

The GH3 advertisement contains the following statements: "Clinical Tests Show ..."; "Scientists have found ..."; "American Scientists Confirm ..."; "Considerable clinical evidence is showing ..."; in addition, as detailed above in subsection 2(c), the ad discusses scientific research and tests. (Koehler Decl., Exh. 3.)

The AntiBetic ad contains the following statements: “World-Renowned Clinic Involved in Tests”; “clinical tests have shown ...”; in addition, as detailed above in subsection 2(c), the ad references expert endorsements and tests. (*Id.* at Exh. 2.)

The Lung Support ad contains the following statements: “Scientists Find Amazing New Remedy”; “scientists have recently found ...”; “clinical tests reveal”; in addition, as detailed above in subsection 2(c), the ad discusses expert endorsements as wells as scientific and clinical tests. (*Id.* at Exh. 1.) As such, these are claims that the representations are supported by scientific evidence. The question presented is, then, is what level of scientific substantiation is needed.

In seeking summary judgment, Revel first asserts that he should not be considered a “full service ‘advertising agency’ ”, and that instead, he should be considered akin to a commercial “spokesperson”, relying on *F.T.C. v. Garvey*, 383 F.3d 891 (9th Cir.2004), and therefore be subject to the substantiation requirement in that capacity. This Court concludes that *Garvey* is inapplicable. In *Garvey*, Steve Garvey, retired first baseman for the L.A. Dodgers, was hired by Enforma Natural Products, Inc., creator of a weight loss system, to promote its system through infomercials and radio and television appearances. The FTC filed a complaint against Garvey alleging that in marketing the Enforma System, Garvey violated Sections 5(a) and 12 of the FTCA. After a bench trial, the district court entered judgment in favor of Garvey concluding that Garvey could not be held liable under a “participant” theory of liability or as an “endorser.” *Id.* at 896. Importantly, in making its determination, the Ninth Circuit noted:

> The Garvey defendants note that there is no settled standard for the level of inquiry to which a commercial spokesperson is held when he or she is hired to participate in a television advertisement. In the context of the knowledge requirement, we find that the fact that the individual is merely a spokesperson is relevant.

Id. at 902-903 n. 12. Here, Revel cannot seriously contend that he was “merely a spokesperson.”

Indeed, Revel does not dispute that he was responsible for conceiving and drafting advertisements for Lung Support Formula, AntiBetic Pancreas Tonic and Gero Vita GH3. The FTC offers examples of instances where Revel exercised control over things such as specific font types, font sizes, and the ages of models in the photographs. (*See* Koehler Decl., Exhs. 14-16.) Revel's correspondence and the written “guidelines for handling [his] work” demonstrate the control he asserted over the advertising he drafted: “There will be NO changes or additions to my copy other than the normal proofing and editing.... A copy of the typeset piece must be faxed or [sent] to me for my approval before being sent to the printer.” (*Id.* at Exh. 15; *see also id.* at Exh. 16.) According to Revel: “[F]rom the onset, in fact, ... I wrote all of the advertisements that would go out to acquire new customers” from 1990 to 1998. (*Id.* at Exh. 33 at 132-133.) As such, Revel is not comparable to Steve Garvey in *Garvey* who was hired merely as a celebrity spokesperson. To the contrary, Revel's actions and duties reflect his role as an advertiser.

***10** Revel asserts next that even if Revel/Admax is considered to be an advertising agency, he was entitled to rely on the studies provided by the client to satisfy the reasonable basis requirement. In response, the FTC contends that the reasonable basis standard for the claims at issue here consist of double-blind, placebo-controlled, randomized clinical studies. This Court concludes that the FTC has set forth sufficient evidence to establish a genuine issue for trial as to the applicable standard.

In support of its claim regarding the need for double-blind, placebo-controlled, randomized clinical studies, the FTC relies on its expert witnesses who each have opined that the adequate substantiation required by qualified experts in the relevant fields for the efficacy claims at issue in the Complaint for Lung Support Formula, AntiBetic

Pancreas Tonic and GH3 would include at least one double-blind, placebo-controlled, randomized clinical study. (Koehler Decl., Exh. 6 at 13-16; 7 at 7-13; 8 at 13-16.) The Court can look to what experts in the relevant area of study would consider to be adequate in determining the amount of and type of evidence that is sufficient. *See Thompson Medical*, 104 F.T.C. at 821. The FTC also points to other courts which have found or upheld that double-blind, placebo controlled studies are required to provide adequate substantiation for various efficacy claims, including claims for dietary supplements. *See, e.g.*, *Pantron I*, 33 F.3d at 1097-98 (placebo control required for hair growth product); *FTC v. SlimAmerica, Inc.*, 77 D. Supp.2d 1263, 1274 (S.D.Fla.1999)("Scientific validation of the defendants' product claims requires a double blind study of the combination of ingredients used in [the product formula]."); *FTC v. Sabal*, 32 F.Supp.2d 1004, 1008-09 (N.D.Ill.1998)(rejecting study as valid substantiation, in part, because it was not blinded or placebo controlled); *FTC v. California Pacific Research, Inc.*, 1991 U.S. Dist. LEXIS 12967 at *12-13 (D.Nev. Aug. 27, 1991) (only placebo-controlled, double-blind clinical studies meet "the most basic and fundamental requirements for scientific validity and reliability").

Finally, the FTC points out that Revel himself acknowledges the importance of a double-blind, placebo controlled, randomized clinical study. In the opening paragraphs of a 1999 book he co-authored, he acknowledges the importance of double-blind, placebo controlled testing because "[u]nfortunately, most [stories about the benefits of nutritional supplements] are written by vitamin companies or herbalists who are touting their own products, often stretching the truth." He states:

> Today we live in a scientific world where technology has reached a point that we can test the use of a medicine or nutritional supplement and carefully evaluate its effects in an unbiased way. The accepted method of evaluating a substance by scientists worldwide is called a 'double blind' study. A scientist must eliminate the possibility of bias and the placebo effect.

***11** (Hans Kugler and Chase Revel, *Amazing Medicines the Drug Companies Don't Want You to Discover* at vii (1999), excerpts attached as Exh. 25 to Koehler Decl.) Similarly, at his deposition, when Revel testified regarding his "concept of an appropriate clinical study" that he "would want to rely on in making a claim," he addressed the importance of "choosing the participants randomly," as well as "a double blind situation ... and placebo controlled, of course." (Koehler Decl., Exh. 33 at 126-128.)

Revel cites to *Federal Trade v. Enforma Natural Products*, 362 F.3d 1204 (9th Cir.2004), for the proposition that "the Ninth Circuit has not adopted such a rigid standard [double blind, placebo controlled clinical tests] when adjudicating whether an individual or entity had a reasonable basis for making a claim." This Court does not disagree. In *Enforma*, the defendant appealed the district court's issuance of a preliminary injunction against it, restricting the sale and marketing of its diet supplement products. *Id.* at 1208. The Ninth Circuit, however, was unable to make any determinations because of the insufficiency of the district court's findings of fact. *Id.* at 1215. It acknowledged that "[t]here are genuine disputes about the scientific requirements underlying [the defendant's] substantiation claims." *Id.* at 1217. It therefore remanded to the district court for "factual findings sufficient to determine the basis on which the district court rejected [the defendant's] studies." *Id.* Thus, the only guidance that *Enforma* offers is that the scientific requirements underlying substantiation claims depend on the facts of the case and the evidence presented. [6]

[6] Revel also cites *Litton Indus., Inc. v. FTC*, 676 F.2d 364 (9th Cir.1982). However, *Litton* addresses findings concerning comparison advertising of "independent microwave oven service technicians" ' preferences and not the efficacy of health claims. Further, the Ninth Circuit noted that "[t]he order covered only microwave ovens." *Id.* at 368.

Thus, in sum, Revel seeks summary judgment on the basis that the FTC cannot establish that he lacked a reasonable basis for the advertisements. However, by offering unrefuted evidence that the standard should be double-blind, placebo-controlled tests, the FTC has offered sufficient evidence to withstand summary judgment.

Further, because the legal determination of the level of substantiation required will be determined by the Court based upon the evidence at trial, this Court cannot presently address whether Revel has met the standard. The Court, as the trier of fact, will determine that issue at the time of trial once the standard is determined. Revel is therefore not entitled to summary judgment on the ground that the FTC cannot prove that he lacked a reasonable basis.

4. Summary judgment is not warranted on the issue of restitution

Revel argues that the FTC cannot meet its burden of demonstrating any proper restitution award against Revel regarding Lung Support Formula. This Court construes this argument as Revel seeking partial summary judgment on the issue of restitution. [7]

[7] This argument is insufficient for Revel to seek summary judgment as to Count I because the FTC seeks not only restitution but also a finding of liability, injunctive relief, the costs of bringing this action and any other discretionary equitable relief. (*See* FAC at 44-45.)

In support of his argument, Revel asserts that the FTC's reliance on the database from former defendant JOL is insufficient to provide a reasonable calculation of a restitution award against him. Revel relies on testimony from JOL's director of information who testified that for the period of time before 2000, there are no back-up tapes of the data; one can search the accounts payable system only back to 2000; he (JOL's director of information) cannot testify whether the information in the database is true, complete and accurate; and there were corruption problems with the database during the period of 1998-2000. Revel also asserts that there are no available financial documents that show that Admax received any payments for Lung Support Formula.

***12** In response, the FTC contends that it is undisputed that the Gero Vita Companies had total sales of $35,786,574.73 for Lung Support Formula during the relevant period from 1998 through 2001; Revel was paid a royalty of 5% on every sale made (less refunds) of Lung Support Formula attributable to the advertisements he drafted; and Revel was paid approximately $5 million for advertising copy he wrote for the Gero Vita Companies during the relevant period from 1998 through 2001. The FTC also points out that Revel has not provided any financial information in response to the FTC's discovery requests, and that the FTC's motion to compel production of this financial information is currently pending before Magistrate Judge Walsh.

Based on the foregoing, this Court concludes that summary adjudication on the issue of restitution is not warranted. Triable issues of fact exist regarding, at a minimum, the existence of records and the adequacy of those records.

5. Summary judgment is not warranted on the issue of injunctive relief

Finally, Revel seeks summary judgment on the basis that the FTC cannot meet its burden of proof to show that Revel should be subject to any injunctive relief. More specifically, he argues that he acted in good faith, and therefore there is no basis to subject him to a permanent injunction.

As the FTC cites, good faith is not a defense to relief sought under Section 13(b) for violation of Section 5 of the FTC Act. *See Federal Trade Commission v. World Travel Vacation Brokers*, 861 F.2d 1020, 1029 (7th Cir.1988) ("An advertiser's good faith does not immunize it from responsibility for its misrepresentations."); *Beneficial Corp. v. Federal Trade Commission*, 542 F.2d 611, 617 (3d Cir.1976). Instead, good faith may be offered as an affirmative defense to the granting of a permanent injunction. *See FTC v. Medicor, LLC*, 2001 WL 765628, ----2-3 (C.D.Cal.2001); *FTC v. Hang-Ups Art Enterprises, Inc.*, 1995 WL 914179, *3 (C.D.Cal.1995).

As such, in asserting the affirmative defense of "good faith," Revel bears the burden of proving said defense. Here, this Court concludes that Revel has not established he is entitled to such a determination as a matter of law.

The granting of a permanent injunction requires that "there exist some cognizable danger of recurrent violation." *See* Hang-Ups, 1995 WL 914179 at *3 (citing *United States v. W.T. Grant Co.*, 345 U.S. 629, 633, 73 S.Ct. 894, 97 L.Ed. 1303 (1953)). The determination of whether the alleged violations are likely to recur requires the Court to look at: (1) the deliberateness ... of the present violation, and (2) the violator's past record." *Id.* (citing *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 392 (9th Cir.1982)). The FTC provides evidence that Revel was aware of, and knew or should have known, the appropriate standard for making the kinds of claims at issue in the Complaint. More specifically, Revel had prior experience with the FTC through a Stipulated Final Judgment and Order signed by him in *FTC v. LaserVision, Inc.*, 94-CV-1961 WJT (C.D.Cal. March 23, 1994). Among other things, this Order put Revel on notice that it was a violation to "misrepresent[ ], in any manner, directly or by implication, the existence, contents, validity, results, conclusions or interpretations of any test or study." (Koehler Decl., Exh. 12 at 8.) Thus, Revel is not entitled to summary adjudication with respect to injunctive relief.

III. *CONCLUSION*

***13** Accordingly, this Court DENIES Defendant Chase Revel's Motion for Summary Judgment or Partial Summary Judgment.

IT IS SO ORDERED.

Parallel Citations

2006-1 Trade Cases P 75,267

End of Document

2009 WL 4799954
Only the Westlaw citation is currently available.
United States District Court,
N.D. Illinois,
Eastern Division.

In re TRANS UNION CORP. PRIVACY LITIGATION.
This Document Relates to: All Case.

No. 00 C 4729. | MDL Docket No. 1350. | Dec. 9, 2009.

MEMORANDUM OPINION AND ORDER

ROBERT W. GETTLEMAN, District Judge.

***1** The remaining issues in this multi-district litigation arise from an overabundance of greed by two sets of lawyers recognized by the court as among the attorneys representing the plaintiff class. After many years of litigation and hammering out a successful global settlement,[1] this court and Magistrate Judge Michael Mason encouraged plaintiffs' attorneys to agree on the amount of fees that would be sought, and Magistrate Judge Mason attempted to mediate an agreement among the various groups of lawyers as to amount and allocation. That attempt failed because Texas counsel[2] demanded $2.85 million in fees, which was greater than the (undisclosed) allocation agreed by the remaining attorneys, who sought a total fee award of $15.1 million.

1 The settlement created a $75 million cash fund (the "Fund") to be distributed to a nationwide class pursuant to a complex formula (see Order entered September 17, 2008, Doc. No. 515) and capped attorneys' fees at 25% of the Fund ($18.5 million) subject to approval by the court. The settlement also included substantial in-kind relief.

2 Michael A. Caddell, Cynthia B. Chapman and Corey Fein of Caddell & Chapman, and Mitchell A. Toups of Weller, Green, Toups & Terrell, L.L.P.

By order dated April 6, 2009 (the "April 6 Order"), this court decided to award a total of $10.83 million in fees. *In re Trans Union Corp. Privacy Lit.*, 2009 WL 937158. When that order was vigorously contested by Texas and Louisiana counsel,[3] by order dated June 11, 2009 (Doc. No. 635) the court vacated the award and appointed Edward W. Feldman as Special Master pursuant to Fed.R.Civ.P. 53 to: (a) examine the time records of all counsel; (b) recommend a fee award; (c) investigate any ethical issues, including those related to Louisiana counsel identified in the April 6 Order; and (d) perform additional inquires related to the duties specified above.

3 Dawn Adams Wheelahan, and Steven J Lane, Stephen I. Herman and Soren E. Gisleson of Herman, Herman, Katz & Cotlar, L.L.P.

On October 1, 2009, the Special Master submitted (but did not file in the public record) a 76 page Report and Recommendation (the "R & R"), which the court finds to be remarkable not only for its content, but for its style, thoroughness and overall excellence. Consequently, because the court approves and adopts the R & R in its entirety, the court attaches and incorporates the R & R to this opinion.

The R & R recommends a total fee award of $12,980,000, representing 17.3% of the Fund, allocated as follows: $7,836,683 to MDL and Frey counsel (hereafter, together, "MDL counsel");[4] $2,722,360 to Louisiana counsel; $1,815,319 to Texas counsel; $550,000 to liaison counsel;[5] and $55,638 to the Special Master. The award to liaison counsel was agreed by all parties and has been distributed, as have approved out-of-pocket expenses. The

award to the Special Master represents½ of his fees and expenses, and was so ordered by this court's June 11, 2009, order. The other half is to be paid from the proceeds remaining to be distributed to the class.

[4] Joy Ann Bull and Eric J. Niehaus of Coughlin, Stoia, Geller, Rudman & Robbins, L.L.P.; Jon W. Borderud of Law Offices of Jon W. Borderud; Matthew Righetti of Righetti Law Firm and John N. Zarian of Zarian, Midgley & Johnson PLLC.

[5] Terry Rose Saunders and Thomas A. Doyle of Saunders & Doyle.

The only parties to object to the R & R were, not surprisingly, Louisiana and Texas counsel. In addition to seeking even more fees, Louisiana counsel seeks to suppress the Special Master's discussion of the ethical issues that this court directed him to investigate. For the reasons discussed below, the objections to the R & R are overruled, Louisiana counsel's request to suppress the portions of the R & R dealing with attorney Dawn Wheelahan's ethical lapses is denied, and MDL counsel are directed to distribute the money remaining in the Fund to the attorneys pursuant to the allocation recommended by the Special Master, with the remaining funds to be distributed to the plaintiff class as specified in the order approving the settlement agreement.

Louisiana and Texas Counsels' Objections to the R & R

***2** Louisiana counsel's principal objection to the R & R can be summed up simply: they (principally attorney Dawn Wheelahan) believe that they should be credited with most if not all of the difference between the original and final settlement agreements, and awarded a generous percentage of that difference (and 75% of the fees associated with that difference). Texas counsel's objection to the R & R is limited to the Special Master's conclusion that MDL counsel should be awarded 50% of the difference. These arguments ignore many factors that distinguish this case from the cases these lawyers—particularly Ms. Wheelahan—rely on.[6] These factors are unique to the instant litigation and are well known to this court through its extensive involvement in the contested proceedings as well as the settlement negotiations. These include:

[6] These cases include *In re Synthroid Marketing Litigation*, 264 F.3d 712 (7th Cir.2001), and *In re Synthroid Marketing Litigation*, 325 F.3d 974 (7th Cir.2003), and their progeny.

(a) Trans Union's liability in the instant case, at least for its target marketing activities, was never in doubt, as this court noted in its April 6 Order. The 2001 opinion by the United States Court of Appeals for the District of Columbia confirmed Trans Union's liability for violating the FCRA. *See*, *Trans Union Corp. v. FTC*, 245 F.3d 809, (D.C.Cir.2001). The principal challenges facing plaintiffs' counsel were how to structure the class(es) and achieve a recovery that would be collectible without forcing Trans Union (which had a net worth of approximately $1 billion) into bankruptcy.

(b) Louisiana and Texas counsels' entry into the MDL litigation was relatively late,[7] after many of the issues had been litigated and narrowed through the efforts of MDL counsel.

[7] The instant litigation began in 1999, and was approved as an MDL in 2000. Louisiana counsel filed the *Andrews* action (03 C 4331) in 2003, and successfully sought to remand it to state court in Louisiana. It was not until December 2004 that Louisiana counsel filed the *Morse* action (05 C 831) in the U.S. District Court for the Eastern District of Louisiana, which that counsel unsuccessfully sought to remove from the MDL. Louisiana counsel later brought in Texas counsel, who had filed their case (*Jowers*, 06 C 3074) in the Eastern District of Texas in April 2006.

(c) The increase in the Fund resulted as much from the tireless, patient efforts by Magistrate Judge Mason as from the efforts of any of plaintiffs' counsel.[8] Magistrate Judge Mason, with the concurrence of this court, made it quite clear that the original settlement offers were inadequate, and that Trans Union would have

to put substantially more money on the table if the court were to seriously consider a proposed class-wide settlement. As detailed below and in the R & R, the course of these discussions took some rather unusual turns.

8 Unlike Louisiana counsel, MDL counsel is gracious enough in its fee petition briefs to acknowledge this indisputable fact.

(d) The path that led the parties and the court to the ultimate settlement in this case took some novel, unexpected twists and turns that belie Louisiana counsel's attempts to denigrate and minimize the contribution of other attorneys to the settlement ultimately achieved. First, shortly after Pretrial Order No. 1 was entered by Judge Aspen (who preceded the undersigned judge) in late 2000, at Judge Aspen's urging the parties attempted to mediate a settlement with Judge Abner J. Mikva (Ret.). Next, in 2002, based on the circuit court precedent then existing, this court denied a nationwide statutory damages class under the FCRA, dismissed claims for declaratory and injunctive relief and nominal damages, and dismissed state law claims for invasion of privacy and misappropriation. [9] These holdings were reaffirmed by the court in connection with the second amended complaint filed in November 2002. [10] These rulings obviously diminished the settlement value of the case at that time.

9 *In Re Trans Union Privacy Litigation*, 211 F.R.D. 328 (N.D.Ill.2002).

10 *In Re: Trans Union Privacy Litigation*, 326 F.Supp.2d 893 (N.D.Ill.2004).

***3** (e) Despite these setbacks, MDL counsel aggressively pursued this litigation, taking extensive discovery, resisting a series of motions filed by the defendants, and successfully seeking a certification of a statewide firm offer class. *In re Trans Union*, 2005 WL 2007157. These efforts, among others pursued by MDL counsel, kept this litigation alive throughout the years that led to the March 2008 hearing in which this court informed the parties that, in light of recent changes in precedent and other matters, it might reconsider the denial of a nationwide class (even if that meant putting Trans Union out of business), and encouraged the parties to reconsider their settlement positions. [11] As detailed in the R & R and in MDL counsels' briefs, this event was a major factor that led the parties to the ultimate settlement. [12]

11 Indeed, as the Special Master has noted, at a January 15, 2009, hearing the court discussed the change in precedent and the possibility of revisiting certification of a nationwide class.

12 For these reasons, Texas counsel's narrow objection to the R & R's conclusion that MDL counsel should receive 50% of the enhancement of the Fund is overruled.

(f) Louisiana counsel's initial efforts in the MDL were aimed at displacing the MDL counsel who had been appointed by Judge Aspen in Pretrial Order No. 1. Failing that, Ms. Wheelahan then devoted most of her energy trying to extricate her Louisiana case (*Morse*) from the MDL. A great deal of time and judicial resources were wasted in these activities.

(g) As described in the court's April 6 Order and in detail by the Special Master in his R & R, Ms. Wheelahan has engaged in unprofessional and marginally unethical behavior. Ms. Wheelahan's inexcusable padding of her time records would be cause enough to cut her fees substantially or deny them outright. *Brown v. Stackler*, 612 F.2d 1057, 1059 (7th Cir.1980). Indeed, the lack of integrity of those time records was one of the principal reasons that the court appointed a special master to examine the fee petitions, thus delaying the final resolution of this case and distribution of the Fund to the class, and causing added expense to the class and other counsel. Ms. Wheelahan's ceaseless and irresponsible attacks on MDL and Texas counsel, Magistrate Judge Mason, [13] and even the Special Master, [14] and her needlessly prolonging this litigation would justify sanctions cutting her fees far more than the Special

Master recommends. See *Mirfasihi v. Fleet Mortgage Corp.*, 551 F.3d 682, 687 (7th Cir.2008), *cert. denied.*, *Perry v. Mirfasihi*, —— U.S. ——, 129 S.Ct. 2767, 174 L.Ed.2d 271 (2009).

13 It has recently come to the court's attention that, in her submissions to the Special Master, Ms. Wheelahan disparaged Magistrate Judge Mason's motivations and judicial behavior. As just one example, in an improper October 1, 2009, ex parte email to the Special Master, Ms. Wheelahan states: "Judge Mason seems to have a chip on his shoulder as big as the world, where I'm concerned, simply because I opposed two inadequate settlements that he wanted—and he wanted them because he just didn't know any better, and wouldn't listen in the way that Judge Gettleman, who is intelligent, did. That is what Mason resents."

14 In her latest maneuver, Ms. Wheelahan filed a "Motion for a Status Report" in which she erroneously claimed that the Special Master, through his law firm's representation of an entity related to certain individuals who controlled Trans Union, was somehow disqualified from acting as Special Master. As this court ruled on November 17, 2009 (Doc. No. 687), Mr. Feldman's response to this attack clearly established that no such conflict existed.

As previously recognized by this court, Ms. Wheelahan and her colleagues no doubt contributed to the settlement that was ultimately achieved in this case. They are being rewarded handsomely for their efforts. Their objections to the Special Master's R & R are unseemly and, frankly, embarrassing to the legal profession that has taken enough hits in the public perception. Although this court would have been inclined to impose sanctions on Ms. Wheelahan for her conduct in this case, in light of the thorough and well reasoned discussion by the Special Master, the court chooses to exercise its discretion to forego such sanctions, approve the report in its entirety, and allow the class to receive the relief for which its members have waited far too long.

***4** For these reasons, rather than prolong this opinion unnecessarily, the court incorporates the Special Master's thorough analysis of the arguments advanced by the various sets of lawyers, his analysis of the case law (particularly the *Synthroid* cases relied upon by Louisiana counsel) and the history of this litigation, his application of a percentage basis of recovery, "cross checked" by a "rough" lodestar analysis, and his allocation of fees among counsel. It would be difficult to improve on the Special Master's report, and the court will not endeavor to do so.

Ethical Issues Related to Attorney Wheelahan

With respect to the ethical issues raised by attorney Dawn Wheelahan's conduct, the court, in the exercise of its discretion, reluctantly adopts the Special Master's recommendation not to impose sanctions against her. The R & R thoroughly analyzes the emails Wheelahan sent to her co-counsel in an attempt to threaten them with a circuitous, ill-advised and likely to fail effort to torpedo the settlement to enhance her own fees. The Special Master concluded that, although her conduct was reprehensible, unprofessional and "stray[ed] far beyond conduct becoming of an attorney" (R & R at 61), Wheelahan should not be sanctioned because she took no action to carry out the threats and likely would not have succeeded to defeat the settlement even if she had done so.

This court remains disturbed (and disappointed) by conduct of a lawyer that would even come close to the line of betraying the interests of a client (especially a consumer class for which the court has recognized the lawyer as its representative) in order to augment the lawyer's fees. Even more disturbing is the Special Master's conclusion, amply supported by the record, that Wheelahan made misrepresentations to him in her attempt to explain the emails by claiming that the use of the term "motion to dismiss" in the November 19, 2008, email was an "accident," and that she did not intend to convey a threat to Texas counsel to undermine the settlement in an effort to convince them to lower their fee demand (R & R at 46–61). While the court agrees with the Special Master that Wheelahan's conduct did not rise (or sink) to the level of extortion or sanctionable deception (R & R at 62–69), coupled with her unseemly attacks on her co-counsel and the integrity of both the Special Master and the Magistrate Judge, as well as her grossly excessive time sheets, her conduct deserves censure by the court. [15]

15 In her arguments to the Special Master and in her objections to the R & R, Ms. Wheelahan contends that discussion of her ethical transgressions should be held in confidence pursuant to L.R. 83.25 (governing disciplinary proceedings before the court's Executive Committee). As pointed out in the R & R, L.R. 83.25 does not include "sanctions or contempt" proceedings.

CONCLUSION

For the foregoing reasons, the court approves, adopts and incorporates herein the attached Report and Recommendation of Special Master submitted to the court on October 1, 2009, and orders a total fee award of $12,980,000 to be allocated as follows: $7,836,683 to MDL counsel; $2,722,360 to Louisiana counsel; $1,815,319 to Texas counsel; $550,000 to liaison counsel; and $55,638 to the Special Master. MDL counsel are directed to pay these fees forthwith and distribute the balance to the plaintiff class and the Special Master pursuant to the settlement agreement and the order appointing the Special Master. MDL counsel are further directed to file a report indicating compliance with this order within 28 days.

ATTACHMENT

REPORT AND RECOMMENDATION OF SPECIAL MASTER

EDWARD W. FELDMAN, Special Master.

***5** Edward W. Feldman

Special Master Pursuant to Order of June 11, 2009

Miller Shakman & Beem, LLP

180 North La Salle Street, Suite 3600

Chicago, IL 60601

(312) 263–3700

TABLE OF CONTENTS

***6** Special Master Edward W. Feldman, appointed pursuant to the Court's order of June 11, 2009 (Doc. 635, "June 11 Order"), respectfully submits the following Report and Recommendation.

I. *INTRODUCTION*

A. Summary of Order and Assignment

In the June 11 Order, the Court provided that my duties were to include (i) examining the time records of all counsel, (ii) recommending whether to base the fee award on a lodestar or percentage basis, (iii) investigating any ethical issues raised by Louisiana Counsel's (or any other counsel's) time records and communications discussed in the court's April 6, 2009 memorandum opinion and order (Doc. 591, "April 6 Order"), and (iv) any other similar issues that may be raised during the performance of my duties. By Order dated July 30, 2009 (Doc. 637), the Court clarified that assignment (ii) included making a recommendation as to the total amount of an award and an allocation of that amount among plaintiffs' counsel.

B. Summary of Steps Taken to Carry out the Assignment

Throughout the assignment I was assisted by Roger Perlstadt of my firm. (My partner Diane Klotnia also provided helpful comments on a draft of this Report.) Our work included the following: review of various pertinent pleadings in the record; conducting phone conferences with counsel; requesting from counsel and then reviewing documents, such as detailed time and billing records and communications among counsel relevant to the ethical issues; examining several counsel of record (Ms. Wheelahan and Messrs. Toups, Zarian, Fein, Borderud and O'Neil); researching applicable law; and drafting this Report. All counsel cooperated fully with my investigation.

Plaintiffs' counsel fall generally into four groups, which are discussed herein: MDL Counsel, Louisiana Counsel, Texas Counsel and Liaison Counsel. Louisiana Counsel consists of Dawn A. Wheelahan LLC and Herman, Herman, Katz & Cotlar. Texas Counsel consists of Caddell & Chapman; Weller, Green, Toups & Terrell, LLP, and Edelman, Combs, Latturner & Goodwin, LLC, their local counsel in Chicago. Liaison Counsel is Saunders & Doyle. MDL Counsel consists of all other plaintiffs' counsel in this matter, including Zarian Midgley & Johnson, who may be referred to individually as ("*Frey* Counsel"). Collectively, Louisiana Counsel, Texas Counsel, Liaison Counsel and MDL Counsel will be referred to as "Plaintiffs' Counsel."

C. Summary of Recommendations

1. Total fee recommendation

The Stipulation of Settlement establishes a cap on attorneys' fees of $18.75 million. In the fee petitions previously filed with the Court, plaintiffs' counsel collectively requested $17.95 million. In its April 6 Order, which the Court later vacated, the Court applied the percentage-of-fund method and awarded $10.83 million. For reasons explained below, I recommend that the total attorneys' fee award be determined on the percentage-of-fund method. Having received detailed time records from counsel, which had not been provided to the Court by most counsel, I also used a rough lodestar analysis as a cross-check on the reasonableness of the fees determined by the percentage method. Applying that methodology, I recommend a total attorneys' fee award of $12,980,000. This figure represents 17.3% of the cash settlement fund of $75 million and 11.8% of the total settlement value of $109.6 million.

2. Allocation recommendation

***7** After determining that the total recommended fee would be $12.98 million, I disclosed the figure to plaintiffs' counsel and gave them a short period to determine whether they could agree on an allocation based on that figure. They could not do so. They then submitted briefs regarding a proposed allocation. After careful consideration of their briefs and review of applicable portions of the record, I recommend the following allocation of the $12.98 million award, should the Court adopt it:

- By prior agreement and court order, $550,000 to Liaison Counsel.
- Pursuant to the June 11, 2009 Order, one-half of the Special Master's fees and expenses, $55,638, to the Special Master.
- For the balance, $12,374,362:

$7,836,683 to MDL Counsel (including *Frey* Counsel).

$2,722,360 to Louisiana Counsel.

$1,815,319 to Texas Counsel.

3. Summary of recommendations regarding ethical and billing issues

I investigated each of the ethical issues raised in the Court's April 6, 2009 Order, with primary emphasis on the November 19, 2008 e-mails attached as Appendix B to that opinion. While those e-mails were wholly inappropriate and, as the Court put it, "reprehensible," under the totality of the circumstances I do not recommend that any formal sanction be imposed on Ms. Wheelahan. Likewise, Ms. Wheelahan's inclusion of travel time in her billing detail, although unreasonable and based on an untenable reading of Seventh Circuit case law, was not so egregious as to warrant a sanction. Finally, the other billing issues noted by the Court, while involving excessive or unreasonable time entries, also do not warrant any sanction. It is disappointing that none of Plaintiffs' Counsel appear to have exercised any billing judgment to review duplication or inefficiencies and reduce their raw lodestars. However, I did not find any sanctionable transgression.

II. *FEE AWARD DETERMINATION*

A. Litigation Background

Because the history of the case is relevant to determining the fee award under the *ex ante* market-based approach prescribed by the Seventh Circuit, I give a brief summary. In August 1998, a putative class action was filed by *Frey* Counsel in California state court (the "*Frey* Action"), alleging various violations by Trans Union Corp. ("Trans Union") of the Fair Credit Reporting Act ("FCRA"), 15 U.S.C. § 1681 *et seq.* A similar action against Trans Union was also filed shortly thereafter in California state court (the "*Martinelli* Action"). In early 1999, the *Martinelli* Action was removed to federal court in California. Other cases making similar allegations were filed by various MDL Counsel in other federal district courts in 1999 and 2000. In 2000, the Judicial Panel on Multidistrict Litigation transferred the *Martinelli* Action and the other federal cases to this district. Ultimately, fourteen cases were consolidated in this district, including one filed by Louisiana Counsel in federal court in Louisiana in 2005 (the "*Morse* Action"), and one filed by Texas Counsel in federal court in Texas in 2006 (the "*Jowers*" Action). The fourteen consolidated federal cases will be referred to collectively herein as the "MDL Action." In addition, Louisiana Counsel filed a similar case in Louisiana state court in December 2002 (the "*Andrews* Action").

***8** In 2004, a "target marketing" class was certified in the *Andrews* Action. In 2005, a "firm offer" class was certified in the MDL Action. In 2006, MDL Counsel, Liaison Counsel and Trans Union agreed in principle to a class settlement (the "First Proposed Settlement"), and a motion for preliminary approval of the First Proposed Settlement was filed in November 2006. The amount of the First Proposed Settlement was $20 million cash, plus in-kind relief. Louisiana Counsel objected to the motion for preliminary approval, and the motion was ultimately withdrawn in April 2007.

After further negotiations, a motion for preliminary approval of another proposed settlement (the "Second Proposed Settlement") was filed in September 2007. Under the Second Proposed Settlement, Trans Union agreed to provide to a nationwide class of consumers free online credit monitoring services valued at around $50 per consumer, and establish a $20 million fund to provide cash payments of $25 each to class members without internet access. Louisiana Counsel again objected to the motion for preliminary approval, this time joined by Texas Counsel. In January 2008, Magistrate Judge Mason recommended that the Second Proposed Settlement not be approved. The Court overruled all objections to the recommendation, and ordered a settlement conference before the Magistrate Judge.

Further negotiations quickly led to a third proposed settlement in April 2008 (the "Final Settlement"). The Court granted preliminary approval of the Final Settlement in May 2008 and final approval in September 2008. [16] The Final Settlement provided $75 million cash, plus "basic" and "enhanced" in-kind relief, the retail value of which ultimately redeemed by class members totaling just over $34.6 million.

16 Several objectors filed appeals of the final approval, all of which have now been resolved.

The Final Settlement capped the potential attorneys' fee award at 25% of the cash settlement fund of $75 million, *i.e.*, $18.75 million. After the Final Settlement was approved, in October and November 2008, Magistrate Judge Mason attempted to mediate an agreement among Plaintiffs' Counsel as to the total amount of attorneys' fees that would be sought from the Court, and the allocation of such fees. No agreement was reached, and Plaintiffs' Counsel moved for a fee award. All Counsel except Texas Counsel jointly requested $15.1 million in fees, to be allocated pursuant to an undisclosed agreement among them. Texas Counsel requested a total fee award of $2.85 million. Only Louisiana Counsel submitted hourly detail in support of the request. Other Plaintiffs' Counsel alleged total hours worked and amounts claimed, breaking the work down in seven broad categories without supporting billing detail.

On April 6, 2009, the Court entered an order awarding all Plaintiffs' Counsel a total attorneys' fee of $10.83 million. This award was based on the "percentage-of-fund" method notwithstanding the Court's general preference for the "lodestar" approach. The Court directed Plaintiffs' Counsel to determine whether they could agree on an allocation of the $10.83 million award. They were unable to agree. In addition, Louisiana Counsel filed a Rule 59(e) motion to amend the fee award. The Court ultimately vacated the April 6 Order. Among the tasks assigned to me was to recommend whether to use the percentage or lodestar method, and recommend an appropriate award and allocation based on the chosen method.

B. Legal Standards for Determining Common Fund Fee Awards

***9** In common fund cases such as this, a court has the equitable power to compensate attorneys from the recovery won for plaintiffs. *Harman v. Lyphomed, Inc.*, 945 F.2d 969, 973 (7th Cir.1991). Because the payment of attorneys' fees comes from the common fund, after attorneys secure a settlement, their role with respect to fees changes from one of fiduciary for their clients to that of claimants against the fund created for their clients' benefit. *Cook v. Niedert*, 142 F.3d 1004, 1011 (7th Cir.1998). Consequently, "the court becomes the fiduciary for the fund's beneficiaries and must carefully monitor disbursement to the attorneys by scrutinizing the fee applications." *Id.* Basically, "the district court must ensure that plaintiffs pay no more than what is reasonable." *Id.* at 1012. As an agent of a court, a special master necessarily assumes the same fiduciary function.

Courts in common fund cases have discretion to choose either the lodestar or percentage method of calculating fees. *Florin v. Nationsbank of Ga., N.A.*, 34 F.3d 560, 566 (7th Cir.1994). The Seventh Circuit has noted advantages and disadvantages to both approaches. The chief advantage of the percentage approach is simplicity of administration. *See, e.g., Florin*, 34 F.3d at 566; *In re Continental Ill. Sec. Litig.*, 962 F.2d 566, 572–73 (7th Cir.1992). The chief advantage of the lodestar approach is accountability. *See, e.g., Harmon*, 945 F.2d at 974; *Cook*, 142 F.3d at 1013 (citing *Harmon*).

Ultimately, in the Seventh Circuit, the market controls. Thus, the Seventh Circuit is less concerned with the choice between the lodestar or percentage method than with approaching the determination through the lens of the market. The analysis should be determined from what an arms-length negotiation between the class and the lawyers at the beginning of the case would have likely produced. *In re Synthroid Marketing Litig.*, 264 F.3d 712, 718–19 (7th Cir.2001) (*"Synthroid I"*) ("Timing is more important than the choice ... between percentage and hourly rates, for [both] of these systems have their shortcomings."). Thus, under either approach, the Seventh Circuit requires that "when deciding on appropriate fee levels in common-fund cases, courts must do their best to award counsel the market price for legal services, in light of the risk of nonpayment and the normal rate of compensation in the market at the time." *Id.* at 718.

While the Seventh Circuit is agnostic as between the lodestar and percentage methods, this Court expressed a preference for the former, although it ultimately employed the latter in the April 6 Order because of the inadequacy

of the time records submitted by Plaintiffs' Counsel. Now that Plaintiffs' Counsel have produced hourly billing records pursuant to my request, it would now be possible to engage in a thorough and detailed lodestar analysis. However, I chose to employ the percentage method and recommend that to the Court. I did this for two reasons.

***10** The first is time and expense. As noted above, the percentage method is much less burdensome than the lodestar method to administer. As a fiduciary to the class, I am particularly sensitive to that factor here. I do not wish to charge the class what it would cost for me to pore line by line through the billing records of over thirty law firms recording time in some sixteen lawsuits. In most lodestar cases, the district court judge presiding over the class action assesses the reasonableness of the hours and an adversary has culled the billings to flag issues. I have no familiarity with the efforts of Plaintiffs' Counsel in the MDL Action during the litigation and there is no adversary. And neither I nor the Court is familiar with the work that was done in the separate lawsuits outside of the proceedings in the MDL Action. Engaging in detailed line-by-line review, including review of activities in other venues, which would be required to assess reasonableness, would be expensive under any circumstances and even more so here. These burdens do not outweigh any purported advantage of the lodestar approach over the percentage approach. Rather, by employing a rougher "lodestar cross-check" below, I have retained most of the "accountability" of that approach, while preserving the administrative ease of the percentage approach.

A second advantage to the percentage approach in this case is that it is more consistent with the market-mimicking approach endorsed by the Seventh Circuit. As discussed below, that approach suggests that an *ex ante* arms-length negotiation between a hypothetical class representative and a hypothetical single law firm would have resulted in a contingent, percentage-based fee agreement rather than an hourly fee arrangement. While that fact is not determinative, *see* *Cook*, 142 F.3d at 1013 ("market's preference" for percentage-based fee is only one of several factors), it does lend additional support to following the percentage approach.

C. Relevant Market Data

In *Synthroid*, determining a market-based percentage fee was relatively easy. One group of sophisticated plaintiffs had, at the outset of their relationship, negotiated an arms-length fee agreement. Thus, there was an actual market-based transaction in the record that, in that case, "*define[d]* the market." *Synthroid I*, 264 F.3d at 720 (emphasis in original). No such luck here. Instead, I must hypothesize an arms-length negotiation at the outset between a sophisticated party representing the interests of the class and counsel seeking to represent the class. While recognizing the mistiness of trying to determining *ex post* (nearly 10 years later) what an *ex ante* fee agreement would have looked like, the Seventh Circuit has suggested three guiding lights: (1) any actual fee agreements between plaintiffs and their attorneys, (2) data from other common fund cases, and (3) information on class-counsel auctions, in which judges solicit bids from different attorneys seeking the right to represent a class. *See* *Synthroid I*, 264 F.3d at 719; *Taubenfeld v. Aon Corp.*, 415 F.3d 597, 599 (7th Cir.2005). I address each of these guides in turn.

1. Actual fee agreements

***11** This is the least helpful guide in this case. At my request, Plaintiffs' Counsel provided their contingent fee agreements with individual plaintiffs in the various actions here, which range from 25% to 45%. Such agreements shed only a flicker of light here, for two reasons.

First, *Synthroid I'* s reference to negotiated fee agreements is not well-suited beyond the type of facts in that case. The fee agreements in *Synthroid* were negotiated by insurance companies, "sophisticated purchasers of legal services," at the outset of their engagement of counsel. *Synthroid I*, 264 F.3d at 720. *See also* *In re Synthroid Marketing Litig.*, 325 F.3d 974, 976 (7th Cir.2003) (*"Synthroid II"*) ("All of the [insurance companies] are sophisticated financial intermediaries with in-house counsel who can (and do) shop for legal services in a national market."). As noted above, such agreements, where they exist, can *"define* the market." *Synthroid I*, 264 F.3d at

720 (emphasis in original). Here, in contrast, the fee agreements were entered into by presumably less sophisticated individual consumers. *See id.* ("The [insurance company] contracts provide little guidance on how to compute fees for the consumer class.").

Second, the contingent fee agreements here are between the lawyers and individual plaintiffs, not the entire class.[17] As one district court applying the Seventh Circuit's market-mimicking approach has noted, "the paramount question remains what the lawyer would hypothetically charge in a *class action* specifically." *Nilsen v. York County*, 400 F.Supp.2d 266, 279 (D.Me.2005) (emphasis in original).[18] In *Synthroid*, the insurance companies were negotiating over *their* money. The fees were going to come out of any award to the clients negotiating the agreements. Here, in contrast, no individual plaintiffs were negotiating over the class's money, and thus, "no member of the class ha[d] a sufficient stake to drive a hard-or any-bargain with the lawyer." *Continental*, 962 F.2d at 572. *See also In re Comdisco Sec. Litig.*, 150 F.Supp.2d 943, 949–50 (N.D.Ill.2001) (Shadur, J.). Thus, in this context, the fee agreements have minimal relevance to determining a proper award. *See Nilsen*, 400 F.Supp.2d at 279–80. *See also Vizcaino v. Microsoft Corp.*, 290 F.3d 1043, 1049 (9th Cir.2002).

17 Indeed, one of the fee agreements submitted to me expressly declines to establish a fee if a class is certified, noting that the attorneys will ask the Court to award attorneys' fees if a class is certified.

18 Although obviously not bound by Seventh Circuit precedent, the court in *Nilsen* "adopt[ed] the methodology of the Seventh Circuit as most reflective of what a judge does instinctively in setting a fee as well as most amenable to predictability and an objective external constraint on a judge's otherwise uncabined power." 400 F.Supp.2d at 278.

2. Awards in other cases

In *Synthroid I*, the Seventh Circuit's consideration of fees in other common fund cases appeared to be limited to other cases in which fees had been privately negotiated. 264 F.3d at 720 ("A second benchmark for determining legal fees is data from securities suits where large investors have chosen to hire counsel up front."). Thus, under the market-based approach, the pertinent awards in other common fund cases may be limited to cases in the securities or similar contexts where there were institutional or sophisticated plaintiffs to negotiate fees up front.[19] Our research uncovered no FCRA suits in which sophisticated plaintiffs negotiated attorneys' fees up front. Nevertheless, awards in other class actions generally (even where no fees were negotiated *ex ante*) may provide some marginally useful information about hypothetical market negotiations, because they may influence the expectations of lawyer and client engaging in the hypothetical negotiation. *See Nilsen*, 400 F.Supp.2d at 282–83 ("Other courts' awards necessarily affect the expectations of lawyers and, therefore, what they might agree to in voluntary negotiation.").

19 For example, in the Enron securities litigation, a large sophisticated lead plaintiff (the Regents of the University of California) negotiated an *ex ante* fee agreement with one of the MDL Counsel law firms (Coughlin Stoia), which provided an increasing sliding scale of an 8% fee on the first billion dollars, 9% on the second billion, and 10% on recoveries above $2 billion. The Court ultimately approved a fee award of $688 million, representing 9.52% of the total recovery. *See In re Enron Corp. Securities, Derivative & ERISA Litigation*, 586 F.Supp.2d 732, 766–79 (S.D.Tex.2008). The Enron fee agreement is of limited guidance here, since the balance of risks and rewards were much higher in that case (there was never any realistic prospect of a recovery in the billions here), and the work and out-of-pocket expenditures required to litigate the matter dwarfed what was required here. See *id.* at 771 *et seq.* (detailing the risks and work).

***12** A body of academic literature analyzes data on attorneys' fees in various class actions. A few recent published opinions attempt to sift through some of the literature, with varying conclusions. The court in *Nilsen* found that "[m]edian attorney fee awards in other class actions generally ... range within a few percentage points on either side of 30%." 400 F.Supp.2d at 281. Another court determined that "considerable authority (both statistical and judicial) exists to support a finding that the prevalent percentage attorney fee awards range from a low of around

20 percent ... to a high of between 25 to 30 percent....” *In re Cabletron Sys. Inc. Sec. Litig.*, 239 F.R.D. 30, 42 (D.N.H.2006). [20] The court in *Cabletron* pointed out, however, that one of the studies it cited determined that awards were typically lower in non-securities common fund cases as compared to securities cases. *Id.* at 42 (citing Theodore Eisenberg & Geoffrey P. Miller, *Attorney Fees in Class Action Settlements: An Empirical Study*, 1 J. Empirical Legal Stud. 27 (Mar.2004)). Indeed, Eisenberg and Miller determined that the mean fee award in common fund consumer class actions ranges from 16.2% to 24.3%. 1. J. Empirical Legal Stud. at 51, Table 1.

20 Like *Nilsen*, the court in *Cabletron* was not bound by Seventh Circuit precedent, but nonetheless adopted its market-mimicking approach. 239 F.R.D. at 40–41.

Eisenberg and Miller further found that “the level of client recovery is by far the most important determinant of the attorney fee amount [and that a] scaling effect exists, with fees constituting a lower percent of the client's recovery as the client's recovery increases.” 1 J. Empirical Legal Stud. at 28. As noted above, the client recovery here was $75 million cash, plus in-kind relief valued at over $34 million. The Eisenberg and Miller study reports the mean fee award for a recovery of $109 million to be 17.6% to 19.5%, and, looking only at the cash component here, the mean fee for a recovery of $75 million to be 16.9% to 23.9%. *Id.* at 73, Table 7. [21] Eisenberg and Miller propose that an attorneys' fee award within one standard deviation of the mean for any particular recovery level should be viewed as generally reasonable. *Id.* at 74. Applying the standard deviations reported by Eisenberg and Miller suggests a reasonable range of 8.4% to 27.8% of the $109 million total, or 6.7% to 32.9% of just the cash component. *Id.* at 73, Table 7. [22]

21 Table 7 of the Eisenberg and Miller study reports mean fee award percentages based on two data sets: published federal and state opinions reporting class action fee determinations, and an article in Class Action Reports that surveyed more than 600 common fund class actions. The award percentages reported from each data set are broken into deciles by size of client recovery, which is measured in 2002 dollars. The percentages based on the Class Action Reports data further breaks out non-securities cases. Thus, the figures noted above were taken from the mean fee award percentages reported in Table 7 based on the published opinion data and the non-securities Class Action Reports data for client recoveries in the ninth decile ($79 to $190 million) for the total value of the settlement here, and the eighth decile ($38 to $79 million) for only the cash portion of the settlement. *See* *Turner v. Murphy Oil USA, Inc.*, 472 F.Supp.2d 830, 864 n. 30 (E.D.La.2007) (“[Looking to Eisenberg and Miller's data sets to determine an average percentage for cases of similar magnitude] is similar to the ‘market-mimicking approach’ employed by courts within the Seventh Circuit.”).

22 The standard deviation reported for the 17.6% mean fee award on a $109 million recovery in the published opinion data set is 9.2. The standard deviation reported for 19.5% mean fee award on a $109 million recovery in the Class Action Reports data set for non-securities cases is 8.3. The standard deviation reported for the 16.9% mean fee award on a $75 million recovery in the published opinion data set is 10.2. The standard deviation reported for the 23.9% fee award on a $75 million recovery in the Class Action Reports data set for non-securities cases is 9.0.

3. Class Counsel Auctions

The Seventh Circuit has described class counsel auctions as follows:

> [T]he word “auction” is an imprecise description of the process that judges have used to choose lead counsel in class actions. Judges don't look for the lowest bid; they look for the best bid-just as any private individual would do in selecting a law firm, an advertising firm, or a construction company. Bidding law firms provide the judge with firm profiles, testimonials of former clients, predictions of expected recovery, fee proposals, and arguments on why their firm provides good value. The judge in turn acts as an agent for the class, selecting the firm that seems likely to generate the highest recovery net of attorneys' fees.

***13** *Synthroid I*, 264 F.3d at 720 (internal citations omitted). One district court in 2006 reported the winning bid structures of seven auction cases from various other courts. *Cabletron*, 239 F.R.D. at 43–44. Although the court did not attempt to survey every case in which an auction was used, it reported "bidding cases for which information relating to the fee structure was readily accessible electronically." *Id.* at 43 n. 21. The results of that survey are reprinted below:

In re: Oracle Securities Litigation

No. 3:90–cv–0931–VRW (N.D.Cal.)

Recovery	***0–12 Months***	***13+ Months***
First $1M	24%	30%
Next $4M	20%	25%
Next $ 10M	16%	20%
Excess of $15M	12%	15%

In re: Wells Fargo Securities Litigation

No. 3:91–cv–1944–VRW (N.D.Cal.)

Recovery	***<12 Months***	***>12 Months***	***Trial Forward***
First $3M	24%	27%	32%
Next $7M	22%	25%	30%
Excess of $10M	20%	23%	28%

In re: Amino Acid Lysine Antitrust Litigation

No. 1:95–cv–7679 (N.D.Ill.)

Recovery	
First $5M	20%
Next $10M	15%
Next $10M	10%
Excess of $25M	no additional fee

Wenderhold v. Cylink Corp.

No. 3:98–cv–4292–VRW (N.D.Cal.)

Recovery	***Pleading–MTD***	***MTD–SJ***	***SJ–Trial***	***Posttrial–Final Appeal***

$0–$.5M	10%	25%	30%	35%
Next $.5M	10%	17.5%	25%	30%
Next $4M	5%	15%	17.5%	20%
Next $5M	5%	10%	15%	12.5%
Next $5M	5%	7.5%	12.5%	12.5%
Next $5M	5%	5%	10%	10%
Excess of $20M	5%	2.5%	5%	10%

In re: Bank One Shareholders Class Actions

No. 1:00–cv–880 (N.D.Ill.)

Recovery

First $5M	17%
Next $10M	12%
Next $10M	7%
Excess of $25M	no additional fee

In re: Comdisco Securities Litigation

No. 1:01–cv–2110 (N.D.Ill.)

Recovery

Any sum recovered	7.5%

In re: Quintas Corp. Securities Litigation

No. 3:00–cv–4263–VRW (N.D.Cal.)

Recovery	*Pleading–MTD*	*MTD–SJ*	*SJ–Trial*	*Posttrial–Final Appeal*
First $4M	7.5%	8.5%	9%	9%
Next $4M	7%	8%	8.5%	8.5%
Next $4M	6.5%	7.5%	8%	8%
Next $4M	6%	7%	7.5%	7.5%
Next $4M	5.5%	6%	6.5%	6.5%
Excess of $20M	5%	5.5%	6%	6%

Id. at 43–44. Applying these fee structures to the present settlement would result in fee awards ranging from 4.4% to 23.3% if only the $75 million cash portion is considered, or from 3.8% to 23.2% of the entire $109.6 million cash plus in-kind amount. [23]

23 As former math and physics majors, respectively, who fled a life of mathematical rigor for the law, Mr. Perlstadt and I arguably should not be trusted with a calculator. Nevertheless, if we are right, our calculations reveal that application of the auction case fee structures to the settlement here would result in the following fee awards: *Wenderhold:* 4.4% of cash, 3.8% of total; *Bank One:* 7.0% of cash, 6.4% of total; *Amino Acid Lysine:* 8.0% of cash, 7.1% of total; *Quintas:* 6.0% of cash, 5.8% of total; *Comdisco:* 7.5% of cash, 7.5% of total; *Oracle:* 16.4% of cash, 16.0% of total; *Wells Fargo:* 23.3% of cash, 23.2% of total. In the cases of *Bank One* and *Amino Acid Lysine,* we modified the scale slightly. The winning bids in each case had a self-imposed cap on fees. The Seventh Circuit criticized that result in *Synthroid I,* 264 F.3d at 720–21, as eliminating an incentive for class counsel to increase recoveries for the class. Thus, our calculations assumed a 5% fee recovery at the highest tier in each of those two cases.

It should be kept in mind that, except for *Amino Acid Lysine,* an antitrust case, these auction cases were all in securities litigation, which Eisenberg and Miller noted generally result in higher fee awards. (A typical securities or antitrust case involves more risk than was present in this case; I discuss risk below.) In any event, as with the *ex post* fee awards in other cases considered above, the fee structures in the auction cases considered here are, at best, only illustrative. Each case has unique facts and risk factors. Yet the auction cases do offer insight into what attorneys may be willing to accept to represent a class before the outcome of litigation is known. These cases belie common rules of thumb or conventional wisdom, such as a "norm" of a 25% or 33% contingent fee, which underlie some of the *ex post* fee awards from other Circuits analyzed in the Eisenberg & Miller study discussed earlier.

D. Application

***14** In trying to apply *Synthroid I'* s imperative to "do [my] best to award counsel the market price for legal services, in light of the risk of nonpayment and the normal rate of compensation in the market at the time," 264 F.3d at 718, I now try to imagine a hypothetical negotiation at the outset of the litigation between a single sophisticated representative of the potential class and a single-group of lawyers proposing to represent the potential class. This approach obviously omits much of the complexity present in this litigation, but my goal here is not the impossibility of replicating exactly an *ex ante* market transaction, but simply to approximate one as best I can given the information available. *See Synthroid I,* 264 F.3d at 719 (noting that it is "impossible" to derive the *ex ante* result years later, but consideration of other market transactions is a "starting point"); *Nilsen,* 400 F.Supp.2d at 279.

First, I believe a negotiation likely would have resulted in a contingent, rather than a pure hourly, fee arrangement, as were most of the insurer agreements in *Synthroid. See Synthroid II,* 325 F.3d at 976. The fact that the individual fee agreements here were contingent lends further support to this conclusion. [24]

24 It is not uncommon that a blended arrangement might be negotiated, e.g., a discounted or blended hourly rate combined with a contingent bonus at a smaller percentage than would pertain to a pure contingency fee situation. However, such arrangements are negotiated when the client has the funds to pay a reduced hourly rate. That is not the case in a consumer class action like this case.

Next, I believe that a negotiation likely would have resulted in a downward sliding scale, such that, as in most of the auction cases noted above, the attorneys' fee award percentage decreases as total class recovery increases. While some judges in the auction cases told bidding law firms that they preferred a sliding scale, Judge Shadur in *Bank One* and *Amino Acid Lysine* left it within the discretion of bidding counsel to determine how to formulate their proposals. *See* Laura L. Hooper & Marie Leary, *Auctioning the Role of Class Counsel in Class Action Cases: A Descriptive Study,* 32 (Fed. Judicial Ctr.2001) (reprinted at 209 F.R.D. 519). Whether as a result of judicial pressure or on counsel's own initiative, the auction cases suggest (consistent with the Eisenberg and Miller study)

that counsel competing in the market are willing to accept class action representations on a downward sliding fee basis. A hypothetical sophisticated representative of the class here would likely have demanded it. *See also Synthroid II*, 325 F.3d at 975 ("[T]he market rate, as a percentage of recovery, likely falls as the stakes increase."). Further, in its own application of the market-mimicking approach in *Synthroid II*, the Seventh Circuit ultimately awarded fees to consumer class counsel on a downward sliding scale. 325 F.3d at 980 (awarding class counsel 30% of the first $10 million in class recovery, 25% of the next $10 million, 22% of the next $26 million, and 15% of all amounts over $46 million up to the $88 million recovery).

Finally, I believe that a hypothetical *ex ante* negotiation would have resulted in a lower contingent fee percentage for in-kind relief. Presumably, the class here (indeed, probably most classes) would rather have cash than in-kind relief. A check for $60 is more valuable to most people than getting free credit monitoring services with a retail value of that amount. The consumer might prefer to spend the money on groceries or something else. Thus, the class would want to incentivize counsel to push for more cash relative to in-kind relief. The class also would not want attorneys' fees on in-kind relief to drain the cash portion of any settlement. And they would want the in-kind recovery forming the basis for a fee award to be valued at the amount of in-kind benefits actually redeemed, not those potentially available. Valuing a coupon recovery based on redeemed value is now required for percentage fee awards under the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1712(a). While not applicable to this case, CAFA's objective of tying the attorneys' fee to the actual redeemed recovery is likely a point the negotiator for the class would have insisted on. Thus, the *ex ante* agreement would assign a lower percentage to the redeemed in-kind recovery of the class.

***15** Determining the foregoing criteria (contingent fee, sliding scale, lower fee for in-kind relief) was the easy part. Now comes the hard part. In an exercise that is clearly more art than science, I must attach actual numbers to the hypothetical downward sliding contingent fee agreement. To summarize the three types of data discussed above (with their varying relevance and utility), the actual fee agreements here entered into between individual plaintiffs and their counsel range from 25% to 45%, fee awards from other (mostly *ex post*, non-market based) cases suggest a total fee award here of anywhere from 6.7% to 32.9%, and the auction cases suggest a total fee award of anywhere from 3.8% to 23.3%. The breadth of these ranges reveals an irony. The Seventh Circuit criticized the non-market approach of other Circuits as "chopped salad" because they relied on vague and ultimately arbitrary notions of fairness without the objectivity and discipline of the market. *Synthroid I*, 264 F.3d at 719. However, as is evident from the above discussion, when trying to imagine a hypothetical market transaction nearly a decade after the fact, the market data provide only limited and inconsistent guidance. In this case, the market approach may not produce "chopped salad," but the variety of data it generated still seems to yield something akin to a vegetable stir-fry.

Culinary metaphors aside, one additional, important factor advances the analysis and helps narrow the range of market information: consideration of the *ex ante* risks and potential rewards of the litigation. *See Sutton v. Bernard*, 504 F.3d 688, 693 (7th Cir.2007) (market price is determined, in part, by risk of nonpayment and the stakes of the litigation), *citing Synthroid I*, 264 F.3d at 721. [25]

25 Obviously other factors would affect the final outcome of any negotiation, such as skill of the negotiators on each side, the relationship between the parties, and the class negotiator's assessment of the attorneys' quality. Such intangibles are impossible to consider in the absence of actual *ex ante* negotiations, and their omission here does not undermine this approach, which, as noted above, is market-mimicking, not market-replicating.

The potential rewards here were substantial. If a nationwide class could be certified, and statutory damages were available, the potential exposure to Trans Union was in the billions. [26] Facing potentially company-destroying exposure, a settlement of eight or low-nine figures appears to have been a reasonable *ex ante* prospect, anywhere from $20 million at the low end, to $40 or $50 million in the middle, to $75 to $100 million or more at the high end.

26 The FCRA provides for statutory damages from $100 to $1,000 for willful violation of the act. 15 U.S.C. § 1681n(a)(1)(A). A nationwide class reportedly could have covered 190 million people.

In contrast, regarding risk, the Court determined in its April 6 Order that the risk to the attorneys in taking on this litigation was relatively low. By 1994, the FTC had determined that Trans Union was violating the FCRA. Although that decision was reversed by the D.C. Circuit in 1996, the FTC on remand again held in 2000 that Trans Union was violating the FCRA, which was ultimately upheld by the D.C. Circuit in 2001. *See generally Trans Union Corp. v. FTC*, 245 F.3d 809 (D.C.Cir.2001). Up to this point, I have not specified exactly *when* the hypothetical negotiation should be considered to have taken place, other than to describe it as *ex ante* or "at the outset." Recall that the *Frey* Action and the *Martinelli* Action were filed in 1998 and 1999. In 1998, the FTC action appears to have been in the remand stage following the D.C. Circuit's original reversal. Thus, Trans Union's liability for FCRA violations had not been definitively determined at that time. However, since we are considering a negotiation concerning a nationwide recovery, I think it is reasonable to assume that the hypothetical negotiation would have occurred some time during 2001, after the MDL assignment to this Court and coordinated, nationwide proceedings were commencing. Given the FTC's continued litigation against Trans Union, and the ultimate affirmance of Trans Union's liability by the D.C. Circuit in 2001, I believe that the negotiating parties would assess the risk of a ruling that Trans Union did not violate the FCRA as relatively low. *See* April 6 Order at 9 ("[T]he risk of no recovery was virtually nonexistent due to the FTC action."). The anticipated costs of discovery and experts would have been less here than in many large class cases with complicated technical issues, such as securities, product liability or antitrust cases. As the Court found, *id.* at 3, the *ex ante* risks in the actions here would have revolved around the scope and structure of class certification, and establishing willfulness for purposes of statutory damages, matters that go to the amount rather than fact of recovery. I am unable to quantify these risks with precision, but the total *ex ante* risks to counsel in accepting these representations were relatively low, certainly lower than most contingent class actions. That conclusion is borne out by the fact that over thirty law firms here ultimately participated as plaintiffs' counsel. Many law firms plainly perceived a favorable risk/reward ratio here.

***16** In any event, the risks to Plaintiffs' Counsel here appear to be lower than the risks facing the consumer class counsel in *Synthroid*. *See Synthroid II*, 325 F.3d at 978 ("Consumer class counsel ... took the risk that they would come away with nothing ... [and] that was a significant risk, for the consumer class did not have an easy road."). In *Synthroid*, the district court had divided plaintiffs into two classes, one of consumers, and one of third-party payors such as insurers. *Synthroid II*, 325 F.3d at 976. After noting that the consumer class faced much more risk than the third-party payor class, the Seventh Circuit held that in order to compensate for risk-bearing, the marginal attorneys' fee rates for each band of recovery should be higher for consumer class counsel than for the third-party payor class counsel, who had negotiated a flat 22% rate. *Id.* at 978. Applying that concept here, given the lower risks to counsel here than to class counsel in *Synthroid* and the absence of any market data other than the broad ranges discussed earlier, I conclude that a reasonable and plausible *ex ante* negotiation here would have resulted in something akin to the *Synthroid* fee structure awarded to consumer class counsel, with reduced percentages of 5% to 7% at each potential band of recovery. Further, as discussed above, I believe a reasonable *ex ante* negotiation here would have resulted in a lower percentage fee for in-kind than cash relief. Therefore, I believe the following fee structure is a reasonable approximation of what an *ex ante* arms-length market transaction would have produced in this action, as compared to that determined by the Court in *Synthroid II:*

Recommendation		**Synthroid II**	
Recovery	***Fee Percentage***	***Recovery***	***Fee Percentage***
$ 0–10 million	25%	$ 0–10 million	30%

$10–20 million	20%	$10–20 million	25%
$20–45 million	15%	$20–46 million	22%
$45+ million	10%	$46+ million	15%
In–Kind Relief	5%		

Plugging these percentages into the $75 million cash recovery and the $34.6 million value of the in-kind relief yields a total attorney fee award of $12.98 million.

Of course, it is possible that an actual negotiation might have resulted in a higher scale or a lower scale. It might have yielded a formula resulting in something like the $10.83 million award in the Court's April 6 Order, or something closer to the $18.75 million cap. But no one can know here what *the* market-based result would have been in a transaction that never occurred. There are no market tables, Kelly Blue Books or Ebay auctions to consult to gauge the going rate in 2001 for multi-district FCRA lawsuits. However, the above analysis yields *a* plausible and reasonable market-based result consistent with the criteria set forth in the Seventh Circuit cases. That is sufficient under the cases. In addition, the cross-checks discussed below confirm the reasonableness of the recommended award.

E. Cross–Checks

***17** On an overall percentage basis, the award of $12.98 million represents 17.31 % of the $75 million cash portion of the settlement, and 11.84% of the $109.6 total settlement amount (cash plus in-kind). These numbers fall comfortably within the ranges suggested by Eisenberg and Miller (6.7% to 32.9% of the cash, 8.4% to 27.8% of the total) and the auction cases (4.4% to 23.3% of the cash, 3.8% to 23.2% of the total). I recognize, as the Court in *Nilsen* noted, “that the fact that my award falls within the range of other judicial awards serves mostly to give me comfort against embarrassing comparisons.” 400 F.Supp.2d at 283 n. 41.

As a further check on the reasonableness of this recommended award of $12.98 million, I think it is useful to run “cross-checks.” First, as a final exercise of *ex ante* imagination, I have tried to gauge how the hypothetical plaintiffs' law firm would have evaluated the tiered percentages recommended above. Any rational firm engaged in such an *ex ante* negotiation would want to estimate the opportunity cost of the engagement: How many hours would it need to invest that might be more profitably spent elsewhere? What likely lodestar would be generated and would the engagement probably provide a premium over the forecast lodestar to compensate for the risk? As noted above, the plaintiffs' firm would probably have valued the case at about $20 million at the low end, $50 million in the middle and $75 to $100+ million at the high end. The tiering suggested above would yield a fee of $4.5 million on a cash recovery of $20 million, $8.75 million on a cash recovery of $50 million, and $11.25 to $13.75 million on a cash recovery of $75 to $100 million. At an assumed blended 2001 hourly rate of about $300 (which is probably generous), the lower recovery would support a projected hourly investment of about 15,000 hours (without multiplier) while the top recovery would support an hourly investment of 25,000 to 33,000 hours (without multiplier). The hypothetical plaintiffs' firm would find a fair amount of cushion for these investments of time and find the suggested tiering attractive in this case. [27]

[27] Here, Plaintiffs' Counsel reported a combined total of over 38,000 hours worked, but, as discussed below, that figure is excessive.

As an additional cross-check, I turn now to an *ex post* analysis, based on the actual historical lodestars. I first discuss the lodestars claimed by Plaintiffs' Counsel, and then I discuss my estimate of what the actual lodestars would be after a more rigorous analysis, which I believe provides a more valid cross-check than simply taking the claimed lodestars at face value.

Many courts, including at least one court in this district, have used a lodestar cross-check against a percentage fee award. *See, e.g.*, *In re Rite Aid Corp. Sec. Litig.*, 396 F.3d 294, 305 (3rd Cir.2005); *Goldberger v. Integrated Resources, Inc.*, 209 F.3d 43, 50 (2d Cir.2000); *Abrams v. Van Kampen Funds, Inc.*, No. 01 C 7538, 2006 WL 163023, at *7–*8 (N.D.Ill. Jan.18, 2006) (Hart, J.).

The purpose of a lodestar cross-check is simply to determine whether a proposed fee award is excessive relative to the hours reportedly worked by counsel, or whether the fee is within some reasonable multiple of the lodestar. *Rite Aid*, 396 F.3d at 306 ("The lodestar cross-check serves the purpose of alerting the trial judge that when the multiplier is too great, the court should reconsider its calculation under the percentage-of-recovery method...."); *Vizcaino*, 290 F.3d at 1050 ("[T]he lodestar may provide a useful perspective on the reasonableness of a given percentage award."). [28] When used merely as a cross-check, the lodestar analysis can be "abridged." *Rite Aid*, 396 F.3d at 305; *see also id.* at 306–07; *Goldberger*, 209 F.3d at 50.

28 *But see In re Comdisco Sec. Litig.*, 150 F.Supp.2d 943, 948 n. 10 (N.D.Ill.2001) ("To be sure, when a fee award is enormously disproportionate to the lawyers' expenditure of time ..., it may be useful for a court to express the disapproval of that disparity in terms of pointing to a correspondingly staggering lodestar multiplier-a sort of *Jacobellis v. Ohio* ('I know it when I see it') demonstration. But when the issue comes down to whether a multiplier of 2 or 5 or 7 (or what have you) is or is not 'reasonable,' so as to serve as some sort of check on the reasonableness of a percentage-of-recovery fee award, candor compels recognition of the fact that the process has become wholly subjective....").

***18** I believe there is a role for a lodestar cross-check, notwithstanding the statement in *Synthroid II* that the efficiency (or lack thereof) of counsel should not be used "to reduce class counsel's percentage of the fund that their work produced." 325 F.3d at 979–80. Consistent with *Synthroid II*, the *ex ante* percentages above were derived from the *Synthroid II* tiers and without regard to any lack of efficiency of counsel during the lawsuit. However, as noted above, this case lacks the type of actual, arms-length agreement that "defined" the market in *Synthroid*, and we were forced to engage in the imprecise estimation of the *ex ante* agreement. That approach relied on several assumptions and widely dispersed data from other cases. The uncertainty here is greater than in *Synthroid II*. In this context, then, there is a proper role for considering the actual hours spent in the case as a cross-check on the proposed percentages. A wide divergence between the lodestar and the percentage might indicate a problem that would warrant revisiting the assumptions underlying the percentage method. As discussed below, as it turns out, there is no wide divergence here, and no reason to reconsider the percentages.

MDL Counsel, Liaison Counsel, *Frey* Counsel, and Louisiana Counsel reported a total lodestar of $18.25 million. (Doc. 564–2 at 18.) Texas Counsel, after my request to remove time related to the attorneys' fee proceedings, reported a lodestar of $1.49 million. (Texas Counsel's Response to Special Master's Request, Aug. 18, 2009, at 2.) Combined, all counsel reported a total lodestar of $19.74 million. The actual award of $12.98 million thus represents a multiplier of 0.66 on the lodestar claimed by Plaintiffs' Counsel. This fractional multiplier does not raise a red flag for me to suggest that the $12.98 million award is unreasonable for several reasons.

First, Plaintiffs' Counsel (except Texas Counsel), in their joint fee petition, acknowledged that their total fee request of $15.1 million was significantly less than their claimed lodestar. Courts employing a lodestar cross-check have entered percentage awards that did not fully compensate counsel for their claimed lodestar. *See In re Insurance Brokerage Antitrust Litig.*, MDL No. 1663, 2009 WL 2855855, at *32, *35 (3d Cir. Sept.8, 2009) (lodestar multiplier of 0.4); *Blackman v. O'Brien Envtl. Energy, Inc.*, No. Civ.A. 94–5686, 1999 WL 397389, at *2 (E.D.Pa. May 12, 1999) (0.82 multiplier); *Fanning v. Acromed Corp. (In re Orthopedic Bone Screw Products Liability Litig.)*, No. 1014, C.A. 97–381, 2000 WL 1622741, at *8 (E.D.Pa. Oct.23, 2000) (0.62 multiplier).

Second, and more importantly, even without conducting a detailed lodestar analysis, it is readily apparent that the lodestars claimed by Plaintiffs' Counsel are excessive. The 0.66 multiplier is, essentially, a fiction resulting

from plugging an excessive lodestar into the denominator. While some courts take claimed lodestars at face value for purposes of running the cross-check, *see, e.g.*, *Rite Aid*, 396 F.3d at 307; *Goldberger*, 209 F.3d at 50; *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 342 (3d Cir.1998), courts are not required to do so. Indeed, under the venerable principle "garbage-in-garbage-out," the cross-check itself can have little validity if the lodestar itself is invalid. Thus, "any lodestar cross check should be based on billings that have some semblance of reasonableness." *In Re Keyspan Corp. Sec. Litig.*, No. 01 CV 5852(ARR), 2005 WL 3093399, at *18 (E.D.N.Y. Sept.30, 2005) (reducing claimed fee lodestar by 20% to account for excessive rates, excessive hours and failure to bill certain tasks at lower rates, resulting in a 1.42 multiplier as compared to 1.14 multiplier based on claimed lodestar); *Abrams*, 2006 WL 163023, at *7–*8 (Hart, J.) (reducing claimed fee lodestar by about 40% to account for excessive hourly rates and top-heavy staffing, resulting in a multiplier of 1.88 as compared to 1.14 multiplier on claimed lodestar). I therefore consider the claimed hourly rates and hours billed to determine an adjusted lodestar with "some semblance of reasonableness."

***19** The lodestar reported by Plaintiffs' Counsel reflects a total blended hourly rate of roughly $514.[29] This appears excessive relative to normal Chicago area rates (assuming Chicago market rates apply to all counsel, which is debatable[30]). For example, of the four Chicago law firms responding to a 2008 survey of the nation's largest law firms by The National Law Journal, none reported a firm-wide average hourly rate of more than $500. *See A Nationwide Sampling of Law Firm Billing Rates*, The National Law Journal (Dec. 8, 2008) (available at http://www.law.com/jsp/nlj/PubArticleNLJ.jsp? id=1202426491559) (last visited Sept. 19, 2009).[31] Indeed, only seven of the 127 law firms responding to the survey reported a firm-wide average hourly rate of more than $500.[32] And these firms represent the peak of the market. In a lodestar analysis, counsel is entitled to a reasonable, market-based rate, not the highest rates that lawyers can cherry-pick from the market. Some recent decisions in this district in statutory fee cases have approved of market rates substantially below those claimed by many Plaintiffs' Counsel here. *See, e.g.*, *Dupuy v. McEwen*, No. 97 C 4199, 2009 WL 2498197, at *5–*6 (N.D.Ill. Aug.13, 2009) (Pallmeyer, J.) (approving 2007 attorney rates ranging from $230 to $520, with two experienced lead counsel at $460 and $415)[33]; *Robinson v. City of Harvey*, No. 99 C 3696, 2008 WL 4534158, at *7 (N.D.Ill. Oct.7, 2008) (Lefkow, J.) (finding reasonable and below market an hourly rate of $395 for "singularly formidable" civil rights trial lawyer). And in 2004, this Court approved rates ranging from $175 to $375 for the Edelman firm, who serve as local counsel for Texas Counsel. *Zaghloul v. DaimlerChrysler Services, LLC*, No. 03 C 4499, 2004 WL 2203427, at *2 (N.D.Ill. Sept.29, 2004).

29 MDL Counsel, Liaison Counsel, *Frey* Counsel, and Louisiana Counsel reported over 35,800 hours worked. Texas Counsel reported over 2,600 hours worked. Dividing the $19.74 million total lodestar by the 38,400 hours claimed by all counsel equals approximately $514 per hour.

30 One might question whether Chicago rates should be used, as opposed to the rates prevailing in each of the cities in which the various lawsuits here were filed or of the cities in which each Plaintiffs' Counsel normally practices. The law is not entirely clear on this point. In statutory fee shifting cases, the Seventh Circuit presumes that the attorney's actual billing rate, rather than a local forum market billing rate, applies, although a court has some discretion to use forum rates in some circumstances, such as where an attorney (like Ms. Wheelahan, whose practice is entirely contingent) is unable to provide evidence of actual billing rates. *See Mathur v. Bd. of Trustees of Southern Ill. Univ.*, 317 F.3d 738, 743–44 (7th Cir.2003). Matters are more complex in an MDL matter. This is not a single lawsuit. It may not make sense for the hourly rates to depend upon the fortuity of the venue chosen by the MDL Panel, as opposed to the venues in which the individual lawsuits were filed or the "hometown" rates of Plaintiffs' Counsel. However, since I am merely looking to the lodestar as a cross-check against the market-mimicking application of a percentage recovery, and not rigorously examining the hours and rates and each of the dozens of counsel from across the country, my simplifying comparison to a single market is not unreasonable. *Cf. In re "Agent Orange" Product Liability Litig.*, 818 F.2d 226, 232 (2d Cir.1987) ("[W]e conclude that, in an exceptional multiparty case such as this, where dozens of non-local counsel from all parts of the country are involved, public policy and administrative concerns call for the district court

to be given the necessary flexibility to impose a national hourly rate when an adequate factual basis for calculating the rate exists."); *Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals, Inc.*, 264 F.Supp.2d 753, 764 (S.D.Ind.2003) (MDL cases may justify use of a single "national" rate scale). For present purposes, a comparison to the Chicago market, with which I am most familiar, is not unfair either to Plaintiffs' Counsel or the class. *See In re Folding Carton Antitrust Litig.*, 84 F.R.D. 245, 264–65 (N.D.Ill.1979) (adopting a report recommending that "a proper hourly rate structure for a national class action would reflect the rates prevalent for attorneys in the Chicago Metropolitan Area").

31 Jenner & Block, one of the four responding Chicago firms, did not report a firmwide average. It did, however, report an average billing rate of $616 for partners, and $393 for associates. Brinks Hofer Gilson & Lione reported a firmwide average billing rate of $392, Vedder Price reported a firmwide average billing rate of $385, and Winston & Strawn reported a firmwide average billing rate of $448.

32 Though I note that two of those seven, Milwaukee firm Foley & Lardner ($508/hour) and New York firm Loeb & Loeb ($534/hour) do have offices in Chicago.

33 Disclosure: I represented plaintiffs' counsel regarding the fee petition in *Dupuy*, and my 2007 hourly rate of $410 was among the rates approved by Judge Pallmeyer. My 2009 rate is $440.

A comparison to the so-called *Laffey* Matrix, adjusted for the Chicago market, also suggests that a total blended hourly rate of $514 is too high. The *Laffey* Matrix is a chart of hourly rates for attorneys of varying experience prepared and updated by the Civil Division of the United States Attorney's Office for the District of Columbia. *See Laffey Matrix 2003–2009* (available at http:// www.usdoj.gov/usao/dc /Divisions/Civil_Division/ Laffey_Matrix_7.html) (last visited Sept. 19, 2009). Although the *Laffey* Matrix was designed for use in statutory fee-shifting cases, *see id.* (explanatory note 1), it has been used in lodestar cross-checks of awards in common fund cases. *See, e.g., Martin v. FedEx Ground Package Sys., Inc.*, No. C 06–6883, 2008 WL 5478576, at *6–*8 (N.D.Cal. Dec.31, 2008). [34] Because the *Laffey* Matrix is tailored to the Washington D.C. market, an upward adjustment of 1.1% is appropriate. [35] This adjustment yields a range of $227 per hour for attorneys with one to three years of experience, to $470 per hour for attorneys with over twenty years of experience. As with the National Law Journal Survey results, the adjusted *Laffey* Matrix suggests that a total blended hourly rate of $514 is too high.

34 Judge Lefkow also considered the Matrix in reviewing the hourly rates for a statutory fee award in *Robinson, supra.*

35 The 1.1% figure comes from comparing the U.S. Office of Personnel Management's 2009 General Schedule Locality Pay Tables for Chicago and Washington D.C., available at http:// www.opm.gov/oca/09tables/indexGS.asp. *See generally In re HPL Techs., Inc. Sec. Litig.*, 366 F.Supp.2d 912, 921–22 (N.D.Cal.2005) (adjusting *Laffey* Matrix to San Francisco market).

***20** The excessiveness of the blended rate becomes more apparent when one makes a brief granular inspection of claimed rates of individual lawyers and firms. Louisiana and Texas Counsel provide clear examples. Ms. Wheelahan, who logged most of the hours claimed by Louisiana Counsel, claims an hourly rate of about $625. Even if we assume Chicago rates apply to her, as opposed to something closer to the hourly rate of $225 approved in 2005 by the court in her home district, *see White v. Imperial Adjustment Corp.*, No. Civ.A. 99–3804, 2005 WL 1578810, at *8 (E.D.La. June 28, 2005), *and see* n. 15 above, it is likely that a reasonable Chicago market rate for her would be at least 25–30% lower. Similarly, the claimed rates of Houston lawyers Caddell ($725), Chapman ($600), and Fein ($450), are about 20% or more above what I would recommend in a lodestar analysis based on their respective years of experience. Indeed, the Chicago rates of Liaison Counsel, Ms. Saunders ($575), and local counsel for Texas Counsel, Mr. Edelman ($550), are in the ballpark of reasonableness for attorneys of their experience, which coincides with the $575 rate of Texas Counsel's Mr. Toups. Finally, while the rates of some MDL Counsel appear reasonable and may be below the Chicago market (e.g., Boise attorney and *Frey* counsel, John Zarian, who claims a $395 rate and is one of the few counsel in the case who has clients actually paying that rate), other claimed MDL Counsel rates are too high and would warrant a reduction similar to that of Texas Counsel. For example, the blended hourly rate of The Righetti Law Firm was nearly $670 and Coughlin Stoia nearly $517.

Turning from rates to claimed hours, it is clear that deep cuts in hours would be made if a formal lodestar analysis were used. The most obvious case is the more than 7,000 hours claimed by Ms. Wheelahan. Even after eliminating the obvious excesses identified by the Court in its April 6 Order (the travel time of about 400 hours and hours for clerical tasks), the hours appear excessive. There are vast numbers of hours spent on research and writing, for example. Not only is it likely that fewer hours could have been expended, much of that time should have been billed at lower rates than the single "partner-level" rate she charges for all of her tasks. [36] I conservatively estimate that a detailed review of Ms. Wheelahan's claimed hours would result in a reduction of at least 25–33%, and possibly much more. *See* *White*, 2005 WL 1578810, at *15–*16 (reducing Ms. Wheelahan's research and writing time by 25% and reducing total time by about 34%). [37]

36 Sometimes partners can do research more efficiently than associates, due to greater experience or familiarity with a case. However, it is often the case that research tasks can and should be done by associates at lower rates, and fee-paying clients sometimes insist on that. A practitioner is free to make a business decision not to hire associates, but neither a paying client, nor a court acting as a fiduciary to a class, must accept partner-level rates for associate-level work where such work can be more efficiently done at the lower level.

37 I note that this reduction gives Ms. Wheelahan the benefit of a substantial doubt. I have not deducted from her lodestar the more than 1,300 hours she claims to have spent on the state court *Andrews* Action. MDL Counsel point out that in persuading this Court to remand that action to Louisiana state court in 2003, Ms. Wheelahan " 'disclaim[ed] any right to recover attorney's fees in the state law [complaint],' either from defendant or from any recovery by the class members by way of common fund or otherwise." Dec. 3, 2003 Op. and Order at 4. Ms. Wheelahan acknowledges this disclaimer, but contends that the waiver was only of the namedplaintiff's right to seek a statutory fee award, which would have increased the amount in controversy, not counsel's right to seek a fee from a common fund, which does not bear on the amount in controversy. Further, she argues that the Stipulation of Settlement put the *Andrews* lodestar back in play because the Stipulation's definitions included that case within the settled "Actions" and it further provided that the fee award would cover fees "incurred in connection with prosecuting and settling the Actions." Doc. 462–3 at 24, § 4.1. These definitions, however, do not answer whether fees, if previously waived, can be unwaived, particularly where they were arguably waived in order to convince a court that federal jurisdiction was lacking. This raises a question of judicial estoppel, which, if valid, would reduce the claimed Louisiana lodestar by about another $800,000. However, since I am only performing a rough cross-check, I am giving Louisiana Counsel the benefit of the doubt and am not resolving the issue or making any deduction.

While Texas Counsel made some use of professionals billed at lower rates where appropriate, my cursory review of their billing records reveals some duplication, top-heaviness and excess that would result in moderate hourly cuts of at least 10% on top of the rate cuts of about 20%. The same is true of MDL Counsel, and one could legitimately question whether substantial cuts would be made in the hours they expended unsuccessfully pursuing the First and Second Proposed Settlements. Finally, all counsel had duplication in the parallel motions for final approval of the Final Settlement, which resulted from the failure of counsel to agree on a common approach. Without assigning blame for that result, I nevertheless am confident that a detailed lodestar analysis would not charge the class for the consequences of counsels' failure to agree, and substantial reductions would be made.

***21** For the foregoing reasons, the more realistic and reasonable lodestar of Plaintiffs' Counsel is well below the claimed amount of $19.74 million. While Louisiana Counsel claim a lodestar of about $4.7 million based on 7,524.6 hours, the reductions in hours and rates noted above would result in a total lodestar reduction of *at least* 50–60%, to around $1.88 to $2.35 million. Texas Counsel's claimed lodestar of $1.49 million would probably be reduced by about 25–33%, to around $990,000 to $1.12 million. The claimed lodestar of about $12.9 million by MDL/*Frey* Counsel would also likely be reduced by about 25–33%, to about $8.6 to $9.7 million. Thus, adding in the $550,000 agreed payment to Liaison Counsel (whose lodestar was claimed to be about $613,000) the lodestar that reflects a "semblance of reasonableness" would range from about $12 to $13.7 million (and quite possibly lower). As compared to the recommended percentage-based award of $12.98 million, this yields a multiplier

of 0.95 to 1.08. Accordingly, I am satisfied that the recommended fee award of $12.98 million derived from application of the market-mimicking approach is comfortably within the range of reasonableness.

F. Allocation

1. The amounts requested by counsel

"Allocating a limited pot of common benefit fees among numerous counsel, all of whom are talented and capable attorneys and many of whom have made a significant contribution to the ultimate success of this case, is an unenviable task that is sure to lead to hurt feelings and bruised egos. Nevertheless, it has to be done." *Turner v. Murphy Oil U.S.A., Inc.*, 582 F.Supp.2d 797, 812 (E.D.La.2008) (internal citation omitted). To avoid the "unenviable task," I gave Plaintiffs' Counsel advance notice that I would recommend a total fee award of $12.98 million, so that they could make another attempt at agreeing to an allocation. After the attempt failed, I requested briefs.

The allocation briefs were remarkable for the size of the requests. While I expected counsel to aim high, I did not expect them to ask for *more* than they had previously requested from the Court. Nor, in light of the $12.98 million pie they were asked to divide, did I expect them collectively to shoot for more than the settlement cap of $18.75 million. Yet they did ask for more. Much more.

Most remarkable was the swelling of Texas Counsel's request. In their fee petition to the Court, Texas Counsel requested $2,850,000 in fees. They claimed their lodestar was $1,613,578.75. (Doc. 570–2 at 15.) This request was made when it was unknown what total fee the Court might award, subject only to the overall cap of $18.75 million. When I reviewed Texas Counsel's billing records (which had not been provided to the Court), I determined that they had incorrectly included in their lodestar a substantial amount of fees related to the attorneys' fee proceedings, which are not recoverable from common fund awards. *See* April 6 Order at 7. I asked them to revise their billing statement to eliminate such time. Their revised, adjusted claimed lodestar dropped to $1.49 million. Even though the funds potentially available for allocation had dropped from $18.75 million to $12.98 million, and their claimed lodestar had fallen by about $121,000, Texas Counsel *increased* their requested share of the fees by nearly a million dollars, from $2,850,000 to $3,729,212.50. The claimed lodestar multiplier implicit in this request increased from 1.77 in the initial request to 2.50. Texas Counsel provided no explanation for this tacit amendment of their original fee petition, nor any explanation for why their share should have increased by $1 million in the face of a shrunken available pie.

***22** Not to be outdone, Louisiana Counsel's allocation brief requests $7,915,000, which represents about 61 % of the total recommended fee award. As part of that request, as if to provide a new definition of the term *"chutzpah,"* Louisiana Counsel claims an entitlement to the entire increase of about $2 million between my recommended award and the award in the Court's vacated April 6 Order. Louisiana Counsel attributes the increase entirely to the Rule 59(e) motion she filed, which is not only incorrect, but ignores her involvement in the ethical issues prompting my appointment.

The allocation position of MDL/*Frey* Counsel, who consist of about thirty law firms, is more realistic under the circumstances. They seek $9,380,000, about 72% of the total. All told, the fees sought by Plaintiffs' Counsel, including the $550,000 allocated to Liaison Counsel by agreement, total $21,574,212.50, nearly $3 million over the settlement cap and nearly $9 million more than the pie they were asked to divide. Clearly, something has to give.

The following chart summarizes the proposed allocations of counsel and the recommended allocation I determine below. [38]

38 The figures in the chart do not include the $550,000 allocated to Liaison Counsel or one-half of the Special Master's fees and expenses (which I had told them to assume would be about $50,000, and turned out to be $55,638), and, thus, do not add up to $12.98 million. Texas counsel only suggested a figure for themselves, without recommending allocation between MDL and Louisiana Counsel. Louisiana and MDL Counsel proposed allocations among all counsel. Louisiana's figures apparently did not subtract anything for Special Master fees.)

	MDL	*Louisiana*	*Texas*	*Total*
MDL Proposal	$9,380,000	$1,800,000	$1,200,000	$12,380,000
Louisiana Proposal	$3,115,000	$7,915,000	$1,400,000	$12,430,0 00
Texas Proposal	N/A	N/A	$3,729,212.50	N/A
Special Master's Recommendation	**$7,836,683 (63.33%)**	**$2,722,360 (22%)**	**$1,815,319 (14.67%)**	**$12,374,362 (100%)**

I approach the allocation issue mindful of my limitations. Of all of the relevant participants (the Court, Plaintiffs' Counsel, and me), I know the least about the history of the case and the relative contributions of counsel to the outcome. I was not there. I have gleaned a fair amount from review of the court record, the billing records, some of the statements of counsel made in e-mails produced to me, and the allocation briefs. But this after-the-fact education is no match for the Court's immersion in the case and knowledge of the participants. Nevertheless, sometimes the perspective of an outsider has value, and I hope the following analysis is helpful to the Court.

2. Allocation standards

I directed counsel to include in their allocation briefs citations to cases setting forth the standards applicable to the allocation analysis. Only MDL Counsel attempted to comply with this request, and the authority they cited was not directly apposite. They cited *Sutton*, 504 F.3d at 692–93, which reaffirmed the *Synthroid* standards that, in approximating the *ex ante* market determination of fees at the outset of the litigation, the Court should consider factors such as the "risk of nonpayment," "amount of work necessary to resolve the litigation," and "the stakes of the case." But the allocation analysis here cannot be based on the *ex ante* approach of *Synthroid* and *Sutton.* In some cases, it might be possible to approximate what allocation terms might have been negotiated at the outset of a lawsuit, but here no one would have predicted that outside lawyers would parachute into the case, successfully object to a proposed class settlement, become involved in negotiating the final settlement, and earn an entitlement to share in the common fund recovery. Little can be said other than it would reasonable to assume that the class would agree at the outset that the allocation be based on relative contributions of counsel to the ultimate recovery. Beyond that broad generalization, the allocation analysis must be done on an *ex post* rather than *ex ante* basis.

***23** "There is very little case law concerning the allocation of attorneys' fees among co-counsel." *In re FPI/Agretech Securities Litigation*, 105 F.3d 469, 473 (9th Cir.1997). Relevant criteria include whether the attorney's services benefitted the fund by helping create, increase, protect or preserve it, as well whether the allocation is reflective of the relative work performed (*i.e.*, lodestars). *Id. See also id.* at 474 ("we hold that the relative efforts of, and benefits conferred upon the class by, co-counsel are proper bases for refusing to approve a fee allocation proposal"). This is an equitable determination as to which the Court necessarily has broad discretion and which requires no more than a concise explanation. *Id.* at 473. Some of the *ex ante* factors noted in *Sutton* thus appear to remain relevant after all to the *ex post* analysis: risk of nonpayment, quality of performance and amount of work (lodestar). All of these relate to the overarching factor noted above: the extent to which each group of lawyers contributed to the ultimate success of the case. Thus, the analysis below will focus on this question of "contribution," with attention paid to additional factors such as relative risk and lodestars. I note that Plaintiffs' Counsel implicitly assumed that "contribution to the outcome" is the most important inquiry, since that was the focus of their briefs.

3. Allocation analysis

The competing groups of counsel gave widely divergent accounts of their relative contributions to the overall settlement. Louisiana Counsel and Texas Counsel rely heavily on the fact that they successfully objected to the prior proposed cash settlement of $20 million, which resulted in the ultimate realization of $55 million of additional cash relief and about $14 million of "enhanced" in-kind relief. They argue that MDL Counsel is entitled to little or no credit for fees based on the additional settlement value Louisiana and Texas allegedly procured for the class.

Their agreement ends there. As for allocating fees between them, Louisiana and Texas Counsel train their fire on each other. Louisiana Counsel claims that they (primarily Ms. Wheelahan) bore most of the risk and did most of the work. They argue that Texas Counsel were opportunistic latecomers, who stood on the sidelines, jumping into the fray in earnest only after the Second Proposed Settlement was rejected and a bigger settlement and ultimate payday for counsel were a virtual certainty. (MDL Counsel also point out that about 70% of Texas Counsel's hours were incurred after a March 4, 2008 status hearing, in which the landscape and risks changed dramatically.) In contrast, Texas Counsel claims that Louisiana Counsel is writing revisionist history, and is ignoring the substantial contributions they made to the ultimate outcome, which they made at the behest of Louisiana Counsel, who repeatedly praised their efforts in e-mails.

MDL Counsel, on the other hand, acknowledge the contributions of Louisiana and Texas Counsel to the ultimate outcome, but argue that they contributed substantially as well to the final result notwithstanding their unsuccessful promotion of the earlier proposed settlements. They point out that they began filing their initial lawsuits in 1998 (*Frey*) and 1999, when the risk was greatest and outcome least certain. They sought and achieved the MDL reassignment. They conducted extensive discovery. They catalog various additional tasks they performed. As for the failed First and Second Proposed Settlements, they say they took a reasonable, albeit unsuccessful, position, based on the then-current risk analysis, which included the fact that the Court had held in 2002 that it would not certify a national "target marketing" class due to the potentially catastrophic liability it would impose on Trans Union and the fact that the Magistrate Judge had supervised the mediation that resulted in the proposed settlements. It was not until March 4, 2008, after the Court adopted the Magistrate Judge's recommendation that the Second Proposed Settlement be rejected, that the landscape changed. At that hearing, the Court stated that it was open to reconsideration of the denial of a national target marketing class, Mar. 4, 2008 Tr. at 8; and that Trans Union needed to put "a lot more money on the table." *Id.* Although not noted by MDL Counsel, the Court had suggested a few months earlier that class certification law had evolved since 2002, and reconsideration of the denial of a national class might be warranted. Jan. 15, 2008 Tr. at 7 ("my original opinion on class certification is going to be influenced by later case law from this circuit that calls into question my original conclusion, because I think it was based on current case law at the time. But things have changed since then.") In any event, MDL Counsel contend that the steep increase in the value of the settlement resulted primarily from these comments by the Court, which had much more influence on increasing the settlement value of the case than the efforts of Louisiana and Texas Counsel, and the ultimate outcome resulted primarily from the foundation MDL Counsel had laid by prosecuting the case up to that point.

***24** I think the truth lies somewhere between these positions. I agree with Louisiana and Texas Counsel that they are entitled to credit for being "right" about the First and Second Proposed Settlements and judging that this case had much greater value than MDL Counsel had thought. They reached that correct conclusion before the Court changed the landscape in early 2008 with comments about potentially reconsidering class certification. Indeed, internal e-mails submitted by Texas Counsel indicate that Texas Counsel had recognized the evolution in class action law and were urging the filing of a reconsideration motion. However, I disagree that their correct analysis vested them with an entitlement to 100% credit for the additional $69 million ($55 million cash and $14 million enhanced in-kind relief) in settlement value that was realized. MDL Counsel are right that they laid the foundation and created much of that value.

The argument of Louisiana and Texas Counsel proves too much and would, in my judgment, result in a windfall to them. Their premise is that the first two proposed settlements did not reflect the true value of the case for the class. But who "created" that extra value? It was principally the efforts of MDL Counsel, enhanced somewhat later by the Court's comments in early 2008, and also by the certification of a target marketing class in Louisiana. The argument of Louisiana and Texas Counsel tacitly acknowledges that the value was already there when they made their objections. Under their logic, MDL Counsel should be deemed to have forfeited any right to share in the value MDL Counsel created because they miscalculated the value or did not anticipate the Court's later comments about reconsidering a nationwide class. I do not believe such a forfeiture would be fair or reasonable. Louisiana and Texas Counsel may have correctly adduced and helped unlock the true enhanced value in this case, but they did not solely create it. MDL Counsel remain entitled to share in the value of the case above and beyond the original $20 million in cash and $20 million of in-kind value embodied in the rejected settlement.

That brings us, again, to the hard part, the actual calculation of an allocation. As with the determination of the total fee award, this cannot possibly be done with scientific precision. Rather, it is based on broad estimates. In light of the foregoing discussion, I assign the relative contributions of counsel to the settlement as follows.

Regarding the cash value of the settlement, $75 million, MDL Counsel are entitled to full credit for having created the first $20 million of value through their efforts leading up to the prior proposed settlements. Under the analysis above, it would also be fair to give them credit for 50% of the additional $55 million in cash settlement value ultimately realized. Louisiana and Texas Counsel therefore get credit for the remaining 50% of the additional $55 million in cash value realized through their objections and subsequent efforts. Thus, MDL Counsel get credit for "creating" 63.33% of the total cash settlement value. [39]

[39] This is calculated as follows: 100% credit times $20 million in value, plus 50% credit times $55 million in value, yields $47.5 million in created cash value. That is 63.33% of the $75 million cash recovery.

***25** That leaves 36.67% of cash value created jointly by Louisiana and Texas Counsel, to be divided between them. I recommend a 60/40 split, respectively, resulting in an assignment of 22% "credit" to Louisiana Counsel and 14.67% to Texas Counsel. I am persuaded by the arguments of Texas Counsel, supported by time records and contemporaneous e-mails, that they came into the case at the behest of Louisiana Counsel, in part because of the additional firepower and credibility they would bring to her status as lonely objector; that Ms. Wheelahan was responsible in part for their relatively passive role before the rejection of the Second Proposed Settlement; and that they contributed substantially to the final result, including by conducting essential legal analysis and fronting the expenses of hiring helpful expert witnesses.

Louisiana Counsel exaggerate their contribution relative to that of Texas Counsel. The ratio Louisiana proposes, of about 5.5 to 1, is excessive. A ratio of 3 to 2 (a 60/40 split) more accurately and fairly reflects their relative contributions, including the fact that Louisiana Counsel were involved longer, bore greater risk, secured a class certification in *Andrews*, and fought for a time from the difficult and lonely position of being a solitary objector. Ms. Wheelahan gets credit for correctly determining that the initial settlements were inadequate and for bringing Texas Counsel into the case. Notwithstanding her unorthodox ways, and her alienation of her co-counsel and, sometimes, the Court and the Magistrate Judge, the simple and undeniable fact remains that she was instrumental in increasing the class cash recovery by $55 million. Results count, and she delivered. Thus, allocating a somewhat larger share to Louisiana Counsel than to Texas Counsel is appropriate under the circumstances.

Next, I conclude that the same percentages should apply to assigning "credit" for the in-kind portion of the settlement. Texas Counsel suggest that their "credit" (and, implicitly, that of Louisiana Counsel) should be based on the value of about $14 million in "enhanced" in-kind relief added to the final settlement. One could try to derive different percentages to apply to the in-kind portion of the recovery, but I conclude that the foregoing percentages

(63.33%, 22%, 14.67%), being themselves rough approximations, are close enough to the relative contributions to the in-kind portion of the award. There is no reason to complicate the analysis further by estimating different percentages for that portion. Thus, those are the percentages I recommend for assigning "credit" for relative contributions to the total settlement value. The allocation figures set forth in the table on page 33 above represent a simple application of these percentages to the $12,374,362 recommended fee award remaining after deducting fees of Liaison Counsel and Special Master.

As with the determination of the total fee award, a cross-check of the lodestars against these figures is useful to determine whether any assumptions in the analysis might warrant reconsideration. Earlier, I concluded that after applying reductions for appropriate hourly rates and elimination of excessive or duplicative time, the lodestars would be roughly as follows (and perhaps lower): MDL, $8.6 to $9.7 million; Louisiana, $1.88 to $2.35 million; Texas $990,000 to $1.12 million. The allocation suggested above is reasonable when compared to these estimated lodestars. MDL Counsel would receive a slight discount on their adjusted lodestar. The lack of an enhancement fairly accounts for the misjudgment they made regarding the proposed settlement. In contrast, my recommended allocation would give each of Louisiana and Texas Counsel moderate multipliers on their approximate adjusted lodestars. Although they had less risk than MDL Counsel (especially Texas Counsel), they "bet right" on the earlier proposed settlements, so some enhancement over lodestar is appropriate under the circumstances.

***26** MDL Counsel have asked me to recommend that the Court enter separate judgments with respect to the fees allocated to each of the counsel groups because they expect Ms. Wheelahan to appeal any award lower than her request. I sympathize with the motivation for their request. They want to get paid. But I do not see how separate judgment orders would give MDL Counsel the realistic option of avoiding participation in an appeal and getting paid their fees. Unless Louisiana Counsel were to limit the appeal to seeking for themselves fees in excess of the $12.98 million I have recommended, any appeal will almost certainly implicate the allocation issues and drag MDL Counsel in. Also, this request may ultimately touch upon Rule 62 matters such as appeal bonds or stays pending appeal, and as such, I decline to make any recommendation regarding the form of judgment(s) unless asked to do so by the Court.

III. *INVESTIGATION OF THE WHEELAHAN NOVEMBER 19 E–MAILS AND OTHER ETHICAL ISSUES*

A. Summary of the Issue and Recommendation

Attached to the Court's April 6 Order was a copy of a series of e-mails sent on November 19, 2008 by Louisiana Counsel Ms. Wheelahan to Texas Counsel Mr. Toups. Texas Counsel had given the e-mails to the Magistrate Judge during an *ex parte* mediation session on November 20, 2008. Because of the ethical issues raised in the e-mails and their potential implications for the certified settlement class, the Magistrate Judge subsequently gave a copy of the e-mails to the Court. The Court characterized the e-mails as "reprehensible." April 6 Op. at 8. As part of its assignment to me, the Court directed me to "investigat[e] any ethical issues raised by Louisiana counsel's ... communications." June 11 Order (Doc. 535) at 2.

When I first read the e-mails my initial reaction is that Ms. Wheelahan's conduct was sanctionable. However, I came to view this as a close question. While I agree that the e-mails were "reprehensible," as I understand it, my assignment is not to evaluate the e-mails on a tactical, logical or civility level, but rather to investigate and recommend whether any Court Rules or ethical or fiduciary duties were broken such that a sanction should be imposed on Ms. Wheelahan. In carrying out this task, my principal concerns were whether there was ever any real danger to the rights that had been secured for the settlement class, any serious violation of applicable rules of professional conduct, or any serious affront to the integrity and administration of the judicial process. As I explain below, based on my review of the documents produced to me by counsel, my examinations of Ms. Wheelahan and Mr. Toups, my inquiries of other counsel for plaintiffs and Trans Union, and my analysis of the context in

which the remarkable e-mails were sent, while I do not condone her conduct in any respect, I do not recommend that the Court sanction Ms. Wheelahan in connection with the sending of the e-mails or conduct relating to the subject matter of the e-mails.

B. Ms. Wheelahan's Procedural Objections

***27** Ms. Wheelahan raises several procedural objections to the ethics inquiry. First, Ms. Wheelahan questions the propriety of Texas Counsel giving a copy of the November 19 e-mails to the Magistrate Judge. She claims that doing so violated Local Rule 83.5, which provides generally for the confidentiality of statements made in "ADR" proceedings. I disagree, but, more importantly, the Court has already implicitly rejected this argument. *See* May 1, 2009 Order at 2 (Doc. 613) (denying Motion of Louisiana Counsel to Strike from the Record Confidential Materials based on LR 83.5). The shroud that generally covers settlement communications does not and cannot envelop potential ethical violations or other misconduct that may have occurred in such proceedings. Having received the November 19 e-mails on November 20, it was proper for Texas Counsel to give a copy promptly to the Magistrate Judge. Although, as discussed below, Texas Counsel were perplexed as to what Ms. Wheelahan was up to, they rightly concluded that, read literally, the e-mails did appear to raise a potential violation of ethical duties owed by an attorney to the same certified settlement class they represented. In that circumstance, it was appropriate to disclose that communication to the tribunal with jurisdiction over the settlement and duties to the class. I also disagree with Ms. Wheelahan's assertion that Texas Counsel's motivation for disclosing the e-mails was entirely tactical. Texas Counsel were motivated, at least in part, by ethical rather than parochial concerns. [40]

[40] Contrary to Mr. Toups's testimony (Toups Tr. 77–78), however, I doubt they were motivated entirely by duty: I think it likely that they also believed that giving the e-mails to the Magistrate Judge might produce a collateral benefit to them in the negotiation process or litigation over fees thereafter. Further, it would have been a better practice for Texas Counsel to have informed Ms. Wheelahan that they had given the Magistrate Judge a copy of the e-mails, although Mr. Toups testified that they believed that the Magistrate Judge had discussed the e-mails separately with her and they therefore thought there was no need to notify her.

Second, Ms. Wheelahan asserts that the investigation of her alleged ethical transgressions was required to be conducted in confidence pursuant to Local Rule 83.25(e). She misreads the Rule. The confidentiality provision in that Rule pertains to "[p]roceedings before the Executive Committee." Such proceedings concern whether "discipline" should be imposed on a lawyer practicing in this district.

> The term "discipline" shall include disbarment, suspension from practice before this Court, reprimand or censure, and such other disciplinary action as the circumstances may warrant, including, but not limited to, restitution of funds, satisfactory completion of educational programs, compliance with treatment programs, and community service. ***The term discipline is not intended to include sanctions or contempt.***

Local Rule 83.25(a)(3) (emphasis added). Local Rule 83.25(c) and the Committee Comment also make clear that the rules are not intended to usurp the authority of a judge over conduct in proceedings before him or her. While the Court could have chosen to refer this matter to the Executive Committee to investigate whether "discipline" is appropriate, it was not required to do so. It plainly had not been stripped by Local Rule of its inherent authority to investigate whether to "sanction" a lawyer for a possible ethical transgression, occurring under the auspices of a mediation conducted by a Magistrate Judge, which had implications for a settlement class that the Court had certified and to which it owed fiduciary obligations. The e-mails also had potential implications for the fee award and allocation questions at issue before the Court, since a full or partial fee forfeiture might have been an available sanction if Ms. Wheelahan had actually engaged in a "clear and serious violation of duty to a client." *Restatement (Third) of the Law Governing Lawyers*, § 37 (2000).

***28** Finally, Ms. Wheelahan objects that the Court publicly aired the e-mails and criticized her without prior notice and an opportunity to explain her position regarding the e-mails and other matters cited by the Court. However, the Court imposed no sanction, vacated the April 6 Order containing the criticism, and appointed a Special Master to investigate the ethical issues. Ample notice and process have been afforded Ms. Wheelahan. Throughout my assignment, I have allowed Ms. Wheelahan to present whatever evidence and arguments she wanted in connection with my investigation and report, and she was represented by counsel for at least part of the proceedings before me.

C. Description of the Relevant E–Mails

The following facts are drawn from the November 19 e-mails and Ms. Wheelahan's testimony. The relevant e-mail string contains four e-mails, written *seriatim* by Ms. Wheelahan and sent to Mr. Toups without any intervening response. She acted alone. She had no input from any other counsel. She thumbed the first three on her BlackBerry while having a solitary late dinner the night of November 19, 2008. This followed a long and frustrating mediation session conducted by the Magistrate Judge, during which he tried to facilitate an agreement regarding the amount and allocation of fees among the various groups of Plaintiffs' Counsel. The settlement talks were stalling, and Ms. Wheelahan was particularly upset that Texas Counsel's position was higher than a lodestar she considered already inflated, while she was being asked to take less than what she considered to be her lodestar and her contribution to the success of the lawsuits.

Although the printed document states that the first three e-mails were sent during the wee hours of November 20, it appears there was a problem with the clock on her BlackBerry. I find credible Ms. Wheelahan's testimony that she typed the first three messages during her late dinner, probably between 9 and 10 p.m. She then apparently forwarded the three e-mails to her America Online e-mail address, and sent a fourth e-mail shortly before midnight to Mr. Toups from her laptop in her Chicago hotel. Mr. Toups did not see the e-mails until the next morning.

The first two e-mails, which are fairly innocuous, state Ms. Wheelahan's displeasure with the then-current state of the fee negotiations. She wanted to persuade Texas Counsel to reduce their requested share of the fee pie, which she felt was not only inflated, but unfair relative to her contribution to the class settlement outcome. She drank at least three glasses of wine at dinner while sending the e-mails, and it is apparent that her frustration with the day's events increased. The third e-mail upped the temperature from the first two. It said:

> But here's what can happen. The 7th van [*sic*] find that class claims for statutory. Damages [*sic*] were abandoned after cert. denied in 2002 when MDL coins [*sic*] didn't move to certify them, and cert of the punitives was denied in 2005. Leaving no live class claims. Then I'll amend my LA suit to add FCRA claims and settle w TU for less than 75M but plenty. More to me than 4.5.

***29** This e-mail, on the surface and standing alone, is illogical in the context of the negotiation, since it does not make sense that the outcome of the objectors' appeal should affect the settlement position of Texas Counsel in the fee negotiations. By itself this e-mail does not raise ethical red flags, since it does not overtly threaten to undermine the class settlement. The fourth e-mail, on the other hand, expanded on the third, and gave rise to this investigation (italics added):

> And the more I think about this, *the better it's looking to me. The 7th rejects the settlement, on a motion to dismiss,* and there are then no live class claims that can be certified, because the statute has run on them. LA asserts additional claims that relate back to our original filing in 2002 for the co-extensive LA class, and *we settle with TU for around 40M. TU saves a pile of money, and we get paid in a very friendly LA court, 25% of 40M. So my LA co-counsel get 3M, and I get 7M. And TU saves 35M, and their lawyer looks great.* And

> the MDL counsel who abandoned the statutory damages claims, and failed to certify the punitives, are left with an Illinois class of firm offer claims that they cannot prove up, bec they are not and never were classwide violations—and TU will not settle them. *Tell me why 4.5M shd look better to me than that scenario?*

The meaning of this e-mail is plain: it purports to threaten Texas Counsel. As the Court put it, it "seem[s] to express an intention to manipulate the court proceedings in connection with the settlement for the sole purpose of augmenting the fee award." April 6 Order at 8. Ms. Wheelahan, who was then working on a motion to dismiss the pending appeal, appears to be threatening to somehow cause the Seventh Circuit, via her motion to dismiss, to reject the settlement. Because the settlement had extended the limitations period for many claims, its rejection would put limitations issues back in play. Ms. Wheelahan's Louisiana state case, in which a "target marketing" class had been certified, did not present the same limitations problems. Thus, her e-mail suggested that the rejection of the MDL settlement might actually be "better" for her (and Trans Union) than the $4.5 million fee then on the table in the negotiations, since she claimed she could make a deal with Trans Union in Louisiana that would provide less money for nationwide class members and more attorneys' fees for her. The e-mail does not specify how a motion to dismiss would cause the Seventh Circuit to reject the settlement, but other e-mails sent before and after this e-mail (discussed later) establish that she was contemplating raising the statute of limitations (viz. the objectors) in a motion to dismiss the appeal, which she thought could prompt the Seventh Circuit to *sua sponte* reject the settlement on jurisdictional grounds.

D. Ms. Wheelahan Did Not Actually Betray or Harm the Settlement Class.

Notwithstanding the clearly threatening tone and content of the November 19 e-mails, Ms. Wheelahan denies that she intended the e-mails to convey any threat to undermine the settlement. I discuss the issue of her intent in the next section. As a threshold matter, regardless of her testimony about her intent, I sought to determine whether or not Ms. Wheelahan ever actually engaged in any conduct to undermine the settlement, whether pursuant to the plan outlined in the November 19 e-mails or otherwise. If Ms. Wheelahan had taken any step to implement such a scheme—*i.e.*, to plant a limitations or other issue in a motion to dismiss the appeal, designed to scuttle the approved settlement so that she could cut a deal with Trans Union in Louisiana that would pay her more and class members less—there is no question she would thereby have earned a severe sanction and a referral to the Executive Committee for additional "discipline." The duty of loyalty to a client is perhaps the most basic duty of a lawyer, especially of one appointed counsel for a certified settlement class. Among the applicable ethical rules such conduct would implicate are Rule 1.1(a) (duty of competent representation); Rule 1.2(a) (duty to abide by client's decision whether to accept an offer to settle a matter); Rule 1.7(a)-(b) (regarding conflicts of interest between clients and between lawyer and client, here conflicting interests among the Louisiana state court class, the national MDL class and Ms. Wheelahan herself); Rule 1.8(b) (regarding conflicts of interest and prohibited transactions, here the use of information regarding the statute of limitations to the disadvantage of a client); Rule 8.4(a) (4) (conduct involving dishonesty, fraud, deceit or misrepresentation, here the appearance of acting on behalf of the Settlement Class in the course of filing a motion planting a time bomb calculated to blow up the settlement).[41] However, for several reasons, I am convinced that Ms. Wheelahan did not actually attempt to overturn the Settlement. She remained loyal to the Settlement Class. Despite the November 19 e-mails, the Settlement Class was never in any genuine danger of betrayal.

41 I cite to the Rules via the nomenclature of the ABA's Model Rules of Professional Conduct. The Rules applicable here to Ms. Wheelahan are part of the Court's Local Rule 83.50.1 *et seq.* Thus, the actual cite, for example, to Rule 1.7 is Local Rule 83.51.7.

1. Ms. Wheelahan's denial is supported by the record and common sense.

***30** The record and surrounding circumstances corroborate Ms. Wheelahan's categorical denial of taking any step intended to harm or betray the class. None of the documents produced to me suggest that she took any step to undermine the settlement, including during the time period from November 20 to April 6, when she had no reason to think that the Court or anyone other than Texas Counsel had seen the e-mails. To the contrary, it appears that, in fact, she opposed the objectors in the Court of Appeals and participated to some extent in the settlement proceedings in that Court with the goal of ending the appeal and preserving the settlement.

I also conclude that the class was never in danger because the scenario Ms. Wheelahan spun out to Mr. Toups made no sense. What she proposed there could not have been pulled off, and Ms. Wheelahan is more than smart enough to have understood that.

First, it is unlikely that the Seventh Circuit would "reject the settlement" based on a motion to dismiss the appeal. Such a motion, if successful, would lead to dismissal of the appeal, not rejection of the settlement. (Ms. Wheelahan testified that the "motion to dismiss" phrase was nonsensical and a mistake; that is discussed further below.) Although it is not unheard of for the Seventh Circuit to opine on issues not presented by the parties, particularly jurisdictional issues, it is almost inconceivable here that it would have vacated a settlement—resolving a nearly decade-old MDL matter—on limitations grounds that had been knowingly waived by Trans Union and that were not pressed by the objectors. Indeed, a fundamental premise of the "threat scenario" in the November 19 e-mails was incorrect: that the Seventh Circuit might decide *sua sponte* that the statute of limitations was a *jurisdictional* impediment to the settlement that could not be waived. Although to my knowledge the Seventh Circuit had not addressed this issue in the context of FCRA, it has emphatically declared that federal statutes of limitation are generally non-jurisdictional; private parties may waive them. In *Lawyers Title Ins. Corp. v. Dearborn Title Corp.*, 118 F.3d 1157, 1165–67 (7th Cir.1997) (Posner, J.), the Seventh Circuit held that the one-year statute of limitations of the Real Estate Settlement Procedures Act ("RESPA"), 12 U.S.C. § 2601, is non-jurisdictional and waivable. In so ruling, the Court wrote: "we cannot find any case that holds a federal statute of limitations jurisdictional on this ground. With one exception to be noted, courts hold federal statutes of limitations to be jurisdictional only when the United States is a defendant-that is, out of regard for the defendant (and in keeping with the general reluctance of courts to estop the government to assert its statutory rights) rather than out of regard for the courts or for the social interest in burying old claims." *Id.* at 1166. The Seventh Circuit also observed that federal statutes of limitations are "universally regarded as nonjurisdictional," including the limitations period of the Truth in Lending Act, and it declined to follow the "one exception," a D.C. Circuit TILA case going against the "universal" rule. *Id.* Hence, while RESPA and TILA are not FCRA, the likelihood was virtually nil that the Seventh Circuit would *sua sponte* issue a decision finding FCRA not subject to the "universal" rule.[42] The FCRA statute of limitations is waivable and presented no jurisdictional risk in the appeal. If the e-mails were threatening sabotage by raising a limitations question (which Ms. Wheelahan denies), the threat was empty.

42 I also asked plaintiffs' counsel to provide me any authority of which they were aware holding that the FCRA statute of limitations is jurisdictional. None was provided.

***31** Second, it is speculative and highly doubtful that Trans Union would have agreed to the sweetheart deal imagined in the e-mail or that Ms. Wheelahan could have secured the large fee based on it. Ms. Wheelahan and Mr. Toups testified, and I have no doubt, that Trans Union was represented by excellent lawyers. The Settlement they negotiated contains a statute of limitations waiver. They certainly knew what their client was waiving, and what the applicable limitations law is. If the limitations period here were jurisdictional and if Trans Union could have defeated much of this lawsuit on that ground and secured a more favorable resolution in Louisiana, its sophisticated counsel would have pursued that path before agreeing to settle the MDL matter for over $100 million in cash and in-kind benefits. Any notion that Ms. Wheelahan had a silver bullet unbeknownst to Trans Union was fantasy. And Trans Union in fact worked to settle the appeals with the objectors rather than take any risk of the settlement being overturned. It clearly believed the settlement was in its best interest, better than cutting some sweetheart

deal in Louisiana. Finally, there may have been no sweetheart deal to cut. When Ms. Wheelahan wrote the e-mail she probably had forgotten that the Court had stated that she had waived a fee recovery in *Andrews* in connection with persuading the Court to remand that case to Louisiana. *See* n. 22 above. But Trans Union would not have forgotten that arguable waiver, and so the prospect of a better fee recovery in *Andrews* was doubtful.

Third, notwithstanding what the November 19 e-mails say, it was plainly not in Ms. Wheelahan's interest—it was not really "better" for her—to seek to undermine the MDL settlement. Her ultimate share of the $109 million MDL settlement, if upheld on appeal, even the $4.5 million fee then apparently on the negotiating table (or, as it turns out, the much lower fee I recommend above), was more valuable than gambling on derailing the MDL settlement to land a better fee (even if one had not been disclaimed) from a speculative Louisiana settlement.

Finally, there is no plausible way in which Ms. Wheelahan could actually have succeeded in betraying the class. Any attempt to have done so would have been bizarre and subject to an immediate coordinated attack from at least some of her co-counsel, and probably from Trans Union as well. Texas Counsel had already taken a step in that direction by giving the e-mails to the Magistrate Judge. The prospect of a lawyer betraying the class she represented would have ensured that the betrayal would quickly flame out. Accordingly, I conclude that there was neither actual harm nor realistic threat of harm to the settlement class occasioned by the sending of the e-mails or Ms. Wheelahan's subsequent conduct relating to the threat in the e-mails.

2. Texas Counsel's theory that Ms. Wheelahan actually tried to undermine the settlement is implausible and unsupported.

***32** As noted, if Ms. Wheelahan had done anything to try to undermine the settlement, it is unlikely that other counsel would not have found out about it and immediately taken action to squelch it. To confirm that she had not done so, I specifically directed Plaintiffs' Counsel (after reminding them of their duties to the Settlement Class and the Court) to advise me if they "know or have reason to suspect that the drafting or transmission of the Wheelahan November 19–20, 2008 emails caused any harm to the settlement class, or that Ms. Wheelahan ever took any affirmative step to undermine the approved MDL settlement in order to pursue a separate settlement in the Louisiana lawsuit?" July 30, 2009 Memo from Special Master to Counsel. I also asked them to produce any documents relating to this question. No counsel other than Texas Counsel claimed there was any such evidence. The single fact identified by Texas Counsel in its written response was, in my judgment, irrelevant and non-responsive. (It was Ms. Wheelahan's recent purported refusal to dismiss the Louisiana lawsuit that prompted a motion by Trans Union's counsel (Doc. 641) that was later withdrawn. (Doc. 647.))

However, Mr. Toups contended during my examination of him that he had recently concluded that Ms. Wheelahan did, in fact, try to undermine the settlement in a manner outlined in the November 19 e-mails. Toups Tr. at 53–57. He claimed she did so in a motion to dismiss the appeal, which she ultimately filed on June 15, 2009, nearly seven months after sending the November e-mails, two months after this Court rebuked her for sending the e-mails, and four days after my appointment as Special Master. When Ms. Wheelahan filed the motion, the appeal had been stalled in mediation for several months under the auspices of the Seventh Circuit's mediation program. Mr. Toups identified the following paragraph from page 2 of Ms. Wheelahan's motion to dismiss as a "Trojan Horse" through which he believes she was providing the Seventh Circuit ammunition to overturn the settlement on jurisdictional grounds:

> The conduct that is the subject of all of the actions in the MDL ceased in 2001 pursuant to an injunction imposed after the Federal Trade Commission's successful enforcement action. Other than the claims of the certified Louisiana *Andrews* class that are included in the settlement, no state law claims have been asserted based on the conduct that is the subject of the MDL actions, after the district court's dismissal of state law claims in July, 2004. Objectors have not appealed that order.

Motion to Dismiss Appeals (Examination Exhibit 21) at 2 (internal citations omitted). I am unpersuaded that this paragraph was written to initiate the demise of the settlement, or could have done so. While a reader of the statement might infer that newer state law claims might be untimely (if one knew the applicable state limitations period), I believe the point of the paragraph, like other statements in the brief, is to make the factual and equitable point that the settlement is *good* for the class and for the objectors. Later in the motion, Ms. Wheelahan refers to the fact that the settlement does not release individual claims and extends the limitations period to bring such claims. *See id.* at 4. Part of her argument for dismissal was that the appeals were moot since the objectors' rights to bring individual claims would not be improved by overturning the settlement; they could only be harmed by overturning the settlement. The limitations waiver in the settlement was germane to that argument. And, as noted earlier, the law is quite clear that the FCRA statute of limitations is non-jurisdictional. Thus, although one could question the legal strategy of filing the motion to dismiss during the midst of a mediation, I detect no whiff of foul play in this filing. Indeed, the possibility that Ms. Wheelahan would try to undermine the settlement in June 2009, after the Court had publicly aired the November 19 e-mails and appointed a Special Master to investigate the matter, is remote. Ms. Wheelahan may sometimes march to the beat of her own drummer, but she is not suicidal, as Mr. Toups's argument implies.

***33** Although I found Mr. Toups's theory improbable and born, at least in part, from deep mistrust of Ms. Wheelahan arising from the deterioration of their working relationship, I found his belief in it sincere and I took it seriously, particularly because he has much greater familiarity than I with the case and with Ms. Wheelahan. Thus, in addition to questioning Mr. Toups on the subject, I questioned his co-counsel Mr. Fein, Trans Union counsel Mr. O'Neil, and MDL Counsel Mr. Borderud. I also requested on short notice and received promptly from counsel documents (principally e-mails) concerning Ms. Wheelahan's filing of the motion to dismiss and its impact, if any, on the settlement of the appeals. The additional testimony and documents do not support Mr. Toups's conclusion, and do not suggest to me that Ms. Wheelahan tried to undermine the settlement.

Mr. Toups says that Mr. Fein had reported to him a conversation he had with Trans Union counsel, Mr. O'Neil, about whether Ms. Wheelahan's motion to dismiss was detrimental to the settlement. Both Mr. Fein and Mr. O'Neil confirmed that they spoke in August 2009, *after* the settlement of the appeal had concluded. Mr. O'Neil called Mr. Fein, probably in connection with the motion he was then preparing concerning Ms. Wheelahan having not agreed to dismiss the Louisiana lawsuit on terms satisfactory to Trans Union. Mr. Fein recalls Mr. O'Neil stating that something in the motion to dismiss "might be geared towards getting the 7th Circuit to take a closer look at the case and maybe dismiss the whole settlement," and that was one reason they settled so quickly with the objectors. Toups Tr. at 143. According to Mr. Fein's account, "[t]hey [Trans Union] were concerned that that was Dawn's secret purpose and it was a risk." *Id.* at 144. Up until the call, Mr. Fein had not suspected anything nefarious about the motion to dismiss. "When I read her motion ... I took it for what it was, that she was trying to get rid of the objectors." *Id.* at 143.

Mr. O'Neil does not know whether Ms. Wheelahan had any specific intent to derail the settlement. He believed that her filing of the motion to dismiss was a mistake, since it created the possibility that the Seventh Circuit might set a briefing schedule and address the merits of the appeal, and he and plaintiffs' counsel wanted to avoid any risk of the settlement being overturned. He thought the filing placed the settlement at risk because it recited facts concerning the merits of the settlement, creating the possibility that the Seventh Circuit might be tempted to address the merits and perhaps render an unfavorable ruling. To avoid any such risk, even a small one, he, MDL Counsel and Texas Counsel worked together to finalize quickly a settlement with the objectors that mooted the appeals. (Ms. Wheelahan did not participate in the final phase of the settlement process, although she had participated in earlier phases.) After the settlement was finalized, Mr. O'Neil was looking anew at the November 19 e-mails and suspected that perhaps the motion to dismiss, because it discussed matters other than the standing issue raised in the motion, might have had a hidden agenda. Sept. 11, 2009 Tr. at 11–18.

***34** Messrs. O'Neil and Borderud's recollections of their conversation were sketchy, and shed no additional light. They agreed, however, that they shared a concern to avoid the unpredictability inherent in a review by the Seventh Circuit of the merits of the appeal. 9/11/09 Tr. at 14. None of MDL Counsel stated that they believed Ms. Wheelahan had a specific intent to undermine the settlement. Rather, they believe that she viewed the Louisiana case as a backup if the settlement should fall apart, but would not go so far as to claim that she tried to make that happen through the motion to dismiss or otherwise. 9/11/09 Tr. at 23–25.

For her part, Ms. Wheelahan explained her strategy in an e-mail to her fellow Louisiana Counsel the day she filed the motion to dismiss, and in other e-mails: she filed the motion to dismiss because the mediation process had languished for half a year. She believed Trans Union had no interest in accelerating the process because delay deferred implementation of the settlement. She concluded that filing the motion to dismiss made sense because (i) it might succeed, (ii) it carried no risk to the merits of the appeal, and (iii) the standing issue might pressure the objectors to come to the table with a more reasonable demand. Document HHKC Trans Union 000296–297 (6/15/09 e-mail from Ms. Wheelahan to other Louisiana Counsel explaining her reasons for filing).

In the final analysis, I view the disagreement among counsel over the filing of the motion to dismiss as one of strategy, not ethical propriety. One could argue that the collective judgment of Trans Union, MDL Counsel and Texas counsel—that the motion to dismiss should not have been filed—was more sound (certainly it was more conservative) than Ms. Wheelahan's, which was, as is her wont, to go it alone and file the motion. But I was not appointed to second-guess strategy. What is important is that the disagreement here is a legitimate one over strategy, and the evidence does not support the notion that Ms. Wheelahan had a hidden agenda to lose the appeal and kill the settlement.[43] Counsel's relationship with Ms. Wheelahan (especially that of Texas Counsel) has so deteriorated that little trust remains and her motives are usually viewed with suspicion and in the worst light. That lack of trust appears to have led some counsel to suspect an unethical motive behind the filing of the motion to dismiss. However, finding no significant evidence to support the suspicion, I respectfully disagree with Mr. Toups's theory and conclude that Ms. Wheelahan did not file the motion to dismiss the appeal as a subterfuge to undermine the settlement.

43 Ironically, whatever one thinks of Ms. Wheelahan's strategy, it led to a result that all counsel wanted: a settlement with the objectors and the dismissal of the appeal. While certain counsel may be unhappy with the particular terms of the settlement (which are subject to a confidentiality provision and will not be discussed herein), it appears from the e-mails produced to me that Ms. Wheelahan's motion did catalyze the remaining parties to come to terms quickly and end the appeal.

E. Ms. Wheelahan's Intent

Having concluded that Ms. Wheelahan took no steps to harm the class, I turn to Ms. Wheelahan's intent. I find credible her testimony that, notwithstanding what the November e-mails say, she never actually intended to betray the class or undermine the approved settlement in the Seventh Circuit. Her success in defeating the prior proposed settlements and helping to achieve the much greater final settlement was a significant professional achievement she had every right to be proud of. “The supposition was never that I would do anything to overturn the settlement that is frankly the pinnacle of my career. I am very proud of that settlement.” Wheelahan Tr. 48–49. I am persuaded that Ms. Wheelahan never harbored any genuine intent to detonate the pinnacle she believed she had just climbed, and, as discussed above, did not try to do so.

***35** But that does not end the analysis. While I have concluded that Ms. Wheelahan never intended or attempted to betray the settlement class, the most natural reading of the November 19 e-mails is that she nevertheless *threatened* to do so. This raises the question of whether it is sanctionable for a lawyer during a negotiation to threaten to commit an illegal or unethical act as bargaining leverage.

1. The e-mails were intended as threats.

Ms. Wheelahan denies the premise of this question. She testified that her e-mails were not intended as a threat or bluff. Rather, she claimed that she was merely trying to communicate to Mr. Toups, albeit carelessly due to the late hour and her anger, "the problems in his case." Wheelahan Tr. 79. She also testified that the phrase in the e-mails, "motion to dismiss," was simply a careless mistake, and what she really meant to do was explain the course of events that could ensue from a successful appeal by the objectors, not from anything she would insert in a motion to dismiss.

For several reasons, I find that portion of her testimony strained and not credible. The e-mails read as a threat. I see no innocent construction. And Ms. Wheelahan's testimony was not entirely consistent on this point. While objecting to the term "threat," she first denied and then acknowledged that there were elements of attempted "arm-twisting" in the e-mails. Wheelahan Tr. 57–59, 72. I questioned her at length about her intent, and, while she did not articulate it clearly, her explanation as to what she was trying to say to Mr. Toups, and why it supposedly was not a threat to blow up the settlement, appears to be: (i) she wanted to keep a "food fight" among Plaintiffs' Counsel out of the record because something said in a public fight might be seized upon by the objectors to overturn the settlement; (ii) if the settlement were overturned on appeal, Texas counsel would lose the limitations protection of the settlement (their suit was filed in 2006), but the certified Louisiana lawsuit would have no limitations problem; and (iii) therefore, Texas Counsel should lower their fee demand because they have more to lose by not settling and risking the public food fight that could give ammunition to the objectors. Thus, she described the e-mails as merely a poorly worded and clumsy attempt to point out to Texas Counsel the problems and risks in their negotiating position. Wheelahan Tr. 67–71.

This explanation is weak, because it does not square with the threatening language or tone of the e-mails (e.g., "the better it looks"), and it does not make sense that a "public fight" over fees should have influenced Texas Counsel's thinking about what fee to negotiate. Any public briefing about fees would be outside the appellate record and irrelevant to the issue on appeal: the Court's decision, well before any public fee fight occurred, to approve the settlement. Because the fee decision was independent of the issues on appeal, there would be no reason for Texas counsel to base their negotiation position on the fate of the appeal. In contrast, the most natural reading of the e-mails—as a threat to sabotage the settlement in the appeal if Texas counsel did not lower its fee demand—does logically link the fate of the appeal to Texas's negotiating position. In this reading, the "threat" makes some internal logical sense because an intentional destruction of the settlement would result in a vacatur of any fee award.

***36** I also reject Ms. Wheelahan's position that the phrase "motion to dismiss" in the November 19 e-mail was a mistake. If the November 19 e-mails were an aberration, a poorly drafted and not entirely coherent product of anger and exhaustion, perhaps Ms. Wheelahan's "mistake" explanation might have some plausibility. But the concept expressed in the e-mail had been germinating for some time before November 19 and similar threats were conveyed or hinted at before and after November 19, during normal business hours and under less exhausting circumstances.

On October 23, 2008, nearly a month before the November 19–20 mediation, Ms. Wheelahan and Mr. Caddell got into an argument via e-mail over a $250,000 refund check from Hilsoft, the third-party involved in providing class notice. Mr. Caddell had asked Hilsoft to send the money to his firm's client funds account and Ms. Wheelahan thought the money should be sent to the Escrow Agent for the settlement. The exchange became personal and, frankly, juvenile, and included some sniping over attorneys' fees and some threats. Ms. Wheelahan dismissed the exchange as "two angry lawyers throwing threats at one another," Wheelahan Tr. 93, and said they "were sent back and forth between us in anger with the intention of annoying one another." *Id.* at 99. Mr. Caddell bragged that his firm had recovered a lot in fees during the past year, while needling Ms. Wheelahan for not having done so. Having tweaked her financially, he said that "we are considering suggesting to Mason and Gettleman that we wait until the settlement is complete [*i.e.*, all claims finalized]

before deciding attorney's fees. ☺" Examination Exhibit 5 (smiley-face "emoticon" in original).

Ms. Wheelahan took the bait, suggested that Texas Counsel had ulterior motives for delaying an attorneys' fee award, and then followed up with an e-mail in the early afternoon:

> And by the way, if the Settlement Agreement is not adhered to, we won't be asking the Louisiana court to dismiss the certified Louisiana class—or perhaps the Louisiana court will decide that the settlement does not release the Louisiana claims, or should not—and then I do not believe there will be any attorney's fees coming from it, now or ever. *It would be a simple thing for me to tell [Trans Union counsel] Brian [Brooks] exactly how his client is in a better position than they know, if the Settlement were overturned. And the judgment of a district court without subject matter jurisdiction is worth exactly nothing.*

Examinations Exhibit 5 (italics added). This e-mail alludes to the "jurisdiction" issue noted above and threatens to "tell Brian" how Trans Union could be put in a better position if the settlement were overturned. The references in this e-mail are oblique, and I do not believe any counsel at the time fully understood what she was implying or took it seriously. None responded to the substance of this last e-mail.[44] This e-mail too was an empty threat, and an unclear one as well. However, its significance is that the concept later expressed more clearly in the November 19 e-mails was in Ms. Wheelahan's mind several weeks earlier and foreshadowed in these e-mails.

[44] Ms. Wheelahan did not realize at the time that defense counsel (although not Mr. Brooks) had been copied on and were privy to the e-mail string. However, I do not believe that this oversight caused any harm because, as discussed earlier, there was no genuine jurisdiction issue.

***37** And the concept remained in play after the November 19–20 mediation. On November 26, 2008 at 10:34 a.m., she sent an e-mail to John Zarian, one of the *Frey* counsel aligned with the MDL Counsel group. Following the failure of the fee mediation, he was acting as a go-between to Toups and Texas Counsel, since they no longer wanted to communicate directly with Ms. Wheelahan. She e-mailed him to offer ammunition for those discussions. Her first paragraph of the November 26 e-mail said:

> Hi, John. Thanks, again, for all your efforts. If it helps you at all to get Tx to come down some-because I'm still not seeing why they're entitled to a multiplier over their lodestar, when everyone else is taking a cut, and when they only submitted one pleading in the entire case-I've attached the Order lifting the stay in our certified state law case. We remain willing to seek fees there. *And if the MDL settlement falls apart, bec the statute has run on the claims, or for another reason, our state law case is ready to go forward, in a very favorable court, as I explained to you.*

Examination Exhibit 10 (italics added). Again, she linked the limitations issue to the MDL settlement "falling apart," followed by pursuing the Louisiana state case "in a very favorable court." Similarly, in a December 1, 2008, 6:24 p.m. e-mail to her Louisiana co-counsel, Mr. Lane, she wrote about the status of Mr. Zarian's efforts to negotiate with Mr. Toups. In relevant part, she wrote:

> I told John [Zarian] that, since I'd be traveling, I thought Friday was my own deadline for filing motions to dismiss the appeals in the 7th Cir. *These are the same motions that would raise the issue that the statute of limitations has run on all claims except ours and John Zarian's. Mitch might be particularly concerned about this,* bec he lost something in the LA 4th Cir on just this issue ....

Examination Exhibit 11 (italics added). Finally, in a December 5, 2008 e-mail, at 10:21 a.m., Ms. Wheelahan wrote directly to Mr. Toups about the apparent collapse of the fee negotiations. The third and fourth paragraphs said:

> And I also think there is a serious chance the 7th Cir. might find a statute problem with all the cases and class statutory damages claims filed after September, 2004, when those were arguably abandoned by the MDL counsel after the Sept 2002 ruling. I think the tolling provision in the settlement might be the only thing keeping those claims alive, but the court had no jurisdiction to enter a judgment approving the settlement if the statute had run and the claims were moot before it did. LA's certified unjust enrichment claims, and John Zarian's CA state claims, might be all that's left. Which is not what I stayed in Chicago to see happen.
>
> John said you've worked hard to bring your group along. We're just about ready to take another road, but hope you can make some progress with them today. Let me know if I can help.

Examination Exhibit 13.

***38** These e-mails establish that the November 19 e-mails were not a mere aberration fueled by anger, wine and exhaustion. Neither was the use of the phrase "motion to dismiss" an accident, since she had been drafting such a motion and thought it might mention the limitations issue. As a general matter, Ms. Wheelahan considered the certified Louisiana lawsuit to be an ace in the hole. It was a fallback for her if the MDL settlement should fall apart (through legitimate process and without her assistance). She also considered it a possible avenue to obtain a separate fee award through a legitimate process involving prior approval of the MDL court.[45] And, as evidenced by the series of e-mails listed above, she tried to use the pendency of the Louisiana lawsuit as leverage to try to persuade Texas Counsel to lower their fee demand, with the threat that a motion to dismiss might cause several dominoes to fall, the last being a rejection of the settlement on limitations/jurisdictional grounds by the Seventh Circuit. Ms. Wheelahan's current characterization of the e-mails as not conveying a threat to undermine the settlement is, under all of the circumstances, unconvincing.

45 Ms. Wheelahan sent several e-mails to her colleagues, and also suggested to the Magistrate Judge during settlement talks, that perhaps the parties and the Court would agree to entry of a lower fee judgment in the MDL Action and permit her to seek additional fees in Louisiana in the *Andrews* Action, so long as the total fees awarded did not exceed the $18.75 million cap in the settlement. The Magistrate Judge immediately rejected the concept and no other counsel showed any support for it. This concept, while it had no genuine chance at being approved, presents no ethical issue.

2. Ms. Wheelahan acted alone in making the threat.

It should be noted that none of plaintiffs' other counsel were party to or, in most cases privy to, the threats. Specifically, Mr. Zarian and Mr. Toups agree that Mr. Zarian did not convey to Mr. Toups any of the "ammunition" Ms. Wheelahan had tried to feed him. Mr. Zarian was neither aware of the November 19 e-mails nor of any intent by Ms. Wheelahan to threaten to undermine the settlement to gain a negotiating advantage. He largely ignored her suggestions, sometimes because he didn't understand them and sometimes because he thought them meritless, and his settlement communications with Mr. Toups were focused on numbers. I do not believe he or other MDL Counsel were privy to or supported the concept of threatening to undermine the settlement. Likewise, Ms. Wheelahan's Louisiana co-counsel, Mr. Lane and others at his firm, were unaware of the November 19 e-mails. While they were privy to some communications with Ms. Wheelahan regarding a possible motion to dismiss the appeals, the limitations issue and the negotiations with Texas counsel, I do not believe that they were aware of or supportive of any clear threat by Ms. Wheelahan to scuttle the settlement.

3. The threats do not warrant a sanction.

Having rejected Ms. Wheelahan's argument that the e-mails were not intended as a threat to undermine the settlement, I turn, finally, to whether the threats in the November 19 e-mails are sanctionable. My conclusion that they are not should not be viewed as condoning Ms. Wheelahan's conduct. I have never seen anything quite like the e-mails. The notion that a lawyer would even threaten to betray a client, let alone a class, is indeed "reprehensible," and strays far beyond conduct becoming of an attorney. However unseemly the conduct, I conclude that it did not violate any specific rule of professional conduct or fiduciary duty. It was disrespectful of Texas Counsel, but not directly contemptuous of the Court. [46] Accordingly, I recommend no sanction.

46 I note that in certain other e-mails produced to me by counsel, Ms. Wheelahan sometimes used sharp and disrespectful language to certain describe rulings or statements by this Court or the Magistrate Judge with which she disagreed. Some of the statements were intemperate, but I do not believe they violated Local Rule 83.58.2(a).

***39** The applicable Rules of Professional Conduct deal extensively with a lawyer's duties to her client and her conduct before a tribunal, but they say little about her conduct with other counsel in the context of a negotiation. There is little question that the Rules and legal culture tolerate and expect less decorum when lawyers bargain in private than when they battle in public. In the hurly-burly of negotiation, depending on the style of the lawyer, it is not uncommon to encounter posturing, brinkmanship, bluster, puffing, bluffing, braggadocio, and some sharp elbows. Styles differ. Some lawyers are quiet persuaders and others are yellers. All lawyers in negotiations make what might be called "threats," to the extent that it is common to point out to the other side the consequences of not agreeing. Many such "threats" cross no ethical boundary, such as a promise to take legal action ("settle for our demand or we'll sue") or assert a legal or factual position in a case ("settle or we'll depose your client and seek summary judgment"). Certain other threats are clearly sanctionable, such as a threat to seek criminal prosecution or disciplinary action (*see* Rule 1.2(e)) or a threat that would itself constitute criminal extortion. *See* *State v. Hynes*, No.2008–371, 2009 WL 2382550 (N.H. Aug.5, 2009) (affirming conviction of lawyer under New Hampshire extortion statute for obtaining $500 settlement from store owner by threatening a suit he had no right to bring because, *inter alia*, he had no client); 720 ILCS 5/12–6 (Illinois crime of "intimidation," defined as including, *inter alia*, threats without lawful authority to inflict physical injury or to defame); *Ethical Guidelines for Settlement Negotiations*, American Bar Association (August 2002), Section 4.3.2 (available at http:// www.abanet.org/ litigation/ethics/settlementnegotiations.pdf) (last visited Sept. 24, 2009) (listing as unethical threats that would be extortion or defamatory); *but see* *In re Finkelstein*, 901 F.2d 1560 (11th Cir.1990) (reversing suspension of civil rights lawyer for writing a letter threatening his opponent in a race discrimination case with a product boycott and embarrassing publicity campaign if a settlement were not reached); *United States v. Pendergraft*, 297 F.3d 1198, 1205 (11th Cir.2002) (threats to file a lawsuit based on a false affidavit do not violate the Hobbs Act).

Here, Ms. Wheelahan's threat fell somewhere between these poles. I have construed the e-mails as a threat, made to attempt to gain a negotiating advantage over co-counsel to the class, to assert a non-frivolous legal proposition in a case for an improper, veiled motive—to betray the class they both represented. At first blush, one might think the threat implicates Rule 1.2(f)(1), which provides that "[i]n representation of a client, a lawyer shall not ... assert a position ... or take other action on behalf of the client when the lawyer knows or reasonably should know that such action would serve merely to harass or maliciously injure another." However, the threat here was not made "on behalf of the client," and the action would not "serve *merely* to harass or maliciously injure another." Similarly, without any action to carry out the threat, I do not believe that the conflict of interest rules, Rules 1.7 or 1.8, were violated.

***40** While a lawyer would not necessarily have to commit criminal extortion to be subject to a civil sanction or discipline for making a threat, extortion cases discussing threats to pursue litigation shed some light on the analysis. Most cases considering the issue hold that threats to sue or file legal papers, even if made in bad faith, do not constitute criminal extortion. *See, e.g.,* *Pendergraft*, 297 F.3d at 1205 (collecting cases). Threatening to file court papers is not considered "wrongful" under the Hobbs Act because courts do not want to discourage parties

from using courts to resolve disputes, and civil remedies (such as malicious prosecution or Rule 11 sanctions) are considered sufficient to police abuses. *Id.* at 1206–07.

The recent *Hynes* case did affirm a conviction of a lawyer for sending extortionate demand letters, but the conduct there differs as well from that of Ms. Wheelahan. Hynes's letters threatened to sue hair salons for discriminatory pricing (for men, women's and children's haircuts) if he was not paid $1,000 to settle. Hynes had neither a client nor any standing to sue individually. One hair salon agreed to pay him $500 to avoid the threatened suit. He was convicted under the New Hampshire theft-by-extortion statute, which provides in relevant part that extortion includes a threat to do any "act which could not in itself substantially benefit him but which would harm substantially any other person with respect to that person's ... business." *Hynes*, 159 N.H. 187, 978 A.2d 264, 2009 WL 2382550, at *2. Hynes had no claim of right to the proceeds or to use the means threatened to procure them. In contrast, as noted, Ms. Wheelahan did have a claim of right to the moneys she was demanding (a higher share of the fee allocation), and the threatened means were in part legitimate (filing a motion to dismiss the appeal).

In sum, the e-mails do not constitute criminal extortion, and, while they have an extortionate flavor, I found no authority suggesting that they are sanctionable as a civil matter. Texas Counsel took it upon themselves to cite a few authorities, which they suggest support the proposition that a threat to breach a fiduciary duty is itself sanctionable. Two of the authorities do indicate that a noncriminal threat itself can be unethical, although in each case the threat was acted upon. More importantly, however, in each case the threat was made directly *to the client*, to whom the lawyer owed the fiduciary duties, not to a sophisticated co-counsel in an arms-length negotiation. In that context, the threat itself was an act of direct disloyalty to the client. *See In re Whitney Dove Hardy*, Comm. No. 03 SH 104 (Ill. ARDC Oct. 27, 2005) (available at http://www.iardc.org/03SH0104RB.HTML) (last visited Sept. 24, 2009) (lawyer threatened client that he would (and later did) reveal confidential information damaging to client's case if client did not pay fee balance); *Sessions & Co., P.S. v. Carlson*, 119 Wash.App. 1066, 2003 WL 23019953, at *3 (Dec. 29, 2003) (unpublished opinion) (lawyer threatened client that he would, without withdrawing, cease work for the client, to the client's detriment, if unpaid bill were not paid). As discussed further below, the fact that the recipient of the threat here was not the client, the opponent or a third party, but rather a sophisticated attorney, who was co-counsel to the same class, is an important factor cutting against a conclusion that the threat should be sanctioned.

***41** Apart from the question of extortion, one might contend that the e-mails were deceptive, and, therefore, potentially sanctionable under Rule 4.1(1) (lawyer "shall not knowingly ... make a false statement of material fact to a third person") or Rule 8.4(a)(4) (a "lawyer shall not ... engage in conduct involving dishonesty, fraud, deceit or misrepresentation"). Because Rule 8.4(a)(4) does not prohibit conduct that is permissible under Rule 4.1, *see* ABA Formal Op. 06–439, *Lawyer's Obligation of Truthfulness When Representing a Client in Negotiation: Application to Caucused Mediation*, at 5 n. 2 (April 12, 2006), I focus on Rule 4.1.

The Rule 4.1 argument would be that, as I've construed them, the e-mails were a deceptive bluff. Ms. Wheelahan made a threat to do something improper that she had no genuine intent to carry out. But the proscriptions of Rule 4.1 apply to statements of fact. The Committee Comments to the Rule state:

> Whether a particular statement should be regarded as one of fact can depend on the circumstances. Under generally accepted conventions in negotiation, certain types of statements ordinarily are not taken as statements of material fact. Estimates of price or value placed on the subject of a transaction and a party's intentions as to an acceptable settlement of a claim are in this category, and so is the existence of an undisclosed principal except where nondisclosure of the principal would constitute fraud.

This comment defines away, as a matter of formal professional ethics, much of the feinting that occurs in some negotiations. In this case, the statement or promise at issue is about future conduct, not historical fact. Such

future-oriented statements are typically not considered "factual" under fraud case law. *See, e.g.*, *Continental Bank, N.A. v. Meyer*, 10 F.3d 1293, 1298 (7th Cir.1993) ("A statement ... which relates to future or contingent events, expectations or probabilities, rather than to pre-existent or present facts, ordinarily does not constitute an actionable misrepresentation under Illinois law.") (internal quotations omitted); *Restatement (Second) of the Law*, Contracts, § 159 cmt. c ("facts" include past events or present circumstances, but not future events unless there is an implication of false present or past fact). Thus, while an attorney can be disciplined for lying in a negotiation about an objective material fact, such as the amount of available insurance coverage or the death of the client, *see* ABA Formal Op. 06–439 at 3,[47] a threat to take particular legal action is a statement about the future and is not generally received as a hard promise, but rather as something the speaker "might" do.

[47] Other examples of misrepresentations of fact in a negotiation include lying about how much a particular term will cost a party or falsely claiming that certain documentary evidence exists. Formal Op. 06–439 at 1.

Context is everything:

> Whether a statement should be so characterized [as one of fact] depends on whether the person to whom the statement is addressed would reasonably regard the statement as one of fact or based on the speaker's knowledge of facts reasonably implied by the statement, or instead regard it as merely an expression of the speaker's state of mind. Assessment depends on the circumstances in which the statement is made, including the past relationship of the negotiating persons, their apparent sophistication, the plausibility of the statement on its face, the phrasing of the statement, related communication between the persons involved, the known negotiating practices of the community in which both are negotiating, and similar circumstances."

***42** *Restatement (Third) of The Law Governing Lawyers*, § 98, cmt. c (2000). These factors, particularly consideration of the audience receiving the threats, cut strongly in favor of construing the threats as non-factual.

- "*Past relationship" and "apparent sophistication.*" Ms. Wheelahan did not threaten a stranger, the opponent to her client, her client, or a vulnerable non-lawyer. She had worked with Mr. Toups on previous matters and was still his co-counsel in this case. He is a very experienced and sophisticated lawyer. He impressed me as someone who would not be intimidated or snookered easily.

- "*Plausibility" and "phrasing of the statement.*" As discussed earlier, the statement was hardly "plausible on its face" and its phrasing was not a model of clarity. Indeed, the "threat," such as it was, baffled Mr. Toups at the time. He testified that he understood the gist as a threat to betray the class, but could not figure out what Ms. Wheelahan was planning or how she could pull it off. He only later came to understand the internal logic of the threat after this investigation began and documents were produced. Toups Tr. 45–46. On the morning he received the threat, he and his co-counsel Mr. Fein exchanged e-mails in which Mr. Fein opined that he thought "she's just making nonsensical threats." Examination Exhibit 20. Mr. Toups testified that he did not concur with that assessment, but he also did not understand at the time how she could carry out the threat. Toups Tr. 81–87.

- "*Related communication between the persons involved.*" As noted above, Ms. Wheelahan sent other e-mails that had other threats, or unorthodox suggestions, such as the suggestion that the MDL Court might agree to enter a lower fee judgment while granting Louisiana Counsel permission to seek additional fees from the Louisiana Court. The paper record reveals that no counsel specifically responded to these suggestions, and none agreed to them. Mr. Toups himself did not respond to her December 5 e-mail that again raised the limitations issue. See above at 59–60. In general, it appears that Plaintiffs' Counsel generally let Ms. Wheelahan blow off steam from time to time and ignored her more unusual statements or unorthodox procedural ideas.

- *"Known negotiation practices in the community."* I cannot comment on negotiation practices in Louisiana or Texas, but doubt that the culture diverges greatly from that in Chicago in this context. In my experience, most lawyers take with a grain of salt statements by adversaries about what they might do in the future in a lawsuit, and do not consider them in the same light as a representation of objective fact.

These considerations lead to the conclusion that, while the threat was imbued with an element of deception, it was not a dishonest misrepresentation of "fact" as meant in the ethical Rules. Making outrageous or misleading statements about future conduct (bluffing) might ultimately damage a lawyer's credibility or poison a relationship with a colleague or opposing counsel. Doing so would be eschewed by many lawyers as "reprehensible" and contrary to their personal ethics and standards for the appropriate practice of law. But they are not *per se* a violation of the applicable Rules of Professional Conduct, and were not so in this factual situation.

***43** Accordingly, I concur with Mr. Fein's initial impression of the e-mails the morning after they were sent. They were "nonsensical threats." They had no real bite. They did not influence Texas Counsel. They caused no harm to the class. They were not acted upon. They were not "prejudicial to the administration of justice." Rule 8.4(a)(5). [48] In light of all of these circumstances, including the fact that there is no rule or clear legal authority specifically addressing this situation, *cf. Finkelstein*, 901 F.2d at 1565 (reversing suspension of lawyer because there was no clear authority prohibiting overreaching threats he made to his opponent), I do not recommend that the Court sanction Ms. Wheelahan for what was, at the end of the day, outrageous "nonsense" spouted to her co-counsel. And, for what it is worth, I also believe that this investigation in and of itself, as well the criticisms expressed above, has already exacted a substantial *de facto* toll on Ms. Wheelahan.

48 The e-mails might have hastened the demise of the fee mediation, but it seems clear that it was heading for impasse in any event.

One last loose end: Texas Counsel cite authority holding that a lawyer who breaches a fiduciary duty to a client might be subject to a full or partial forfeiture of fees. [49] *Burrow v. Arce*, 997 S.W.2d 229, 238–245 (Tex.1999). There is indeed authority, in Illinois and elsewhere, sometimes referred to as the "disloyal servant" doctrine, stating that an agent or other fiduciary can forfeit compensation earned during the period of a willful breach of duty. *See, e.g., Clinton Imperial China, Inc. v. Lippert Marketing, Ltd.*, 377 Ill.App.3d 474, 481–82, 316 Ill.Dec. 8, 878 N.E.2d 730, 737 (1st Dist.2007); *Dowd & Dowd, Ltd. v. Gleason*, 352 Ill.App.3d 365, 385, 287 Ill.Dec. 787, 816 N.E.2d 754, 771 (1st Dist.2004). This includes lawyers' breaches of fiduciary duties to clients. *See generally Restatement (Third) of the Law Governing Lawyers*, § 37 (discussing when a forfeiture of "some or all" of a lawyer's fee is warranted when there has been a "clear and serious violation of duty to a client"). This authority is irrelevant here, since I have concluded that Ms. Wheelahan did not breach her fiduciary duty to a client. Further, even if sending the e-mails were unethical, I do not believe a fee forfeiture would be an appropriate sanction (as opposed to a lesser sanction such as a reprimand or her removal as class counsel), where she took no action intended to betray the class by undermining the settlement. *See Restatement*, § 37 cmts. d & e (and cases cited in Reporter's Note) (describing criteria informing whether any fee forfeiture is proper).

49 At the outset of my appointment, to avoid a feeding frenzy, I had informed Plaintiffs' Counsel that if the ethical issues resulted in any recommended reduction of fees, the reduction would inure to the benefit of the class, not other counsel. Texas Counsel are aware of that, and I believe they did not cite this authority to benefit themselves financially.

IV. *OTHER ETHICAL ISSUES—BILLING PRACTICES*

I now turn to the remaining issues to which the Court referred in the April 6 Order.

A. Charges for Travel

When Louisiana Counsel and Counsel other than Texas Counsel filed their joint fee petition, they sought fees under the percentage method. However, as discussed above, they also made summary claims as to their lodestars in an effort to justify the percentage they were seeking. Ms. Wheelahan also submitted detailed hourly billing records in support of her claimed lodestar. In its April 6 Order, the Court criticized some of the categories of time, most notably a list of nearly 400 hours of time "travel time in Chicago," which it attached as Appendix A. These were recorded in 12–hour increments, one 12–hour entry for each trip to Chicago, regardless of how many days she spent in Chicago for any trip. These charges were in addition to any charges for time actually spent in transit or on work for this matter. Thus, for example, if Ms. Wheelahan spent six hours traveling to Chicago on Day 1 and six hours returning to New Orleans on Day 2, she would bill the twelve hours for the actual travel time *to* and *from* Chicago, and would also add one flat twelve hour charge, on either Day 1 or Day 2, for travel time *in* Chicago. If Ms. Wheelahan worked while traveling to or from Chicago, she did not "double bill" that time with the travel time "to" or "from" Chicago, but the twelve hour flat charges were entered regardless of the number of hours she was actually working on any matter or in transit. Wheelahan Tr. 165. The consequence of this practice is that there were travel days on which she billed close to, or even more than, 24 hours.

***44** Ethical rules mandate that "[a] lawyer's fee shall be reasonable." Rule 1.5(a). *See also* *Cripe v. Leiter*, 184 Ill.2d 185, 198, 234 Ill.Dec. 488, 703 N.E.2d 100, 107 (1998) ("[T]he attorney's fiduciary position prohibits the attorney from charging an excessive fee."). These travel time charges are excessive and unreasonable. In general, if a lawyer tried to charge such time to her fee-paying clients, she would quickly generate a roster of angry ex-clients. Indeed, Ms. Wheelahan testified that if she had fee-paying clients, she would ask for approval before billing for travel as she did here. Wheelahan Tr. 171. Ms. Wheelahan should have treated the Court (which sits as fiduciary for the class on this issue) in the same fashion by raising the issue. However, as explained below, I do not believe a sanction is warranted for Ms. Wheelahan's failure to explicitly raise the issue or delete these charges from her fee detail.

Ms. Wheelahan's law practice is almost entirely contingent and she generally does not bill fee paying clients for travel or anything else. Even in the context of timekeeping for contingent matters, it was not Ms. Wheelahan's regular practice to record travel time in this manner. She did so for the first time in this case, based on her reading of two Seventh Circuit opinions, *In re Maurice*, 69 F.3d 830 (7th Cir.1995), and *Henry v. Webermeier*, 738 F.2d 188 (7th Cir.1984). Ms. Wheelahan explained that these twelve-hour charges were meant to compensate her for the opportunity cost of travel—for time that she was out of her office in New Orleans and away from home. She read *Maurice* and *Henry* to authorize her to bill "for the entire time, door-to-door, that the matter took her out of her offices," and implied that she is being generous to the class in only billing a flat twelve-hour fee (in addition to actual travel and work time) even if her time away from New Orleans was much longer. *See* Mot. to Amend Judgment (Doc. 597 at 22); Wheelahan Tr. 168–72.

Ms. Wheelahan ultimately acknowledged in her testimony that she misread *Maurice* and *Henry*, since the cases "don't say that I can do that [*i.e.*, bill portal-to-portal]. But they don't say that I can't do it either." Wheelahan Tr. 172. The cases plainly do not support her practice. *See* *Henry*, 738 F.2d at 194 (*dictum* stating that "opportunity cost is equal to the fee [lawyer] would have charged that or another client if he had not been traveling"); *Maurice*, 69 F.3d at 834 (stating that a "trip to Chicago that diverts time from other paying engagements" is compensable, but not saying anything about a flat travel charge for time "in" Chicago).

Ms. Wheelahan misunderstood the concept of "opportunity cost" as discussed in those cases. If a lawyer has to be on a plane or in another city on behalf of client, and away from her desk during time when she would otherwise be billing clients, charging her client for the travel time for that client may be reasonable as a lost opportunity cost. But the mere time spent in another city away from family or home, while a personal cost of travel, is not normally a chargeable opportunity cost, unless it is "time [diverted] from other paying engagements," *Maurice*, 69 F.3d at

834, because, while at home, the lawyer doesn't bill a client for eating dinner with her family or sleeping. Ms. Wheelahan's billing practice effectively charged time for sleeping in a hotel.

***45** Most clients would not tolerate such a practice, and it would be an easy decision for a court doing a formal lodestar analysis to eliminate all such entries as unreasonable and excessive. However, the fact that the charges were unreasonable does not make them *per se* sanctionable as a violation of professional ethics. First, in doing lodestar analyses courts routinely delete charges that are labeled "unreasonable," "excessive" or "duplicative." The mere fact that time entries are so labeled does not mean the lawyer submitting them has acted unethically. Second, the practice, while based on a fundamental misunderstanding of the "opportunity cost" concept, is not *per se* prohibited. In theory, an attorney who hated traveling and rarely took out-of-town representations and a sophisticated client who strongly desired that attorney's representation in an out-of-town matter could agree to a billing arrangement that included a travel premium, perhaps even in the form of an additional twelve-hour flat fee per trip. It would be a sort of retainer. Third, Ms. Wheelahan did not act deceptively. While she did not raise the issue, neither did she try to hide or disguise the charges. Although based on a poor reading of the law, they appeared in plain view in her fee detail.

In my view, this is principally a Rule 11 issue. *Maurice* and *Henry* offer such flimsy support for Ms. Wheelahan's interpretation that, if she did not violate it, she skated to the brink of Rule 11(b)(2) (legal contentions must be warranted by existing law or by a non-frivolous argument for extending the law or establishing new law). The Court has authority to impose Rule 11 sanctions on its own initiative, Fed.R.Civ.P. 11(c)(3), but any sanction must be "limited to what suffices to deter repetition of the conduct or comparable conduct by others similarly situated." I believe the criticism of her position set forth herein already suffices to deter repetition by Ms. Wheelahan (who has already admitted her reading of the cases was mistaken) or others. Thus, I do not think it necessary to decide whether her reading was so strained that Rule 11(b)(2) was actually violated.

In the final analysis, then, I conclude that Ms. Wheelahan is guilty of very poor judgment, but not dishonest or sanctionable misconduct. She should have realized that billing 25–hour days would appear grossly overreaching, damage her credibility and anger the Court. She should not have included the time or at least should have explained why it was there. Instead, I suspect that she recorded the time based on her misreading of the law and then forgot about it when submitting her time records. That is, at best, sloppy practice. Nevertheless, because I found her misreading of the law sincere and her conduct non-deceptive, I do not recommend that the Court sanction her.

B. Supreme Court Argument

The Court also criticized Ms. Wheelahan for including in her fee detail time spent traveling to Washington, D.C. to attend a Supreme Court argument in a FCRA case that was not part of this MDL proceeding. April 6 Order at 7. Ms. Wheelahan defends the entries as appropriate because the argument involved the key FCRA issue of "wilfulness," and Trans Union counsel traveled to attend the argument. To the extent this time was for travel time "in" Washington, it presents the same issue discussed above. To the extent this time was for attendance at the argument, the fact that Trans Union's counsel also attended the argument gave Ms. Wheelahan a good faith basis to include the time, although again she should have anticipated that the time would raise a serious question as to reasonableness and she should have explained why it was included. But her inclusion of the Supreme Court time does not, in my view, warrant any sanction.

C. Other Items Flagged by the Court

***46** The Court referred to a few additional billing problems that, along with the preceding ones, caused it to "lack[ ] all faith in the veracity of the hours billed," April 6 Order at 8, not only of Ms. Wheelahan, but all Plaintiffs' Counsel. These involved billing for clerical tasks, billing for unsuccessful tasks (such as MDL billing for the unsuccessful first and second settlements or Louisiana Counsel billing for certain pleadings that were stricken),

billing for duplicative work, and vague billing entries. *Id.* at 4–8. As with the preceding issue, I do not believe these problems present any substantial question of sanctionable unethical conduct. Rather, the issues noted by the Court are ones commonly encountered in lodestar litigation, and result in lodestar reductions. Because they were seeking a recovery under the percentage method, it appears that all Counsel simply dumped their raw lodestars on the Court (perhaps relying on cases, cited above, in which courts did cross-checks based on raw lodestars) and did little or nothing in the way of any review to eliminate administrative, duplicative, inefficient, or unreasonable dead-end time. In my rough lodestar cross-checks above, I accounted for such excesses in conservatively estimating substantial cuts in the putative lodestars. Although Counsel's approach is not sanctionable, if Counsel wish to present lodestar figures or data in support of a common fund percentage fee request, a better practice in the future would be to review and reduce raw lodestars before presenting them to the Court, or to acknowledge to the Court that the lodestar data is raw and unreviewed and attempt to defend that practice.

D. General Review of Billing Records

The June 11 Order appointing me as Special Master directed me to "examin[e] the time records of all counsel." The foregoing discussion makes evident that I requested and examined counsel's time records. Specifically, I asked for (or already had) time records of Louisiana Counsel, Texas Counsel, Liaison Counsel, *Frey* Counsel, Lead MDL Counsel and a representative sample of non-lead MDL Counsel firms. Because I ultimately decided to do a lodestar cross-check rather than a full-blown lodestar analysis, I did not scrutinize every time entry. Rather, I conducted enough of a review to make the rough estimates needed for the check. I also made spot-check reviews of various time entries of Counsel to see whether there were billing irregularities other than those flagged by the Court. I reviewed Louisiana Counsel's time entries in much greater detail. Having done so, I saw no other issues of an ethical nature to report.

V. *CONCLUSION*

For the foregoing reasons, I recommend that the Court (i) order a fee award of $12.98 million including an allocation of $7,836,683 to MDL Counsel, $2,722,360 to Louisiana Counsel, and $1,815,319 to Texas Counsel, and (ii) impose no sanction on Ms. Wheelahan or other Plaintiffs' Counsel. I thank the Court for the opportunity to be of assistance.

***47** Pursuant to the June 11, 2009 Order appointing me, a statement detailing the time and expenses of me and my firm through September 30, 2009 is attached as Exhibit 1and is submitted for the Court's review and approval. Please note that in the exercise of billing judgment, I reduced our raw time of $117,234.50 by $12,000 for a total request of $105,234.50 in fees and $6,041.56 in expenses, for a total request (after dropping the cents) of $111,276. The expenses were incurred principally to pay court reporters for my examinations of counsel and to transcribe telephone conferences with counsel. Charges for hosting conference calls (including for the examinations) and Westlaw research comprise most of the remainder.

2012 WL 2340406 (F.T.C.)

Federal Trade Commission (F.T.C.)

In the Matter of POM WONDERFUL LLC and ROLL GLOBAL LLC, as successor in interest to Roll International Corporation, companies, and STEWART A. RESNICK, LYNDA RAE RESNICK, and MATTHEW TUPPER, individually and as officers of the companies, Respondents.

Docket No. 9344
May 17, 2012

PUBLIC

INITIAL DECISION

TABLE OF CONTENTS

I. INTRODUCTION

A. Summary of Complaint and Answer

***1** The Complaint, issued September 24, 2010, alleges that Respondents POM Wonderful LLC, Roll Global LLC, Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper ("Respondents") disseminated advertising and promotional materials representing that the consumption of eight ounces of POM Juice, one POMx Pill, or one teaspoon of POMx Liquid (the "POM Products") daily "prevents or reduces the risk of" or "treats" heart disease, prostate cancer or erectile dysfunction. Complaint ¶¶ 9, 10, 19. Because, according to the Complaint, Respondents represented that they possessed and relied upon, but in fact did not possess or rely upon a reasonable basis substantiating such claims, Respondents' representations were false or misleading. Complaint ¶¶ 19-21.

The Complaint further alleges that Respondents disseminated advertising and promotional materials representing that "clinical studies, research, and/or trials prove" that consuming the POM Products "prevents or reduces the risk of" or "treats" heart disease, prostate cancer or erectile dysfunction. Complaint ¶ ¶ 9, 10, 12, 14, 16. The Complaint further asserts that these representations are false or misleading because, in fact, clinical studies, research, and/or trials do not prove that consuming the POM Products, "prevents or reduces the risk of" or "treats" heart disease, prostate cancer or erectile dysfunction. Complaint ¶¶ 13, 15, 17, 18.

The Complaint concludes that the foregoing acts and practices of Respondents constitute unfair or deceptive acts or practices, and false advertising, in violation of sections 5(a) and 12 of the Federal Trade Commission Act. Complaint ¶ 22.

Respondents filed their Answer to the Complaint on October 18, 2010. While admitting that they disseminated the advertising and promotional materials attached as exhibits to the Complaint, they denied that such materials make the claims alleged. Answer ¶¶ 9, 10, 12, 14, 16, 19. Respondents also deny making false or misleading claims,

and further aver that "there is substantial scientific research indicating the health benefits of [the POM Products] and substantiating their advertising and promotional materials." Answer ¶¶ 13, 15, 17, 18, 21, 22.

B. Procedural History

The administrative hearing (also referred to herein as the "trial" or "administrative trial") in the instant case began on May 24, 2011 and concluded on November 4, 2011. By Order dated November 18, 2011, the hearing record was closed. The hearing record is voluminous. Nearly 2000 exhibits were admitted. Among these exhibits are the advertisements and promotional materials upon which Complaint Counsel relies to prove that Respondents made the representations alleged in the Complaint. These consist of: 27 print advertisements, some of which comprise multiple pages; 2 multi-page newsletters; 7 separate "web captures" of Respondents' 3 websites, recorded at multiple points in time; 2 internet "banner" advertisements; 4 press releases; and 4 television interviews (the "Challenged Advertisements"); *see* Complaint Counsel's Post-Hearing Brief, Appendix A. Also included in the exhibits are more than 46 scientific studies sponsored by Respondents and offered on the issue of substantiation, numerous consumer surveys, and 14 expert reports. In addition, 24 witnesses testified, either live or by deposition, including 14 expert witnesses, and there are 3,273 pages of trial transcript. The parties submitted 3,929 proposed findings of fact (1,130 by Complaint Counsel and 2,799 by Respondents). The parties' proposed findings of fact and conclusions of law, replies to proposed findings of fact and conclusions of law, post-trial briefs, and reply briefs total 3,396 pages.

Commission Rule 3.51(a) states that the Administrative Law Judge ("ALJ") shall file an initial decision within 70 days after the filing of the last filed initial or reply proposed findings of fact, conclusions of law and order pursuant to Commission Rule 3.46 and that the Administrative Law Judge may extend this time period by up to 30 days for good cause. 16 C.F.R. § 3.51(a). The parties filed concurrent post-trial briefs and proposed findings of fact on January 7, 2012. The parties filed replies to the other's proposed findings and briefs on February 7, 2012. Pursuant to Commission Rule 3.41(b)(6), closing arguments were held on March 6, 2012. [1]

Seventy days from the last filed reply proposed findings and conclusions and briefs was April 17, 2012 and, absent an order pursuant to Rule 3.51, the Initial Decision was to be filed on or before April 17, 2012. Based on the voluminous and complex record in this matter and other grounds, an Order was issued on April 16, 2012 finding good cause for extending the time period for filing the Initial Decision by 30 days. Accordingly, issuance of this Initial Decision on May 17, 2012 is in compliance with Commission Rule 3.51(a).

C. Evidence

This Initial Decision is based on a consideration of the whole record relevant to the issues, including the exhibits properly admitted into evidence, deposition transcripts, and the transcripts of testimony at trial, and addresses the material issues of fact and law. The briefs and proposed findings of fact and conclusions of law, and the replies thereto, submitted by the parties were thoroughly reviewed. Proposed findings of fact submitted by the parties, but not included in this Initial Decision were rejected, either because they were not supported by the evidence or because they were not dispositive or material to the determination of the allegations of the Complaint or the defenses thereto. The Commission has held that Administrative Law Judges are not required to discuss the testimony of each witness or all exhibits that are presented during the administrative adjudication. *In re Amrep Corp.*, No. 9018, 102 F.T.C. 1362, 1670, 1983 FTC LEXIS 17, *566-67 (Nov. 2, 1983). Further, administrative adjudicators are "not required to make subordinate findings on every collateral contention advanced, but only upon those issues of fact, law, or discretion which are 'material.'" *Minneapolis & St. Louis Ry. Co. v. United States*, 361 U.S. 173, 193-94 (1959); *accord Stauffer Labs., Inc. v. FTC*, 343 F.2d 75, 82 (9th Cir. 1965). *See also Borek Motor Sales, Inc. v. National Labor Relations Bd.*, 425 F.2d 677, 681 (7th Cir. 1970) (holding that it is adequate for the Board to indicate that it had considered each of the company's exceptions, even if only some of the

exceptions were discussed, and stating that "[m]ore than that is not demanded by the [Administrative Procedure Act] and would place a severe burden upon the agency").

Under Commission Rule 3.51(c)(1), "[a]n initial decision shall be based on a consideration of the whole record relevant to the issues decided, and shall be supported by reliable and probative evidence." 16 C.F.R. § 3.51(c)(1); *see In re Chicago Bridge & Iron Co.*, No. 9300, 138 F.T.C. 1024, 1027 n.4, 2005 FTC LEXIS 215, at *3 n.4 (Jan. 6, 2005). Under the Administrative Procedure Act ("APA"), an Administrative Law Judge may not issue an order "except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence." 5 U.S.C. § 556(d). All findings of fact in this Initial Decision are supported by reliable, probative, and substantial evidence. Citations to specific numbered findings of fact in this Initial Decision are designated by "F." [2]

Pursuant to Commission Rule 3.45(b), several orders were issued in this case granting *in camera* treatment to material, after finding, in accordance with the Rule, that its public disclosure would likely result in a clearly defined, serious injury to the entity requesting *in camera* treatment. 16 C.F.R. § 3.45(b). Commission Rule 3.45(a) allows the Administrative Law Judge "to grant *in camera* treatment for information at the time it is offered into evidence subject to a later determination by the [administrative] law judge or the Commission that public disclosure is required in the interests of facilitating public understanding of their subsequent decisions." *In re Bristol-Myers Co.*, Nos. 8917-19, 90 F.T.C. 455, 457, 1977 FTC LEXIS 25, at *6 (Nov. 11, 1977). As the Commission later reaffirmed in another leading case on *in camera* treatment, since "in some instances the ALJ or Commission cannot know that a certain piece of information may be critical to the public understanding of agency action until the Initial Decision or the Opinion of the Commission is issued, the Commission and the ALJs retain the power to reassess prior *in camera* rulings at the time of publication of decisions." *In re General Foods Corp.*, No. 9085, 95 F.T.C. 352, 356 n.7; 1980 FTC LEXIS 99, at *11 n.7 (March 10, 1980). Thus, in instances where a document had been given *in camera* treatment, but the portion of the material cited to in this Initial Decision does not in fact require *in camera* treatment, such material is disclosed in the public version of this Initial Decision, pursuant to Commission Rule 3.45(a) (the ALJ "may disclose such *in camera* material to the extent necessary for the proper disposition of the proceeding"). This Initial Decision does not contain any material that requires *in camera* treatment.

D. Summary of Initial Decision

The preponderance of the evidence shows that some of the Challenged Advertisements disseminated by Respondents would reasonably be interpreted by consumers to contain an implied claim that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction, and further, as to some of these advertisements, that these effects were clinically proven, as alleged in the Complaint. These advertisements are attached to this Initial Decision as an Appendix. As to other Challenged Advertisements disseminated by Respondents, the preponderance of the evidence fails to demonstrate that such advertisements would reasonably be interpreted by consumers as containing such claims.

The evidence further shows that the appropriate level of substantiation for claims that a product treats, prevents, or reduces the risk of a disease is competent and reliable scientific evidence. The evidence also demonstrates that where such claims are made in connection with a food, or food-derived product, that is safe, and that is not being offered as a substitute for medical treatment, double-blind, randomized, placebo-controlled clinical trials, such as those required by the Food and Drug Administration, are not required. However, for claims that a food or food-derived product treats, prevents, or reduces the risk of a disease, experts in the relevant fields would agree that competent and reliable scientific evidence must include clinical studies, although not necessarily double-blind, randomized, placebo-controlled clinical trials, that are adequate to show that the product did treat, prevent, or reduce the risk of disease.

Notwithstanding the fact that double-blind, randomized, placebo-controlled clinical trials are not required to substantiate Respondents' implied claims for the POM Products, the evidence demonstrates that Respondents' substantiation was, nevertheless, inadequate. Regardless of whether competent and reliable scientific evidence existed to substantiate highly qualified or generalized health claims about the POM Products, the weight of the persuasive expert testimony demonstrates that there was insufficient competent and reliable scientific evidence to support the implied claims in some of the Challenged Advertisements disseminated by Respondents, that the POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, or erectile dysfunction, or were clinically proven to do so. Whether or not Respondents' substantiation was adequate to support the express language of the advertisements is not the material issue. Because Respondents' substantiation was inadequate to support the implied claims, such claims were false or misleading within the meaning of Section 12 of the Federal Trade Commission Act ("FTC Act"), as interpreted by applicable case law. The evidence further shows that such health-related efficacy claims are material to consumers. Accordingly, the preponderance of the evidence supports the conclusion that Respondents violated Sections 5 and 12 of the FTC Act.

Pursuant to Section 5(b) of the FTC Act, a cease and desist order is entered herewith (the "Order"), the provisions of which will serve to prevent Respondents from engaging in deceptive advertising practices in the future, are reasonably related to the unlawful acts or practices found to exist, and are sufficiently clear and precise. The Order is binding upon the corporate Respondents as well as the individual Respondents, and covers any food, drug or dietary supplement that may be advertised by Respondents in the future. Neither applicable law nor the evidence in this case supports Complaint Counsel's proposed provision prohibiting Respondents from making any disease claim in the future, unless the claim has received prior approval from the Food and Drug Administration in accordance with Food and Drug Administration statutes and regulations.

II. FINDINGS OF FACT

A. The Respondents

1. POM Wonderful LLC

1. POM Wonderful ("POM Wonderful" or "POM") is a limited liability company organized under the laws of the State of Delaware. (Complaint ¶ 1; CX1367 at 0002 (S. Resnick, Welch's Dep. at 8); CX1437; Answer ¶ 1).

2. POM Wonderful's principal office or place of business is at 11444 West Olympic Boulevard, Los Angeles, California 90064. (Complaint ¶ 1; Answer ¶ 1).

3. POM Wonderful is wholly owned by the Stewart and Lynda Resnick Revocable Trust, dated December 27, 1988 (the "Resnick Trust"). (Complaint ¶ 1; Answer ¶ 1; CX1384 at 0008).

4. Respondent POM Wonderful is a member-managed company, and the Resnick Trust is the sole member. (Complaint ¶ 1; Answer ¶ 1).

5. In 2002, POM first launched POM Wonderful 100% Pomegranate Juice, a premium, all-natural pomegranate juice made from pomegranates grown from POM's orchards. (L. Resnick, Tr. 145-46).

6. POM Wonderful is currently in the business of selling fresh pomegranates and pomegranate-related products, including 100% pomegranate juice ("POM Juice") and pomegranate extract products known as POMx pills and POMx liquid ("POMx") ("the POM Products"). (S. Resnick, Tr. 1630-31; CX1364 at 0005 (Tupper, Coke Dep. at 20); CX1374 (Tupper, Ocean Spray Dep. at 26); CX1363 at 0012 (S. Resnick, Coke Dep. at 45-46)).

2. Respondent Roll Global LLC

7. Roll International Corporation is a separate corporation organized under the laws of the State of Delaware. (Complaint ¶ 2; Answer ¶ 2).

8. Roll International Corporation was reorganized at the end of 2010 and is currently known as Roll Global ("Roll"). (S. Resnick, Tr. 1629).

9. Roll is wholly owned by the Resnick Trust. (Complaint ¶ 2; Answer ¶ 2).

10. Roll is a privately held corporation. (S. Resnick, Tr. 1630).

11. POM Wonderful, FIJI Water, Suterra, Paramount Farms, Paramount Citrus, Teleflora, Neptune Shipping, Paramount Farming, and Justin Winery are among the separate operating businesses under Roll's ownership umbrella (hereafter "affiliated companies"). (CX1364 at 0004-05 (Tupper, Coke Dep. at 16-17); CX1374 (Tupper, Ocean Spray Dep. at 36); Perdigao, Tr. 593-94).

***2** 12. Stewart and Lynda Resnick are the sole owners of Roll and its affiliated companies, including POM Wonderful. (S. Resnick, Tr. 1629; CX1360 (S. Resnick, Dep. at 15); CX1376 (S. Resnick, Ocean Spray Dep. at 13-14)).

13. Roll's affiliated companies pay Roll for certain provided services. (CX1376 (S. Resnick, Ocean Spray Dep. at 24-25); L. Resnick, Tr. 89; CX1359 (L. Resnick, Dep. at 26); Perdigao, Tr. 616-17).

14. Fire Station acts as Roll's in-house advertising agency. Fire Station bills POM and other Roll affiliated companies separately. (CX1376 (S. Resnick, Ocean Spray Dep. at 24-25); L. Resnick, Tr. 88-89; CX1359 (L. Resnick, Dep. at 26); Perdigao, Tr. 616-17).

3. Respondents Stewart and Lynda Resnick

15. POM Wonderful is owned solely by Stewart and Lynda Resnick ("the Resnicks"). (S. Resnick, Tr. 1629; CX1360 (S. Resnick, Dep. at 15).

16. The Resnicks have been, and currently are, the sole trustees and beneficiaries of the Resnick Trust. (Complaint ¶ 1; Answer ¶ 1; CX1421 at 0002-03; CX1384 at 0008).

17. The Resnick Trust had owned Roll International Corporation and POM. (JX0001 ¶¶ 10-11, 18; Complaint ¶¶ 1-2; Answer ¶¶ 1-2).

18. The Resnicks are the sole owners of Roll Global, the successor-in-interest to Roll International Corporation, and its affiliated companies, including POM. (JX0003 ¶ B.2; S. Resnick, Tr. 1629; CX1360 (S. Resnick, Dep. at 15); CX1376 (S. Resnick, Ocean Spray Dep. at 13)).

19. Stewart Resnick ("Mr. Resnick") is, and at all times relevant to this action has been, the Chairman and President of Roll. (JX0001 ¶¶ 12, 18; S. Resnick, Tr. 1629; Complaint ¶ 3; Answer ¶ 3; CX1384 at 0008; CX1363 at 0014 (S. Resnick, Coke Dep. at 54-55)).

20. Mr. Resnick is, and at all times relevant to this action has been, the Chairman of POM Wonderful. (Complaint ¶ 3; Answer ¶ 3).

21. Mr. Resnick is the Chief Executive Officer of POM. (S. Resnick, Tr. 1869).

22. Mr. Resnick's responsibilities include making final decisions about POM's investments and corporate expansion. (S. Resnick, Tr. 1631; CX1360 (S. Resnick, Dep. at 20-21); *see also* CX1357 (Kuyoomjian, Dep. at 154-56) (testifying that Mr. Resnick's participation in POM's business included involvement in strategic planning and financial decisions as well as providing feedback on POM's advertising)).

23. Mr. Resnick spends the second greatest amount of his time on the POM business and, among other activities, sets the overall budgets for POM, including the marketing and advertising and medical research budgets. He has been intimately involved in the development of POM's scientific research program. (S. Resnick, Tr. 1631-32; CX 1363 at 0014 (S. Resnick, Coke Dep. at 56); CX1367 at 0014 (S. Resnick, Welch Dep. at 55)).

24. Mr. Resnick's authority includes "any decisions made with respect to what ... [POM] talk[s] about, [and] how ... [POM] talk[s] about it," including "authority for advertising the benefits of POM." (Tupper, Tr. 2975).

***3** 25. Mr. Resnick leaves the marketing of POM mostly to Mrs. Lynda Resnick. He considers himself ultimately responsible for whether advertising should or should not go out, although he delegated day-to-day responsibility to Mr. Matthew Tupper. (Tupper, Tr. 2975; S. Resnick, Tr. 1869-70).

26. When Mrs. Lynda Resnick has chosen to involve him, Mr. Resnick has been involved at a high level with POM's advertising and marketing campaigns, including on occasion seeing headlines before advertisements were disseminated. (CX1376 (S. Resnick, Ocean Spray Dep. at 140-42); CX1360 (S. Resnick, Dep. at 50-51)).

27. Lynda Resnick ("Mrs. Resnick") was, at all times relevant to this action, a director and was Vice Chairman of Roll International Corporation. (JX0001 ¶ 18; Complaint ¶ 4; Answer ¶ 4; L. Resnick, Tr. 287; CX1359 (L. Resnick, Dep. at 24-25).

28. Mrs. Resnick is Vice Chairman of Roll Global. (L. Resnick, Tr. 287; CX1359 (L. Resnick, Dep. at 24-25)).

29. Mrs. Resnick is involved in POM's marketing, branding, public relations, and product development. (CX1363 at 0011 (S. Resnick, Coke Dep. at 41); CX1364 at 0007 (Tupper, Coke Dep. at 27); CX1347 (Glovsky, Dep. at 36)).

30. Mrs. Resnick participated in POM's business on almost a daily basis in the company's early years, and on a weekly or biweekly basis thereafter and through 2010, although Mrs. Resnick reduced her day-to-day involvement in POM's business beginning in 2007 (L. Resnick, Tr. 86, 93, 157-58; *see also* CX1375 (L. Resnick, Tropicana Dep. at 19-22, 78); CX1359 (L. Resnick, Dep. at 22, 108)).

31. As of 2011, Mrs. Resnick was still the chief marketing person at POM. (L. Resnick, Tr. 289), and this was also her role in 2010 and 2009. (CX1375 (L. Resnick, Tropicana Dep. at 24); CX1362 (L. Resnick, Coke Dep. at 47, 77-78)).

32. Mrs. Resnick commissioned, helped develop, and used consumer and marketing research for POM's business. (CX1359 (L. Resnick, Dep. at 76-78).

33. Mrs. Resnick has worked with POM's marketing department and Roll's advertising agency, Fire Station, along with scientists and public relations personnel, to implement creative concepts for POM marketing pieces and campaigns. It was a team approach. (L. Resnick, Tr. 87-89; *see also* CX0409; CX0410; CX1359 (S. Resnick, Dep. at 70)).

34. Mrs. Resnick has the "final say" with respect to POM's marketing and advertising content and concepts. (CX1368 at 0003 (L. Resnick, Welch's Dep. at 9); L. Resnick, Tr. 93).

35. According to Mrs. Resnick, when it comes to marketing and creative issues, everyone has a "dotted line" to her, meaning she is in a position of authority even though she may not have day-to-day responsibilities for each employee. (CX1375 (L. Resnick, Tropicana Dep. at 24); L. Resnick, Tr. 287-88).

4. Respondent Matthew Tupper

36. Respondent Matthew Tupper ("Mr. Tupper") joined Roll in May 2001 as Vice President of strategy. (JX0003 ¶ B.5).

37. Mr. Tupper joined POM as a full-time employee in 2003, as Chief Operating Officer. (JX0001 ¶¶ 12, 18; Tupper, Tr. 886-87).

***4** 38. In 2005, his title at POM changed to President, but his responsibilities did not change from those in his position as Chief Operating Officer. (JX0001 ¶¶ 12, 18; Tupper, Tr. 886-87).

39. Mrs. Resnick considers Mr. Tupper as having been her "partner at POM since 2003." (CX0001 at 0037; L. Resnick, Tr. 230).

40. Mr. Tupper retired from POM at the end of the 2011. (Tupper, Tr. 2973).

41. Mr. Tupper will not be working for Roll Global or any other company owned by the Resnicks after his retirement from POM. (Tupper, Tr. 2974).

42. In his capacity as an officer of POM, Mr. Tupper, together with others, formulated, directed, or controlled the policies, acts, or practices of POM. (Complaint ¶ 5, Answer ¶ 5).

43. Mr. Tupper reported to the Resnicks. Mr. Tupper reported directly to Mr. Resnick. Mr. Tupper had a "dotted line" reporting to Mrs. Resnick. (CX1367 at 0014 (S. Resnick, Welch Dep. at 53); CX1364 at 0007, 0027 (Tupper, Coke Dep. at 27-28, 107); CX1375 (L. Resnick, Tropicana Dep. at 23-24)).

44. Mr. Tupper was responsible for managing the day-to-day affairs of POM, which employs roughly 350 people worldwide, including management of the day-to-day operations of the POM marketing team. (JX0003 ¶ B.6; Tupper, Tr. 2974; CX1363 at 0011 (S. Resnick, Coke Dep. at 42)).

45. Mr. Tupper oversaw and administered POM's budget for all departments, and had authority to sign checks and contracts on behalf of the company. (Tupper, Tr. 903-04, 912-13; CX0606 at 0003).

46. Mr. Tupper's activities included hiring and firing POM employees, including the head of POM's marketing department, on his own, or, depending on the situation, in consultation with either Mr. or Mrs. Resnick. (Tupper,

Tr. 902-03; *see also* CX1360 (S. Resnick, Dep. at 22-23); CX1359 (L. Resnick, Dep. at 41, 45); CX1353 (Tupper, Dep. at 24-25)).

47. At POM, nine or ten people have directly reported to Mr. Tupper, including the Vice President of Marketing (including former Senior Vice President of Marketing, Diane Kuyoomjian, ("Ms. Kuyoomjian"), the Vice President of Clinical Development (currently Bradley Gillespie ("Dr. Gillespie")), and the head of the Operations Department. (Tupper, Tr. 888-89, 2974; CX1353 (Tupper, Dep. at 24-25); CX1378 at 0008 (Kuyoomjian, Ocean Spray Dep. at 27)).

48. Mark Dreher, Ph.D. ("Dr. Dreher"), POM's former Vice President of Scientific and Regulatory Affairs, reported to Mr. Tupper. (Dreher, Tr. 527, 529; L. Resnick, Tr. 249).

49. Fiona Posell ("Ms. Posell"), former Vice President of Corporate Communications at Roll and POM, reported to Mr. Tupper and Mrs. Resnick. (Posell, Tr. 299, 321, 325).

50. The head of POM's Marketing department reported to Mr. Tupper, as did the departments with sales responsibilities. (Tupper, Tr. 891).

51. Mr. Tupper's responsibilities within POM included implementing POM's direction with regard to health benefit advertising and the use of science in connection with the advertising. With respect to this advertising, Mr. Tupper was the "connecting piece" between the marketing vision and the communication of the science. It was Mr. Tupper's job to work with all parts of the POM team, including marketing, scientists, and lawyers, to make sure that the advertising was done in "the right way." (Tupper, Tr. 2975-76).

***5** 52. One of Mr. Tupper's responsibilities was to be a liaison between the marketing staff of POM and the researchers in studies sponsored by POM, to help the marketing team "wade through" the science, of which Mr. Tupper had some understanding. (L. Resnick, Tr. 261; Tupper, Tr. 899, 914).

53. Mr. Tupper had a significant degree of involvement in the research aspects of POM's business, and his responsibilities included discussing which research areas are appropriate for funding, participating in the internal decision-making as to what research to fund, and overseeing for POM the clinical trials on POM's products that were conducted by research institutions. (Tupper, Tr. 895-96, 906; *see also* CX0770; CX0779; CX0800; CX0919; CX0920 (showing Tupper's participation in managing POM's medical and scientific research)).

B. The POM Products

1. Description of the POM Products

54. Respondents have manufactured, advertised, labeled, offered for sale, sold, and distributed products to the public, including POM Juice, POMx Pills, and POMx Liquid. (Answer 6; Complaint 6).

55. The Complaint in this case challenges Respondents' advertisements with respect to three products: POM Juice, POMx Pills, and POMx Liquid. (Complaint 6, 9, 10).

56. Respondents also manufacture, advertise, and sell other products containing pomegranate, including various POM Juice blends, Lite POM Juice, POMx bars, POMx iced tea and iced coffee, and a POMx sports recovery beverage. (JX0003 B.8).

a. POM Juice

57. POM Juice is a 100% juice product derived from whole pomegranate fruits. (PX0353 (Heber, Dep. at 124); CX1362 (L. Resnick, Dep. at 85-86); CX1363 (S. Resnick, Dep. at 46-47)).

58. POM Juice is produced by pressing whole pomegranates, including the arils and peels. (CX0967at 0014, *in camera*). The subsequent cloudy juice is filtered and/or enzyme treated before concentrating. (CX0537 at 0003).

59. The concentrate from POM Juice is stored in 52-gallon drums. (CX1369 (Tupper, Welch Dep. at 22)).

60. To make it ready for sale, the concentrate is reconstituted with water to make "100 percent pomegranate juice," pasteurized, and bottled for sale. (JX0003 B.9; CX1369 (Tupper, Welch Dep. at 19-23)).

61. The final POM Juice product contains "85.4% water, 10.6% total sugars, 1.4% pectin, 0.2-1.0% polyphenols, and organic acids." (CX0537 at 0003).

62. POM Juice does not contain dietary fiber or vitamin C. (CX0537 at 0014; CX0716 at 0041).

63. POM Juice contains a variety of polyphenols, including 80 to 90% ellagitannins and gallotannins, 8 to 15% anthocyanins and 2 to 5% ellagic acid. (CX0163 at 0007).

64. A single serving of POM Juice is eight ounces. (CX1379 at 0008, *in camera*). A serving of POM Juice provides 140 calories and 34 grams of sugar. (CX1306 (Weidner, Decl. at 0020)).

65. POM Juice is sold in the refrigerated produce section of the grocery store. (CX1367 (S. Resnick, Welch Dep. at 122); CX1374 (Tupper, Ocean Spray Dep. at 56-57)). Consumers must go to the fresh produce aisle of a store to purchase any POM Juice product. (CX1362 (L. Resnick, Coke Dep. at 135-36).

***6** 66. POM Juice is not sold in the "drug" or "over the counter" section of any establishment. (CX1362 (L. Resnick, Coke Dep. at 135-36); CX1367 (S. Resnick, Welch Dep. at 122; CX1374 (Tupper, Ocean Spray Dep. at 56-57)).

b. POMx Liquid

67. POMx Liquid "is the product of the pressed whole fruit after most of the juice is extracted and the polyphenols are concentrated by filtering and concentrating using juice processing." (CX0096 at 0014, *in camera*).

68. Consumers can purchase POMx Liquid via the company website or through a telephone call center. (JX0003 B.14).

69. POM's website states that the company's recommended daily serving of POMx Liquid is one teaspoon and recommends consumers take one teaspoon of POMx Liquid daily. (CX1379 at 0008-09, *in camera*).

c. POMx Pills

70. POMx is an extract from the pomegranate, made through a process by which POMx Liquid is first derived from the whole fruit, and then POMx is extracted from the POMx Liquid. (CX1363 (S. Resnick, Dep. at 46-47)).

71. POMx was created to use up the "tens of thousands of tons of discarded, mashed-up pomegranates left over from the juicing process." (CX0001 at 0013; CX0967 at 0014).

72. Consumers can purchase POMx Pills via the company website or through a telephone call center. POMx Pills also are available through a few U.S. Retail outlets that sell dietary supplement products. (JX0003 B.14).

73. Pomegranate extracts, because of the production process, contain no anthocyanins. (CX1352 (Heber, Dep. at 358); *see also* CX1258 at 0003 (POMx has only "trace" anthocyanins)).

74. Mrs. Resnick stated "[m]y marketing team and I were eager to learn if we could produce a pomegranate extract that could deliver the power of eight ounces of POM juice in a capsule." (CX0001 at 00013).

75. POMx caters to those consumers who want the benefits of the juice, without the calories or sugar to get, "The Power of POM, in one little pill." (CX0169 at 0001).

76. POM's website recommends consumers take one POMx Pill daily, preferably with eight ounces of water and food. (CX1379 at 0008, *in camera*).

2. Safety of the POM Products

77. Pomegranates have been safely consumed as nutritious food by humans for thousands of years. (PX0192 (Heber Expert Report at 0013, 0018)).

78. Pomegranate juice and pomegranate extract have a "high degree of safety." (PX0192 (Heber Expert Report at 0013)).

79. Pomegranate juice is safe for human consumption if consumed within the nutritional range. (PX0192 (Heber Expert Report at 0018)).

80. POMx is safe for human consumption if consumed within the nutritional range. (PX0192 (Heber Expert Report at 0018)).

81. Unlike some drugs, pomegranate juice has no adverse side effects. (PX0192 (Heber Expert Report at 0042)).

82. The FDA maintains a list of substances that are identified by the FDA as generally regarded as safe ("GRAS"). (Heber, Tr. 2008-09).

***7** 83. Before a substance can be GRAS identified, the FDA reviews the scientific literature and the traditional intake of the substance. (Heber, Tr. 2009).

84. Both pomegranate juice and pomegranate extract are GRAS identified. (Heber, Tr. 2009, 2032; 21 C.F.R. § 182.20).

85. There have been no reported cases of persons being harmed by eating a pomegranate or drinking pomegranate juice. (Heber, Tr. 1947-48).

86. There have been no reported cases of toxicity where pomegranates or pomegranate juice have been consumed in nutritional amounts. (Heber, Tr. 1948).

87. In all the studies that have been conducted on pomegranate juice and pomegranate extract, there have never been any reports of any material harm caused to the subjects by consuming the products. (Heber, Tr. 2007-08; PX0353 (Heber, Dep. at 115)).

88. None of the clinical studies conducted on pomegranate juice and pomegranate extract found any serious risk to human health from consuming the products. (PX0192 (Heber Expert Report at 0018)).

89. Pomegranate juice is a food. (PX0192 (Heber Expert Report at 0011)).

90. Pomegranate extract is a food-based dietary supplement that has substances found in pomegranate juice at levels within the nutritional range. (PX0192 (Heber Expert Report at 0011)).

91. In 2007, in a peer-reviewed study titled, "*Pomegranate Juice Does Not Impair Clearance of Oral or Intravenous Midazolam, a Probe for Cytochrome P450-3A Activity: Comparison With Grapefruit Juice*," by Farkas D, Oleson L, Zhao Y, Harmatz, J, Zinny M, Court M, and Greenblatt D (J Clin. Pharmocol 2007; 47:286-294), Dr. Greenblatt and his colleagues examined the effect of POM Juice and grapefruit juice on inhibiting enteric cytocrhome P450-3A activity in healthy human volunteers. The study showed POM Juice did not cause drug interaction in humans. (PX0136 at 0008).

92. In 2007, in a peer-reviewed study titled, "*Safety and Antioxidant Activity of a Pomegranate Ellagitannin-Enriched Polyphenol Dietary Supplement in Overweight Individuals With Increased Waist Size*," by Heber D, Seeram N, Wyatt H, Henning S, Zhang Y, Ogden L, Dreher M, and Hill J (J Agric. Food Chem. 2007; 55:-10050-10054), Dr. Heber and his colleagues examined the safety in humans of consuming POMx Pills. The study reported: Although there were 11 minor adverse events reported by 9 of the 64 subjects, none of these minor adverse effects were deemed to be related to POMx Pills. The study further reported: no adverse events related to the POMx Pill consumption or changes in blood count, serum chemistry, or urinalysis were observed in the subjects. (PX0139 at 0001, 0003, 0004).

93. Complaint Counsel's expert, Dr. Sacks, testified that the issue of the safety of the POM Products was not within the scope of his assignment in this case, that his expert report contains no opinions on the safety of the POM Products, and that he has "no opinion about whether [the POM Products are] safe or not." (PX0361 (Sacks, Dep. at 74, 76); CX1291 (Sacks Expert Report at 0008-09)).

***8** 94. Complaint Counsel's expert, Professor Meir Stampfer, admitted that there are no safety concerns with consuming pomegranate juice apart from "the usual harm that comes with fruit juice, sugary beverages ... but that is not specific to pomegranate juice." (PX0362 (Stampfer, Dep. at 195-96)).

3. Sales of the POM Products

95. Respondents began selling POM Juice in 2002. POM Juice is sold in supermarkets nationally and is a major seller in the premium juice category. (CX0967 at 0014, *in camera*).

96. POM's U.S. Sales of 100% Juice, from September 2002 to November 2010, totaled approximately $247,739,776. (JX0001 15).

97. For the 52 weeks ending July 20, 2008, the weighted average base price per unit for POM Juice was $2.93 for an 8-ounce bottle or $4.29 for a 16-ounce bottle. (CX0221 at 0007).

98. In 2007, POM began selling POMx Pills and POMx Liquid. (CX1347 (Glovsky, Dep. at 29-30)).

99. POM's Total POMx Pill Gross Revenue, from May 2007 to November 2010, totaled approximately $4,017,681. (JX0001 16).

100. POM's Total POMx Liquid Gross Revenue, from May 2007 to November 2010, totaled approximately $209,820. (JX0001 17).

101. If bought directly from POM's website, POM charges $29.95 (excluding shipping) for a 30-count bottle of POMx Pills and $77.85 (excluding shipping) for a 90-count bottle of POMx Pills. (CX1379 at 0009-10, *in camera*).

102. If bought directly from POM's website, POM charges $29.95 (excluding shipping) for a five-ounce bottle of POMx Liquid. (CX1379 at 0010-11, *in camera*).

C. Background Facts

1. History of POM and science program

a. Overview

103. In 1987, the Resnicks acquired farmland containing over 100 acres of mature pomegranate trees. (CX0105 at 0002).

104. Between 1989 and 2001, Paramount Farming Company, one of the Roll affiliated companies (F. 11), continued to acquire and plant additional pomegranate acreage, bringing the total to 6,000 acres by 2001. (CX0105 at 0002-08).

105. In 1998, the Resnicks began collaborating with researchers to determine whether, and to what extent, there was any truth to the folklore surrounding the health properties of the pomegranate. (L. Resnick, Tr. 150; CX1363 at 0016-17 (S. Resnick, Coke Dep. at 61-66); CX0105 at 0003; CX1362 at 0018 (L. Resnick, Coke Dep. at 71-72); S. Resnick, Tr. 1853-56); CX1359 (L. Resnick, Dep. at 82); CX1360 (S. Resnick, Dep. at 84-85); CX1372 (S. Resnick, Tropicana Dep. at 32-33; CX1374 (Tupper, Ocean Spray Dep. at 87); CX1358 (Aviram, Dep. at 4); CX1367 at 0004(S. Resnick, Welch's Dep. at 15); PX0004).

106. In 2000, the Resnicks formed Paramount Juice Company and, shortly thereafter, in 2001, changed the name to POM Wonderful LLC. (CX1418 at 0001-03).

107. By spring 2001, the yield from the Resnicks' 6,000 acres of pomegranates “ha[d] progressed exponentially ... making it essential to immediately begin a marketing program for the POM Juice product.” (CX0004 at 0001).

***9** 108. POM began bottling, selling, and marketing POM Juice on a regional basis in the fall of 2002, and in national markets in 2003. (CX1353 (Tupper, Dep. at 41-42); CX1395 at 0003).

109. Currently, the Resnicks own approximately 18,000 acres of pomegranate orchards and are the largest growers of pomegranates in the United States. (CX1374 (Tupper, Ocean Spray Dep. at 29-30)).

110. According to Mrs. Resnick, when Respondents went about creating a market for pomegranate juice, “only about one in ten Americans said they were familiar with pomegranates, and fewer than half of that group said they had eaten one in the past year.” (PX0370 at 2).

111. According to Mr. Resnick, a primary part of POM's messaging to consumers is about the health benefits of its products. (S. Resnick, Tr. 1653; CX1372 (S. Resnick, Tropicana Dep. at 31-32)).

112. Mrs. Resnick has stated her belief that POM juice is “health in a bottle” and that this is part of POM Juice's unique selling proposition. (CX0001 at 0006; L. Resnick, Tr. 77-78).

113. POM uses the results of studies it has sponsored for marketing purposes, as part of “[POM's] unique selling proposition.” At least part of the reason for sponsoring studies was for marketing and public relations purposes. (CX1375 (L. Resnick, Tropicana Dep. at 87); CX1372 (S. Resnick, Tropicana Dep. at 74-75; CX0003 at 0001)).

b. Early research

114. POM began its pomegranate research under the direction of POM's former Medical Director, and the Resnicks' personal friend and family physician, Dr. Leslie Dornfeld (“Dr. Dornfeld”), a professor of Internal Medicine at the University of California, Los Angeles (UCLA). (L. Resnick, Tr. 150; CX1350 (Liker, Dep. at 29); CX0105 at 0003).

115. In 1998, Respondents and Dr. Dornfeld collaborated with Dr. Michael Aviram, the Head of the Technion Lipid Research Laboratory at the Rambam Medical Center in Haifa, Israel, known for his work exploring the antioxidant properties of red wine, to understand the antioxidant effect and potential cardiovascular benefits of pomegranate juice. (CX1374 (Tupper, Ocean Spray Dep. at 87); CX1358 (Aviram, Dep. at 4); CX1363at 0016-17 (S. Resnick, Coke Dep. at 61-66); CX1367 at 0004 (S. Resnick, Welch Dep. at 15); CX0001 at 0010-11; L. Resnick, Tr. 150; PX0004). Dr. Aviram's initial research paper showed that pomegranates possess antioxidative and antiatherosclerotic properties. (CX1358 (Aviram, Dep. at 7); PX0004).

116. Dr. Dornfeld initially oversaw the development of POM's research program until he was no longer able to do so for health-related reasons. In 2001, Dr. Dornfeld recruited Dr. Harley Liker (“Dr. Liker”), a physician and faculty member at UCLA, to be his successor as POM's Medical Director. Dr. Dornfeld and Dr. Liker worked together until 2002, when Dr. Liker became POM's Medical Director. (Liker, Tr. 1873, 1877; CX1350 (Liker, Dep. at 15, 27-28); S. Resnick, Tr. 1858).

117. Dr. Liker also became the Resnicks' personal physician and company wellness coordinator and wellness director in 2001. (Liker, Tr. 1876-77).

***10** 118. Respondents hired Risa Schulman, who was POM's Director of Research and Development from approximately 2002 to 2005. POM subsequently hired Dr. Mark Dreher (“Dr. Dreher”) in 2005 as Vice President of Scientific and Regulatory Affairs. (CX0105 at 0016; Dreher, Tr. 527).

119. After identifying an area of scientific interest, Dr. Liker works with Mr. Tupper and Mr. Resnick to determine the leading experts in that scientific field and contacts them to conduct research for Respondents. (Liker, Tr. 1878-80).

120. Dr. Dreher's duties primarily entailed exploratory research, which was looking at new products such as POMx and developing clinical and basic science for new applications for POM products. “Basic science” refers to test-tube, animal studies, and preclinical research. Dr. Dreher also arranged for contracts and funding of research with universities and contract research organizations, provided the materials for testing, and helped to organize the objectives for the studies and for carrying out the studies. (Dreher, Tr. 528).

121. Dr. Dreher reported to Mr. Tupper and also reported, to a certain extent, to Dr. Liker, to help Dr. Liker manage the logistics associated with some of the larger studies. Dr. Dreher and Dr. Liker met weekly for the first two-and-a-half to three years Dr. Dreher was at POM, and then less frequently in the last year of his employment. (Dreher, Tr. 529-30).

122. After Dr. Dreher left, POM hired Dr. Bradley Gillespie in 2009 as its Vice President of Clinical Development. (CX1349 (Gillespie, Dep. at 10-11); CX1353 (Tupper, Dep. at 28)).

123. POM has also hired scientific consultants, including Dr. Aviram and Dr. David Heber. (CX1380 at 0005; CX1349 (Gillespie, Dep. at 264-65); Heber, Tr. 1941; S. Resnick, Tr. 1637).

c. Relevant studies

124. Respondents' studies have explored the effect of POM products on many different areas of health, including the cardiovascular system, immunity, athletic performance, erectile health, prostate cancer, skin care, cognitive function, dental health, and urinary tract health. (CX1353 (Tupper, Dep. at 48-52); Tupper, Tr. 2979-81).

125. Respondents' research efforts branch in various directions in order to examine the role that oxidation and inflammation play in many seemingly unrelated diseases and conditions. (CX1353 (Tupper, Dep. at 47-49); Tupper, Tr. 2979-81; Heber, Tr. 1957, 2112-13, 2185).

126. The results of five POM-sponsored studies have been referred to in the Challenged Advertisements. The studies are:
a. A study by Dr. Aviram, published in 2001 titled, *Pomegranate Juice Consumption Inhibits Serum Angiotensin Converting Enzyme Activity and Reduces Systolic Blood Pressure* (“Aviram ACE/BP Study”). The Aviram ACE/BP Study, conducted on ten patients, examined the effect of POM Juice consumption on angiotensin converting enzyme (“ACE”). (CX0542; *see e.g.*, CX0013 at 0003; CX0031; CX0473 (Compl. Ex. E-2 at 00:30, 1:25)).

***11** b. A study by Dr. Aviram, published in 2004 titled, *Pomegranate Juice Consumption for 3 Years by Patients with Carotid Artery Stenosis Reduces Common Carotid Intima-Media Thickness, Blood Pressure and LDL Oxidation* (“Aviram CIMT/BP Study”). The Aviram CIMT/BP Study, conducted on 19 patients, examined the effect of POM Juice consumption on carotid intima-media thickness (“CIMT”). (CX0611; *see, e.g.*, CX0029; CX0280 CX0328/CX0331/CX0337; CX0473 (Compl. Ex. E-2 at 00:24)).

c. A study by Dr. Dean Ornish, published in 2005 titled, *Effects of Pomegranate Juice Consumption on Myocardial Perfusion in Patients with Coronary Heart Disease* (“Ornish MP Study”). The Ornish MP Study, examined the effect of POM Juice consumption on 45 patients with coronary heart disease. (CX1198; *see, e.g.*, CX0351; CX0355; CX0473 (Compl. Ex. E-2 at 00:30)).

d. A study by Dr. Allan Pantuck, published in 2006 titled, *Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Following Surgery or Radiation for Prostate Cancer* (“Pantuck Study”). The

Pantuck Study examined the effect of POM Juice consumption on 46 men previously treated for prostate cancer by radiation therapy or surgery. (CX0815; *see, e.g.*, CX0351; CX0355; CX0314 at 0004; CX0372 at 0002; CX0379 at 0002; CX0380 at 0002; CX0473 (Compl. Ex. E-2 at 00:24)).

e. A Study by Dr. C.P. Forest and Dr. H. Padma-Nathan, published in 2007 titled, *Efficacy and Safety of Pomegranate Juice on Improvement of Erectile Dysfunction in Male Patients with Mild to Moderate Erectile Dysfunction: A Randomized, Placebo-Controlled, Double-Blind, Crossover Study* ("Forest/Padma Nathan Study"). The Forest Erectile Dysfunction Study (2007) examined the effect of POM Juice consumption on 53 men with mild to moderate erectile dysfunction. (CX1193; *see, e.g.*, CX0351; CX0355; CX0473 (Compl. Ex. E-2 at 00:24)).

127. POM also sponsored a study by Dr. Michael Davidson titled, *Effects of Consumption of Pomegranate Juice on Carotid Intima-Media Thickness in Men and Women at Moderate Risk for Coronary Heart Disease*, published in 2009 ("Davidson CIMT Study"). The Davidson CIMT Study (2009) tested the effect of POM Juice on CIMT progression rates in 289 subjects at moderate risk for moderate coronary heart disease. (CX1065).

128. In over a decade, Respondents sponsored over 100 studies at 44 different institutions. (Liker, Tr. 1887-88).

129. Of the studies POM had conducted as of 2010, approximately 40 percent were performed at UCLA or by Dr. Aviram at the Technion Faculty of Medicine. (*See* CX1241; CX1360 (S. Resnick, Dep. at 113-17)).

130. More than 70 of the studies sponsored by the Respondents have been published in peerreviewed scientific journals. Seventeen of these published studies are human clinical trials. (Liker, Tr. 1888; CX0611; CX0908; PX0004; PX0005; PX0014; PX0060; PX0061; PX0020; PX0021; PX0023; PX0073; PX0074; PX0075; PX0127; PX0136; PX0139; PX0146 (Trombold JR, Barnes JN, Critchley L, and Coyle EF, *Ellagitannin Consumption Improves Strength Recovery 2-3 d after Eccentric Exercise, Med. Sci. Sports Exerc.*, Vol. 42, No. 3, pp. 493-98, 2010)).

***12** 131. Respondents continue to sponsor medical research to determine the benefits of their pomegranate products. Respondents have invested over 35 million dollars in their research program. (S. Resnick, Tr. 1752, 1861-64; CX1363 (S. Resnick, Coke Dep. at 74)).

132. Respondents currently have ongoing research in the areas of cardiovascular health and prostate health. (Tupper, Tr. 984-85, 994; PX0014; PX0023; PX0060; PX0061).

2. Advertising process

a. Overview

133. Roll has a full-service internal advertising agency called Fire Station. (JX0001 18; L. Resnick, Tr. 88-89; Leow, Tr. 493; Perdigao, Tr. 593-94).

134. George Michael Perdigao ("Mr. Perdigao") is the president of Roll's advertising agency, Fire Station, and Roll's corporate communications department, and reports to the Resnicks. (CX1376 (S. Resnick, OS Dep. at 145); JX0001 18; Perdigao, Tr. 590, 594).

135. Elizabeth Leow Hendry ("Ms. Leow") has been a creative director at Roll since 2005, with POM as one of her clients. Ms. Leow is currently the creative director for Fire Station, one of Roll's companies. She has continued to work on POM's advertising. (Leow, Tr. 415; CX1356 (Leow, Dep. at 16-18, 22)).

136. Prior to Fire Station's creation in approximately January 2008, Roll provided advertising services to its affiliated companies through advertising personnel employed by Teleflora, another Roll affiliate. (F. 11; Perdigao, Tr. 592).

137. This group of advertising professionals at Teleflora and later Fire Station has also been known as "The Agency." (Perdigao, Tr. 592; L. Resnick, Tr. 88-89).

138. POM uses Fire Station for all or virtually all of its domestic advertisement agency needs. (Tupper, Tr. 920-21).

139. Generally, Fire Station would be responsible for coming up with specific creative ideas or media plans, and POM's marketing department would help guide the process and provide input. (CX1357 (Kuyoomjian, Dep. at 88-89)).

140. The creation of POM marketing and advertising was a collaborative effort between Fire Station and POM that entailed coming up with ideas for print, outdoor, or television campaigns, as well as writing copy, creating graphics, and putting the ideas together for a final execution. (Leow, Tr. 420-21; Tupper, Tr. 920).

b. Development of advertising

141. Mrs. Resnick held regular creative meetings with the senior in-house representatives of POM and Roll, including representatives of POM's marketing department ("POM Marketing"), Roll's public relations department, and Roll's advertising agency, Fire Station. Staff members at POM and Roll informally refer to these meetings with Mrs. Resnick as "LRR Meetings." (JX0003 A.12; L. Resnick, Tr. 87-88, 92)).

142. In addition to Mrs. Resnick, Mr. Tupper and employees from POM's marketing and scientific departments, Fire Station employees and someone from Roll's Corporate Communications department regularly attend LRR meetings. (Rushton, Tr. 1366; Perdigao, Tr. 624-25; Tupper, Tr. 929-30; L. Resnick, Tr. 249; CX1351 (McLaws, Dep. at 33-34).

***13** 143. At LRR Meetings and during other interactions with POM Marketing and Fire Station, Mrs. Resnick would approve a general direction for POM's advertising and also approved the lion's share of POM's advertising concepts. (CX1362 at 0008 (L. Resnick, Coke Dep. at 30-31); *see also* Perdigao, Tr. 604, 628 (agreeing that it is fair to say that Mrs. Resnick has final authority on advertising campaigns); Rushton, Tr. 1369-71 L. Resnick, Tr. 99-100, 186-87; Leow, Tr. 470; CX0023 at 0001 (stating that "LRR is going to take a more active role in writing copy[]" and that "[i]f [Mrs. Resnick] writes it, it will be approved"); CX1351 (McLaws, Dep. at 23-24) (stating that the "decision to either move forward or make adjustments [on marketing on advertising] came from Lynda")).

144. Mr. Tupper attended most of the LRR Meetings, at which the highest-level executives involved in marketing discussed how to better market POM's products. (Perdigao, Tr. 624-25).

c. Creative briefs

145. The first step in the creative process for POM advertising is a “creative brief,” prepared by POM's marketing department and provided to Fire Station. (L. Resnick, Tr. 123; Loew, Tr. 451; CX1368 at 0024 (L. Resnick, Welch Dep. at 95)).

146. The creative brief was the document used to formally initiate an advertising project. (Perdigao, Tr. 616-17).

147. A creative brief is an outline of the assignment, with the purpose of providing an overview of the assignment. A creative brief might include information on the key message(s) to be conveyed, a suggested target audience for the advertisement, demographics, and media. (Leow, Tr. 451-52; L. Resnick, Tr. 123; *see* CX0409 (creative briefs ranging from January 2004 to October 2009); *see also* CX0129 to CX0131 (2007 creative briefs for POMx print advertisements)).

148. The creative brief outline addresses matters such as “Objective,” “Target Audience,” “Insights,” “Main Message,” “Benefit” or “Benefits,” and “Tonality,” among other matters. (CX0409).

149. Creative briefs are developed for new marketing campaigns that POM undertakes. (Tupper, Tr. 921).

150. POM's online marketing department prepares creative briefs for online components of POM's marketing initiatives. Such briefs are then submitted to Fire Station. (Rushton, Tr. 1353-54, 1391-92).

151. A creative brief is a concept document, to give the advertising agency (Fire Station) insight on how to start a campaign. The substance of a creative brief may or may not ultimately be reflected in an advertisement. (Tupper, Tr. 921; Leow, Tr. 484-85).

152. By their nature, creative briefs were brief and general, and there would be one or more follow-up meetings to discuss the project. (Rushton, Tr. 1396; Perdigao, Tr. 618).

153. The creative process is a collaborative process in which participants share and mold concepts, thoughts and ideas. “It's not like ... you get a creative brief, a guy goes in a room, and then comes out with an ad. It's not quite that simple.” (Perdigao, Tr. 621-22).

***14** 154. Mr. Tupper participated in discussions with the marketing department about individual parts or elements of creative briefs. (Tupper, Tr. 924).

155. Once the creative brief was received by Fire Station, it would be assigned to appropriate personnel at the agency, depending on the project. (Leow, Tr. 452-53).

156. The creative team(s) at Fire Station would then work together to start creating advertisement concepts, which would be reviewed first by Ms. Leow, then by Mr. Perdigao, and finally by POM Marketing. It is a fluid process, including multiple revisions. Depending on the assignment, the concepts were sometimes also reviewed by Mr. Tupper. These reviews at the concept stage involved the general creative direction, look, tone, and idea of the advertising, rather than body copy. (Leow, Tr. 457-60).

157. Advertising concepts would include the graphics and headlines. A headline is the main message of an advertisement and usually appears in larger type. Body copy is the smaller print usually appearing at the bottom of an advertisement. (Leow, Tr. 462-63, 467).

158. After the creative concepts were approved, the creative team at Fire Station would draft body copy with direction from POM Marketing, using the creative brief as an outline and including any additional input marketing might add. (Leow, Tr. 462-64).

159. There are no scientists or technical writers on Fire Station's staff. Therefore, if the body copy of an advertisement were to contain information on studies and POM Marketing wanted specific wording, it would be provided by POM Marketing. (Leow, Tr. 464-65).

160. After the copy of an advertisement was drafted, it would go to the head of marketing for approval, and sometimes, depending on the project, to Mr. Tupper and Mrs. Resnick for approval. (Leow, Tr. 463-64; L. Resnick, Tr. 187-188).

161. Once the concepts for a big advertising campaign were approved, they would ultimately go to Mrs. Resnick for approval. Fire Station presented advertising concepts to Mrs. Resnick during LRR Meetings. (Leow, Tr. 461; Perdigao, Tr. 623-25; Rushton, Tr. 1358).

162. In addition to approving the body copy, POM Marketing would also thereafter provide final review of the completed advertisement, and depending on the project, Mr. Tupper might approve it as well. (Leow, Tr. 464-66).

163. After proofreading by Fire Station personnel, POM's advertisement would be sent to Fire Station's production department to create the “mechanical” — the completed advertisement in final electronic form that is ready to be sent to publications. (Leow, Tr. 466-67).

164. The process POM uses to connect the science to the advertising includes a “checklist of individuals who need to review and sign off on those ads, ultimately culminating in the legal review.” (Tupper, Tr. 2977-78).

165. POM approves final executions of advertisements created by Fire Station before dissemination. (Leow, Tr. 466; Perdigao, Tr. 637).

***15** 166. Mrs. Resnick would sometimes review finished advertisements. (Leow, Tr. 466).

167. Mrs. Resnick's participation in the creative process included briefing POM Marketing, as well as meeting with POM and Fire Station personnel to review proposed creative pieces developed by Fire Station. (CX1368 at 0003 (L. Resnick, Welch Dep. at 9-10)).

168. Mrs. Resnick has reviewed and provided detailed edits and suggestions for POMx Pill advertisements (CX0126 at 0002) and the POM Wonderful website (CX0024 at 0009-38); approved designs and headlines for advertisements in various media (CX0247 at 0002; CX0248 at 0002); and suggested and reviewed concepts for new advertisements (CX0266 at 0002-03; CX0320 at 0002).

3. Target audience for POM Products advertising

169. The POM Juice print advertisements at issue in this case were disseminated in a wide variety of locally and nationally distributed publications, including but not limited to: the *Chicago Tribune* (CX0016), *Prevention* (CX0029, CX0034, CX0260), *Details* (CX0031), *Rolling Stone* (CX0033, CX0036), *Health* (CX0103, CX0251), I*nStyle* (CX0109), *Town and Country* (CX0109) *Men's Health* (CX0192, CX0260), and *Men's Fitness* (CX0274). *See also* CX0474; CX0371 (declarations describing capture of print advertisements and dissemination information).

170. The POMx Pills print advertisements at issue in this case were disseminated in a wide variety of locally and nationally distributed publications, including but not limited to: *Fortune* (CX0120), the *New York Times* (CX0169, CX0337), *Discover* (CX0122), *Men's Health* (CX0348), *Popular Science* (CX0348), *Time* (CX0350) and *Playboy* (CX0355, CX0470 at 0002; Leow Tr. 496).

171. The POM Products have been advertised in print advertisements in magazines, freestanding inserts ("FSIs") in newspapers, out of home media such as billboards and bus shelters, posters in health clubs and doctors' offices, advertising on prescription drug bags, Internet websites, online banner advertisements, medical outreach, radio, television, and press releases. (L. Resnick, Tr. 81-82 (radio), 186 (FSIs); Leow, Tr. 426-28, 457 (out of home, health clubs, banner ads, television); Perdigao, Tr. 597-98 (press releases), 608-09 (prescription drug bags); Tupper, Tr. 927 (magazine wraps); CX1375 (L. Resnick, Trop. Dep. at 167 (medical outreach)); CX1357 (Kuyoomjian, Dep. at 85-86 (posters in doctors' offices)), 122 (radio)).

172. POM placed advertising in such magazines as *Health Magazine*, *Men's Health*, and *Men's Fitness*, because these publications are geared toward the health-conscious consumer. (Leow, Tr. 425-26).

173. POM has purchased online banner advertisements on websites, including specific websites with audiences interested in personal health, fitness, and physical well-being such as *Men's Health*, *ESPN*, *Livestrong*, and *WebMD*. (Rushton, Tr. 1397-98; CX0463; CX0466; CX0468; Leow, Tr. 428-29).

***16** 174. Current POM Juice buyers tend to be in their forties, possibly older, and are sophisticated to some extent about their health. (L. Resnick, Tr. 127-28).

175. For purposes of a creative brief (*see* F. 145-151) "target audience" refers to the audience to whom the advertisement would appeal. (Leow, Tr. 451-52).

176. Seven creative briefs for POM Juice advertising projects, dating between January 2004 and July 2006, described the "target audience" for the subject advertisement as: "Hip Gen X 25-39. Skews female (60/40) likely to be affluent, professional, college grads who are very health-conscious (hypochondriacs) and live in urban areas. Either single or married without kids." (CX409 at 0001; *see also* CX0409 at 0003, 0005, 0006, 0008, 0010, and 0022). In July 2006, this description was prefaced with the comment, "same as general POM consumer." (CX409 at 0022)

177. Two creative briefs dated June 28, 2006 and July 13, 2006, which stated that they were to be used for all future POMx Pill projects, identified the target audience for POMx Pills as "Age and Gender: 25-64 year old men and women (50/50 split) Psychographic: (1) Core POM Consumer, (2) Consumer who won't drink the juice or tea but who is seeking a natural cure for current ailments or to maintain health and prevent future ailments[.]" These creative briefs further noted, under "tonality," in part, "catchy headlines but serious copy that reflects the fact that antioxidants are important for health. The pill form is more medicinal by nature and attracts consumers that are looking for health benefits but won't drink the juice or tea." (CX0409 at 0016, 0018).

178. A creative brief for POMx Pills, dated September 1, 2006, referred to "a handful of different creative approaches targeting different consumers that include men, seniors and young health conscious females." Under target consumer audience," this creative brief stated: "Age & Gender: Start with men 40+, HH income $75K+, primarily men who are scared to get prostate cancer ... Two other targets based on this plan include seniors 55+ who are heavy supplement users (AARP & Readers' Digest) and young health conscious women (Oprah, More, Health) — both of whom will benefit from the antioxidants (cardiovascular, anti-aging, etc.)." (CX0409 at 0023).

179. In a creative brief for the "Health Benefits" section of the POM Wonderful website, from June 2008, the "target audience" was described as "General population (35+, 60% Female): Consumers ... Who are looking for general information about Pomegranate Health, Antioxidant, Polyphenol or related topics and want to learn more ... or find out the truth about Pomegranates[,] Who have seen articles about pomegranates or antioxidants [,] With an ailment that pomegranates have been rumored to help[.]" The "target audience" for the website was also identified to include "Health Care Professionals" including "Primary care physicians[,] Urologists[,] Dieticians [,] Nutritionalists[,] Other healthcare industry professionals." (CX0200 at 0002).

***17** 180. Ms. Leow, a creative director for Roll, expressed her opinion that scientific information in advertising and marketing material helps sell the products, because the scientific information provides the consumer with a "reason to believe." (Leow, Tr. 512-13).

181. A creative brief attached to an email from Michael Perdigao to Lynda Resnick dated June 25, 2008, noted that the "primary target consumer" for an unidentified referenced POM Juice campaign "should be the 30-something health conscious (hypochondriac?) who is educated and affluent." (CX0211 at 0002).

D. Testifying Experts

1. Complaint Counsel's experts

a. Dr. Meir Stampfer

182. Dr. Meir J. Stampfer is a Professor of Epidemiology and Nutrition, Harvard School of Public Health; Faculty Member, Division of Biological Sciences, Harvard School of Public Health; Professor of Medicine, Harvard Medical School; and Faculty Member, Dana Farber Harvard Cancer Center. (Stampfer, Tr. 689-91; CX1293 (Stampfer Expert Report at 0001)). He teaches epidemiology, advanced epidemiology, and preventive medicine. (CX1293 (Stampfer Expert Report at 0001)). Epidemiology is the study of the determination and distribution of disease in humans. (Stampfer, Tr. 691).

183. Dr. Stampfer has been an investigator in several large studies focused on the relationship between nutrition and cancer and cardiovascular disease ("CVD"), and their precursors. (CX1293 (Stampfer Expert Report at 0003-04)). These include: Nurses' Health Study (started 1976, 121,700 women, cancer prevention, CVD, diabetes, and other health issues); Nurses' Health Study II (started 1989, 116,800 women, same as Nurses' Health Study); Physicians' Health Study (started 1982, 29,000 men, multivitamin supplements, and aspirin, and beta carotene for prevention of CVD and cancer); and Health Professionals Follow-up Study (started 1986, 51,529 men, nutritional factors as related to cancer, including prostate cancer, and heart disease). (CX1293 (Stampfer Expert Report at 0003-04); Stampfer, Tr. 692-94). Additionally, he has participated in research investigating risk factors (including food intake and dietary factors) associated with prostate cancer and conducted randomized clinical trials involving nutrition and health, including dietary interventions to reverse atherosclerosis. (Stampfer, Tr. 698-700).

184. Dr. Stampfer has published more than 850 articles in medical journals, including the *New England Journal of Medicine*, *American Journal of Epidemiology*, *Epidemiology*, and *Journal of American Medical Association*. (CX1293 (Stampfer Expert Report at 0002)). Over 300 of these articles relate to the relationship between nutrition and the prevention or treatment of CVD or prostate cancer. (Stampfer, Tr. 701; *see also* CX1293 (Stampfer Expert Report at 0002)).

185. In 2003, the Institute for Scientific Information identified Dr. Stampfer as the most cited researcher in clinical medicine and epidemiology in the world during the past 20 years. (CX1293 (Stampfer Expert Report at 0002)).

In 2005, the Institute for Scientific Information identified him as the most cited researcher in clinical medicine over the previous decade. (CX1293 (Stampfer Expert Report at 0002)).

***18** 186. Dr. Stampfer currently is an editor for leading medical journals, including the Journal of the *American College of Nutrition, American Journal of Epidemiology, American Journal of Medicine*, and *Clinical Chemistry*. Dr. Stampfer also had editorial positions on the *American Journal of Clinical Nutrition, New England Journal of Medicine*, and *American Journal of Medicine*. (Stampfer, Tr. 701; CX1293 (Stampfer Expert Report at 0001-02)). Dr. Stampfer is a member of professional organizations relating to epidemiology, cancer, and CVD, including the Society of Epidemiological Research, the American College of Nutrition, the American Heart Association, and the American Association for Cancer Research. (Stampfer, Tr. 701-03). He also has consulted for the government on the U.S. Dietary Guidelines. (Stampfer, Tr. 703).

187. Dr. Stampfer was accepted as an expert on: 1) epidemiology; 2) nutrition, including its relation to the prevention and treatment of CVD and prostate cancer; and 3) clinical testing related to the prevention of prostate cancer and CVD. (Stampfer, Tr. 704-05; *see also* CX1293 (Stampfer Expert Report at 0005)).

188. Dr. Stampfer was asked to evaluate, from his perspective as an expert in the fields of epidemiology, nutrition, and clinical testing, whether the following claims were supported by the materials submitted by the Respondents:
• drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart;

• tests prove that drinking eight ounces of POM Juice or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart;

• drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time ("PSADT"); and

• tests prove that drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of prostate cancer, including by prolonging "PSADT."

(CX1293 (Stampfer Expert Report at 0005-06)).

189. To form his opinions, in addition to drawing upon his own expertise, Dr. Stampfer reviewed materials submitted by Respondents and affiliated researchers, including published and unpublished study reports, protocols, data and data analyses from Respondents' sponsored research, information about ingredients contained in the POM Products, and deposition transcripts of researchers who conducted studies for Respondents and related deposition exhibits and reports. Dr. Stampfer also reviewed materials he found through his independent literature search. (CX1293 (Stampfer Expert Report at 0006-07); Stampfer, Tr. 734-36; CX1294).

***19** 190. Dr. Stampfer opined that the materials relied upon by Respondents do not provide competent and reliable scientific evidence to support claims that: (1) drinking eight ounces of POM Juice or taking a daily serving of POMx is clinically proven to treat, prevent, or reduce the risk of heart disease or prostate cancer; (2) a daily eight ounce serving of POM Juice or a serving of POMx treats, prevents, or reduces the risk of heart diseases, including by prolonging PSADT (defined *infra* F.1042); or (3) a daily eight ounce serving of POM Juice or a

serving of POMx treats, prevents, or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart. (CX1293 (Stampfer Expert Report at 0007)).

b. Dr. Frank Sacks

191. Dr. Frank M. Sacks is a Professor of Cardiovascular Disease Prevention, Department of Nutrition, Harvard School of Public Health, and Professor of Medicine, Harvard Medical School. (Sacks, Tr. 1411-12; CX1291 (Sacks Expert Report at 0001)). He has taught pharmacology, epidemiology, and nutrition courses related to human disease, CVD, biochemistry, or preventative medicine. (Sacks, Tr. 1412-13; CX1291 (Sacks Expert Report at 0002)).

192. Dr. Sacks has researched CVD and coronary heart disease ("CHD") and their risk factors, including lipid profiles, hypertension, obesity, and diabetes, and the effects of potential risk-modifying diets, foods, food components, and drugs. (CX1291 (Sacks Expert Report at 0002); Sacks, Tr. 1415-18). He is the principal investigator of several National Institute of Health studies focusing on dietary nutrients and weight loss, carbohydrate amount and type affecting risk of CVD and diabetes, and dietary fat and high-density lipoprotein ("HDL") metabolism in humans. (CX1291 (Sacks Expert Report at 0005-06)).

193. Dr. Sacks has published more than 160 articles in peer-reviewed scientific journals relating to CVD, CHD, and the relationship between nutrition and these diseases. (Sacks, Tr. 1412-13, 1424-25; CX1291 (Sacks Expert Report at 0002-04)). Dr. Sacks has also written over 60 reviews, reports, editorials, and book chapters, addressing CVD, CHD, and the relationship between nutrition and these diseases or their risk factors. (CX1291 (Sacks Expert Report at 0004)).

194. Through his professional memberships and activities, Dr. Sacks keeps current on new developments and research in the areas of nutrition, CVD, cholesterol disorders, and hypertension. (Sacks, Tr. 1424). He served as an editor for the *American Journal of Clinical Nutrition*, *Journal of Clinical Lipidology*, a *Nutrition Journal (BioMed Central)*, and *The Journal of Lipid Research*. (CX1291 (Sacks Expert Report at 0006)). In these positions, he reviewed the adequacy of the design, the conduct of clinical research, and the appropriateness and accuracy of the statistical methodology in hundreds of papers submitted for publication. (Sacks, Tr. 1424-25; CX1291 (Sacks Expert Report at 0006)).

***20** 195. Dr. Sacks serves as a chair of the Nutrition Committee of the American Heart Association (AHA), which advises the AHA on matters of science and public policy and devises guidelines and advisory statements to the government, health professionals, and the public on nutrition. (Sacks, Tr. 1426; CX1291 (Sacks Expert Report at 0006-07)). Dr. Sacks is also a member of the National Cholesterol Education Program of the National Heart, Lung and Blood Institute of NIH, which revises national guidelines on prevention and treatment of CVD. (CX1291 (Sacks Expert Report at 0007); Sacks, Tr. 1426).

196. Dr. Sacks was accepted as an expert in the areas of nutrition, CVD, CHD, cholesterol disorders, hypertension, and analysis of clinical studies. (Sacks, Tr. 1429-30; CX1291 (Sacks Expert Report at 0008)).

197. Dr. Sacks was asked to determine whether the materials he reviewed were sufficient to support claims that: (1) drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart; and (2) clinical studies, trials, and/or tests prove that drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease. (CX1291 (Sacks Expert Report 0008-09)).

198. To form his opinions, in addition to drawing upon his own expertise in nutrition and CVD treatment, Dr. Sacks reviewed materials submitted by Respondents and affiliated researchers, including published and unpublished study reports, protocols, data, and data analysis from Respondents' sponsored research, information about ingredients contained in the POM Products, and deposition transcripts of researchers who conducted studies for Respondents and related deposition exhibits. Dr. Sacks also reviewed materials he found through an independent literature search. (Sacks, Tr. 1447-49; CX1291 (Sacks Expert Report at 0008-09); CX1292, Apps. 2, 3, 4).

199. Dr. Sacks opined that: (1) the materials relied upon by Respondents do not support claims that drinking eight ounces of POM Juice or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents, reduces the risk of, or treats heart disease, including by decreasing arterial plaque, lowering blood pressure and/or improving blood flow to the heart; and (2) clinical studies, research, and/or trials do not prove that drinking eight ounces of POM Juice or taking one POMx Pill or one teaspoon of POMx liquid, daily, prevents or reduces the risk of or treats heart disease, including by, decreasing arterial plaque, lowering blood pressure and/or improving blood flow to the heart. (CX1291 (Sacks Expert Report at 0010)).

c. Dr. James Eastham

200. Dr. James A. Eastham is the Chief of Urology in the Department of Surgery at Memorial Sloan-Kettering Cancer Center in New York. He serves as the Director of Clinical Research, Urology and chairs the protocol review committee for clinical trials in the Department of Surgery. (CX1287 (Eastham Expert Report at 0001); Eastham, Tr. 1207-08). He is a board-certified urological surgeon who has treated more than 2,000 patients with prostate cancer, including some who experienced a rise in prostate-specific antigen ("PSA") after receiving initial therapy. (CX1287 (Eastham Expert Report at 0002); Eastham, Tr. 1206, 1225-28, 1233).

***21** 201. Dr. Eastham has extensive experience, including as an investigator, in the design and conduct of clinical trials studying prostate cancer. (Eastham, Tr. 1215-17). As a member of the Data Safety Monitoring Board for the Selenium and Vitamin E Cancer Prevention Trial, he is familiar with the design and performance of the largest prevention trials studying antioxidants and prostate cancer. (CX1287 (Eastham Expert Report at 0002-03); Eastham, Tr. 1210-11).

202. Dr. Eastham is a member of several professional associations, including the American Urological Association, the Society of Urologic Oncology, and the National Comprehensive Cancer Network ("NCCN") Prostate Cancer Guidelines Committee. He regularly attends and speaks at national and international meetings of professional societies that specialize in urology and prostate cancer. (CX1287 (Eastham Expert Report at 0003); Eastham, Tr. 1211-13).

203. Dr. Eastham has peer-reviewed numerous papers involving randomized, doubleblinded, controlled human clinical studies that were submitted to medical journals, such as *Urology*, *Journal of Urology*, and *Journal of Clinical Oncology*. (CX1287 (Eastham Expert Report at 0003); Eastham, Tr. 1224-25). Dr. Eastham has published over 200 peer-reviewed articles in scientific journals, as well as dozens of book chapters or reviews pertaining to urology and the treatment of prostate cancer. (CX1287 (Eastham Expert Report at 0003-04); CX1288, Ex. A; Eastham, Tr. 1214-15).

204. Dr. Eastham was accepted as an expert in the areas of: (1) urology specializing in prostate cancer, including the prevention and treatment of prostate cancer; and (2) clinical testing related to the prevention and treatment of prostate cancer. (Eastham, Tr. 1234; CX1287 (Eastham Expert Report at 0004)).

205. Dr. Eastham was asked to determine whether the materials he reviewed were sufficient to support claims that: (1) drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time ("PSADT"); and (2) tests prove that drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats or prevents prostate cancer, including by prolonging PSADT. (CX1287 (Eastham Expert Report at 0004-05)).

206. To form his opinions in addition to drawing upon his own expertise in the field of urology, specializing in prostate cancer, including the prevention and treatment of prostate cancer, and clinical testing relating to the treatment and prevention of prostate cancer, Dr. Eastham reviewed the materials submitted by Respondents and affiliated researchers, including published and unpublished study reports, protocols, data and data analysis from Respondents' sponsored research, and information about ingredients contained in the POM Products. Dr. Eastham also reviewed materials he found through an independent literature search. (CX1287 (Eastham Expert Report at 005); Eastham, Tr. 1287-88; CX1288, Ex. B).

***22** 207. Dr. Eastham provided the following opinion: the materials relied upon by Respondents do not provide reliable scientific evidence that POM Juice, POMx Pills, or POMx Liquid effectively prevents, reduces the risk of, or treats prostate cancer or are clinically proven to do so. (CX1287 (Eastham Expert Report at 006, 012)).

d. Dr. Arnold Melman

208. Dr. Arnold Melman is a Professor and Chairman of the Department of Urology at Albert Einstein College of Medicine and Montefiore Medical Center in New York. (Melman, Tr. 1072-73). Dr. Melman is a board-certified, practicing clinical urologist at Montefiore Medical Center and has treated thousands of patients with erectile dysfunction. (Melman, Tr. 1071-73).

209. Dr. Melman has extensive experience in designing and reviewing protocols for well-designed clinical trials. As an editor of *Sexuality and Disability*, the *Journal of Urology*, and the *International Journal of Impotence Research*, Dr. Melman reviewed hundreds of articles involving erectile dysfunction by evaluating, among other factors, the design, data collection and reporting, and statistical analysis of clinical studies. (Melman, Tr. 1075-77; CX1289 (Melman Expert Report at 0002)). Furthermore, Dr. Melman was a principal investigator on two National Institutes of Health research grants relating to erectile dysfunction. (Melman, Tr. 1079-80; CX1289 (Melman Expert Report at 0002-03)).

210. Dr. Melman was chairman of the U.S. Food and Drug Administration's Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee, and was a member of the National Institutes of Health's Urology Special Emphasis Panel. (Melman, Tr. 1077-78; CX1289 (Melman Expert Report at 0001-02)). Dr. Melman is a member of several professional organizations, including the American Federation for Clinical Research, Society of University Urologists, American Urological Association, American Association of Clinical Urologists, International Society of Urology, and International Academy of Sex Research; and has spoken at national and international meetings of professional societies that specialize in urology and erectile dysfunction. (Melman, Tr. 1077-79; CX1289 (Melman Expert Report at 0001-02)). Dr. Melman has published more than 200 peer-reviewed articles relating to urology in scientific journals. Many of these published articles relate to erectile dysfunction. (Melman, Tr. 1076-77; CX1289 (Melman Expert Report at 0002)).

211. Dr. Melman was accepted as an expert in: (1) urology as it relates to the treatment, prevention, and reduction of risk of erectile dysfunction; and (2) clinical testing involving erectile dysfunction. (Melman, Tr. 1080-81).

212. Dr. Melman was asked to determine whether the materials he reviewed were sufficient to support claims that: (1) drinking eight ounces of POM Juice, daily, prevents, reduces the risk of, or treats erectile dysfunction; and (2) clinical studies, research, and/or trials prove that drinking eight ounces of POM Juice, daily, prevents, reduces the risk of, or treats erectile dysfunction. (CX1289 (Melman Expert Report at 0003)).

***23** 213. To form his opinions, in addition to relying on his expertise in urology as it relates to the treatment, prevention, and reduction of risk of erectile dysfunction, and clinical testing involving erectile dysfunction, Dr. Melman reviewed materials submitted by Respondents and affiliated researchers, including published and unpublished study reports, protocols, and data and data analyses from Respondents' sponsored research. (CX1289 (Melman Expert Report at 0003); Melman, Tr. 1083). Dr. Melman also reviewed articles he found through his independent research of peer-reviewed journals. (Melman, Tr. 1083; CX1289 (Melman Expert Report at 0003)).

214. Dr. Melman opined that POM Wonderful pomegranate juice has not been proven to prevent, reduce the risk of, or treat erectile dysfunction. (CX1289 (Melman Expert Report at 0005)).

2. Respondents' experts

a. Dr. Denis Miller

215. Dr. Denis R. Miller is a board certified pediatrician and pediatric hematologist and oncologist licensed to practice medicine in the state of New Jersey. (PX0206 (Miller Expert Report at 1); PX0354 (Miller, Dep. at 16)). He directs one of the largest pediatric oncology/ hematology programs in the world and holds an endowed chair. (PX0206 (Miller Expert Report at 3)).

216. Dr. Miller has, for over 40 years, directed clinical care, education, laboratory and clinical research, and administration, and led departments at some of the most prestigious hospitals in the world. (PX0206 (Miller Expert Report at 2); Miller, Tr. 2190). Dr. Miller has designed, managed, and directed many different research studies calculated to develop new anti-cancer agents. (PX0206 (Miller Expert Report at 2-3)).

217. Dr. Miller has authored or co-authored over 300 book chapters, peer-reviewed articles, and abstracts mostly on cancer and blood disorders. (PX0206 (Miller Expert Report at 4); Miller, Tr. 2191).

218. Complaint Counsel has retained Dr. Miller on several matters, and he testified for Complaint Counsel previously in the matter of *Daniel Chapter One*. (PX0206 (Miller Expert Report at 5, 18)).

219. Dr. Miller was accepted as an expert in the design of clinical research protocols and asked to testify on the areas of the applicable standards of substantiating evidence for fruit and fruit juice or food products in general as opposed to the standard that is applicable to drugs. (Miller, Tr. 2192, 2218).

220. Dr. Miller provided the following opinions: pomegranates are a food that have been eaten for thousands of years and its consumption as a food is without known risks; the appropriate level of scientific substantiation regarding the health benefit claims of pomegranates should be flexible and consider several factors (including risk of harm) with the desirability of getting information to the public; the standard for substantiating foods that are clearly safe need not be as rigorous as that for a new drug or anticancer agent, but should be based on reliable and competent scientific data; and POM Wonderful is not being put forth as a substitute or alternative to conventional and approved drug therapies and medical care. (PX0206 (Miller Expert Report at 15)).

b. Dr. David Heber

***24** 221. Dr. David Heber received his Ph.D. in Physiology from UCLA, an MD from Harvard Medical School, and a B.S. in Chemistry from UCLA. (PX0192 (Heber Expert Report at 0005)). Dr. Heber is the founding director of the UCLA Center for Human Nutrition, which is a center for clinical research, education, and public health endeavors. (Heber, Tr. 1937).

222. Dr. Heber is a treating physician with patients, and has been a member of the faculty of UCLA Medical School for 33 years. He is currently a Professor of Medicine in Public Health. (Heber, Tr. 1937; CX1407 (Heber, Tropicana Tr. 76)).

223. Dr. Heber has co-authored over 200 peer-reviewed publications in the field of nutrition and its relation to various diseases and written 25 chapters in other scientific texts. (Heber, Tr. 1939-40). He was the editor-in-chief of the leading text on nutritional oncology and has written a book on the importance of diet in maintaining health and resisting diseases. (Heber, Tr. 1939).

224. Dr. Heber was accepted as an expert in the relationship between nutrition and various diseases, including coronary heart disease and prostate cancer, as well as other diseases. (Heber, Tr. 1941).

225. Dr. Heber was asked to testify on Dr. Stampfer's expert report and provide opinions on issues related to pomegranate juice and extract, including: (1) antioxidants found in pomegranates, their potency, and how they act in the body (their mechanisms of action); (2) the health and safety effects; and (3) nutritional research methodology relating to the evaluation of scientific research on health benefits. (PX0192 (Heber Expert Report at 0004)).

226. Dr. Heber provided the following opinions: it is not appropriate to require the use of double-blind placebo-controlled studies for evaluating the health benefits of foods; translational nutritional science looks at the best available evidence, as a totality, rather than just one type of clinical study; and the body of research on pomegranate juice and extract, revealing how they act in the body, provides support for potential benefits for heart disease and prostate cancer. (PX0192 (Heber Expert Report at 0013-15)).

c. Dr. Dean Ornish

227. Dr. Dean Ornish is a medical doctor and Clinical Professor of Medicine at the University of California at San Francisco. (Ornish, Tr. 2314).

228. Dr. Dean Ornish is the Founder and President of the Preventative Medicine Research Institute (“PMRI”) in Sausalito, CA. (PX0025 (Ornish Expert Report at 0001)).

229. For over 34 years, Dr. Ornish directed clinical research on the relationship between diet and lifestyle and coronary heart disease. He was the first to prove by a series of RCTs that heart disease could be reversed by making changes in diet and lifestyle. (Ornish, Tr. 2316-17).

230. Dr. Ornish has written six published books on the subject of the effect of diet and lifestyle on heart disease and other diseases. (Ornish, Tr. 2318). Dr. Ornish's research has been reported in many prestigious journals, and he has written numerous articles for distinguished peer-reviewed journals. (Ornish, Tr. 2318-19).

***25** 231. Dr. Ornish was accepted as an expert in the relationship between the heart and nutrition and in cardiovascular disease and its relationship to nutrition and nutrients. (Ornish, Tr. 2321-22).

232. Dr. Ornish was asked to evaluate: (1) whether drinking eight ounces of POM Juice or taking one POMx Pill or one teaspoon of POMx Liquid may be beneficial in maintaining cardiovascular health and lessening the risk of cardiovascular disease; and (2) whether basic science, clinical studies, research, and/or trials show that the consumption of POM Juice, POMx Pill, or POMx Liquid may be beneficial in maintaining cardiovascular health and lessening the risk of cardiovascular disease. Dr. Ornish was further asked to review the report titled, "Expert Report of Frank M. Sacks" and to evaluate the claims and statements made in that document. (PX0025 (Ornish Expert Report at 0004-05)).

233. Dr. Ornish provided the following opinion: the scientific evidence from basic science studies, animal research, and clinical trials in humans indicates that pomegranate juice in its various forms (including POM Wonderful 100% Pomegranate Juice, POMx Pill, or POMx Liquid) is likely to be beneficial in maintaining cardiovascular health and is likely to reduce the risk of cardiovascular disease. (PX0025 (Ornish Expert Report at 0005)).

d. Dr. Arthur Burnett

234. Dr. Arthur Burnett is a Professor of Urology serving on the faculty of the Department of Urology at the Johns Hopkins University School of Medicine/Johns Hopkins Hospital. (PX0149 (Burnett Expert Report at 0001); Burnett, Tr. 2241). Dr. Burnett holds a faculty appointment in the Cellular and Molecular Medicine Training Program of the Johns Hopkins University School of Medicine and is the Director of the Basic Science Laboratory in Neuro-urology of the James Buchanan Brady Urological Institute and Director of the Male Consultation Clinic/ Sexual Medicine Division of the Department of Urology at Johns Hopkins. (PX0149 (Burnett Expert Report at 0001); Burnett, Tr. 2241).

235. Dr. Burnett obtained his medical degree from the Johns Hopkins University School of Medicine in Baltimore, Maryland and completed his internship, residency and fellowship at the Johns Hopkins Hospital. (PX0149 (Burnett Expert Report at 0001); Burnett, Tr. 2240-41).

236. Dr. Burnett has authored and published over 180 original peer-reviewed articles and 40 book chapters. (PX0149 (Burnett Expert Report at 0003)).

237. Dr. Burnett has treated between 10,000 and 15,000 patients for erectile dysfunction. (Burnett, Tr. 2244).

238. Dr. Burnett has conducted world renowned research on nitric oxide ("NO"). (PX0149 (Burnett Expert Report at 0003)).

239. Dr. Burnett was accepted as an expert in the field of urology and sexual medicine to offer opinions on: (1) the science of nitric oxide biology; (2) the mechanisms by which nitric oxide is formed and acts in penile erection and in the promotion of erectile health, erectile function and treatment of erectile dysfunction; (3) the impact of pomegranate juice and antioxidants and nitric oxide on erectile health, erectile function and erectile dysfunction; and (4) scientific studies involving erectile function and dysfunction. (PX0149 (Burnett Expert Report at 0001-07); Burnett, Tr. 2243-44, 2249-51, 2255-56, 2270-74; PX0349 (Burnett, Dep. at 23-25, 103, 112, 116-118, 137)).

***26** 240. Dr. Burnett was asked to provide expert testimony regarding POM's basic science and clinical study, as well as pomegranate juice's effect on the nitric oxide regulatory mechanism, the vascular system/function, and on

erectile health, erectile function and erectile dysfunction. (PX0149 (Burnett Expert Report at 0004-07); PX0349 (Burnett, Dep. at 103, 112, 116-118); Burnett, Tr. 2243-44, 2255-56, 2270-74).

241. To form his opinions, Dr. Burnett reviewed studies on erectile function and nitric oxide, including POM-sponsored studies such as the Forest Erectile Dysfunction Study (2007) and a few *in vitro* and animal studies. (PX0149 (Burnett Expert Report at 0004)). Dr. Burnett relied upon his "education, experience, and knowledge of developments in the fields of urology and sexual medicine, including the promotion of erectile health and treatment of erectile dysfunction." (PX0149 (Burnett Expert Report at 0004)).

242. Dr. Burnett provided the following opinion: pomegranate juice possesses potent antioxidative endothelial NO mechanisms in vasculature. These mechanisms serve potential beneficial effects on vascular blood flow and promote vascular biologic health. Basic scientific and clinical evidence supports the probable benefit of pomegranate juice on the vascular structures involved in penile erection. (PX0149 (Burnett Expert Report at 0005-06)).

e. Dr. Irwin Goldstein

243. Dr. Irwin Goldstein is a sexual medicine physician who has been practicing medicine since 1976 and has been involved in sexual medicine clinical practice, clinical research and basic science research since 1980. (PX0189 (Goldstein Expert Report at 0001-02); PX0352 (Goldstein, Dep. at 14)).

244. Dr. Goldstein has been certified by the American Board of Urology since 1982. He was a Professor of Urology and Professor of Gynecology at the Boston University School of Medicine from 1990 to 2005 and 2002 to 2005, respectively. (PX0189 (Goldstein Expert Report at 0001-03)).

245. Dr. Goldstein has published over 250 original peer-reviewed manuscripts in male and female sexual medicine. (PX0189 (Goldstein Expert Report at 0002-03)).

246. Dr. Goldstein was part of the original advisory board to Pfizer that engaged in an extensive drug development plan that developed sildenafil (Viagra), and was also on the advisory boards of Bayer and Eli Lilly for the development of vardenafil (Levitra) and tadalafil (Cialis). (Goldstein, Tr. 2590-91).

247. Dr. Goldstein was accepted as an expert in the field of sexual medicine, the studies that have been done on sexual medicine and the impact of pomegranate juice and antioxidants and nitric oxide on erectile function and dysfunction. (Goldstein, Tr. 2592). Dr. Goldstein was asked to provide testimony on: (1) sexual medicine; (2) the study, design, and treatment of men with sexual health problems; (3) the studies that have been done on sexual medicine particularly regarding the promotion of erectile health and treatment of erectile dysfunction; (4) the mechanisms by which nitric oxide is formed and acts in penile erection and in the promotion of erectile health and treatment of erectile dysfunction; (5) urology as it relates to the treatment, prevention, and reduction of risk of erectile dysfunction; (6) the impact of pomegranate juice and antioxidants and nitric oxide on erectile health, erectile function and erectile dysfunction; and (7) scientific testing involving erectile health, erectile function and erectile dysfunction. (PX0352 (Goldstein, Dep. at 19-22, 37-42); PX0189 (Goldstein Expert Report at 0003-15); Goldstein, Tr. 2592, 2600-05, 2611, 2620).

***27** 248. To form his opinions, Dr. Goldstein reviewed studies on erectile function, nitric oxide, and the Mediterranean diet, including POM-sponsored studies such as the Forest Erectile Dysfunction Study (2007), an article titled, *Recreational Use of Phsphodiesterase Type 5 Inhibitors by Healthy Young Men* (2010), and several *in vitro* and animal studies. (PX0189 (Goldstein Expert Report at 0005); PX0352 (Goldstein, Dep. at 125)).

249. Dr. Goldstein offered the following opinions: (1) the available body of scientific literature, including *in vitro*, and preliminary clinical trials, strongly suggests that consuming pomegranate juice promotes erectile health; and (2) the use of pomegranate juice to promote erectile health is a separate and distinct concept from the use of a neutraceutical as a safe and effective treatment for the medical condition of erectile dysfunction such as with a PDE5 inhibitor. (PX0189 (Goldstein Expert Report at 0004-05)). Dr. Goldstein concluded that reasonable and competent scientific evidence shows that pomegranate produced a definite benefit to proper and effective erectile function. (Goldstein, Tr. 2605).

f. Dr. Jean deKernion

250. Dr. Jean deKernion is a practicing urologist certified by both the American Board of Surgery and the American Board of Urology. He obtained his medical degree in 1965 from Louisiana State University School of Medicine in New Orleans, Louisiana and did his residencies in surgery and urology at the university hospitals of Cleveland and the National Cancer Institute. (deKernion, Tr. 3039-40, 3127; PX0161 (deKernion Expert Report)).

251. Dr. deKernion was, from 1981 until his retirement in 2011, Chairman of the Department of Urology and Senior Associate Dean for Clinical Affairs (2001-2011) at the David Geffen UCLA School of Medicine. Dr. deKernion's responsibilities included the urological clinical and research education of students, residents, and fellows at all levels; a busy practice in urologic oncology, primarily related to prostate cancer but also bladder and kidney cancer; growth and oversight of large and diverse research programs; and administration of programs for the Dean's office and hospital. (deKernion, Tr. 3039; PX0161 (deKernion Expert Report at 0001)).

252. During Dr. deKernion's tenure as Chair of the Department of Urology at UCLA, he built a multidisciplinary research portfolio, which ranks among the largest and best in the United States. (PX0161 (deKernion Expert Report at 0003)).

253. Dr. deKernion's career in urologic oncology has involved both clinical and basic/translational research. (PX0161 deKernion Expert Report at 0001)).

254. Dr. deKernion co-authored the first book on urologic oncology and has co-authored 133 chapters since. His research has involved both basic laboratory research and clinical research publishing 228 papers to date in peer-reviewed journals and many other invited manuscripts. For six years, Dr. deKernion was the associate editor of the Journal of Urology and has been a reviewer for approximately 20 other peer-reviewed journals. (PX0161 (deKernion Expert Report at 0002); deKernion, Tr. 3041-43).

***28** 255. Dr. deKernion has served on a number of national committees and was a founding member of the Society of Urologic Oncology, was elected as a trustee of the American Board of Urology, and numerous committees of national urological societies and was appointed to the National Cancer Advisory board by President Bush. (deKernion, Tr. 3040; PX0161 (deKernion Expert Report at 0002)).

256. Dr. DeKernion was accepted as an expert in the field of urology and prostate health to offer opinions on research done on pomegranate juice and POM Products as they relate to the prostrate. He was also asked to provide expert opinions on the validity of PSA doubling time in assessing response to POM Products and on the strength of the science supporting the role of POM in prostate health and prostate cancer. In addition, Respondents asked Dr. DeKernion to rebut the opinions in Dr. Eastham's expert report. (deKernion, Tr. 3043-44; 3108-09; PX0161 (deKernion Expert Report at 0003)).

257. To form his opinions, Dr. deKernion reviewed the expert reports of Dr. Eastham and Dr. Miller, the FTC depositions of Dr. Pantuck and Dr. Carducci, protocols for the Pantuck Phase II Prostate Cancer Study (2006), the Carducci Dose Study, and the Pantuck Phase III Study, articles cited in Dr. Eastham's report, scientific articles found by conducting a literature search, and marketing materials. (PX0351 (deKernion, Dep. at 6-8, 27-29); PX0351a04; PX0351a05).

258. Dr. de Kernion provided the following opinions: (1) based on the data available, it is reasonable to state that POM products have shown an effect on prostate cancer with little or minimal toxicity; (2) given the current evidence, Dr. deKernion would suggest to patients and friends who have early prostate cancer that they consider taking POM, among other measures such as exercise, restrict intake of fatty foods, and weight control, to improve their probability for prevention or control of a tumor. (PX0161 (deKernion Expert Report at 0011-12)).

g. Dr. Ronald Butters

259. Dr. Ronald Butters is Professor Emeritus at Duke University and has been on faculty at Duke for over 40 years. He served as the Chairman of the Linguistics Department at Duke and Chairman of Duke University's English Department. (Butters, Tr. 2812).

260. Dr. Butters is a member of the advisory board of the New Oxford American Dictionary and has served as editor and co-editor of multiple prestigious scientific and academic publications. He participates in numerous professional associations and is the past president of the International Association of Forensic Linguistics. (Butters, Tr. 2812-13).

261. Dr. Butters has written textbooks and other books on the subjects of linguistics, which is the study of all forms of human language: semantics and semiotics. (Butters, Tr. 2814-15).

262. Dr. Butters was accepted as an expert in linguistics, including the meaning of language and symbols and the context in which they appear. (Butters, Tr. 2816, 2954-55).

***29** 263. Dr. Butters offered his opinions as a linguistics expert on the meanings of Respondents' advertisements. (Butters, Tr. 2816-17).

264. Dr. Butters concluded that Respondents' advertisements do not convey, either expressly or by implication: that scientific research proves that the use of certain recommended amounts, in recommended frequencies, of Pom Wonderful products successfully treats, prevents, or reduces: (1) the risk of heart disease, including decreasing arterial plaque, lowering blood pressure, and/ or improving blood flow to the heart; (2) the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time (“PSADT”); and (3) the risk of erectile dysfunction. (PX0158 (Butters Expert Report at 0002-03)).

265. Dr. Butters also opined that Respondents' advertisements convey that (1) pomegranate juice is a healthy beverage and (2) Pom Wonderful products contain “antioxidants,” for which there has been preliminary scientific research regarding their potential beneficial properties, and (3) readers and hearers are generally encouraged to investigate scientific research and draw their own conclusions. (PX0158 (Butters Expert Report at 0002-03)).

h. Dr. David Reibstein

266. Dr. David Reibstein is a tenured Professor of Marketing at the University of Pennsylvania in The Wharton School. Dr. Reibstein has taught courses in marketing management, marketing strategy and marketing metrics to MBA Program and Executive MBA Program students; marketing research courses to MBA Program students; and other marketing courses to undergraduate students. Many of these courses involve the use and design of surveys. (Reibstein, Tr. 2482; PX0356a01 at 0002-03).

267. Dr. Reibstein has been a visiting professor at Stanford Business School, Harvard Business School and Purdue University where he taught marketing courses. Dr. Reibstein has taught courses in marketing strategy and advanced industrial marketing strategy at INSEAD, a top business school in Europe. (Reibstein, Tr. 2483; PX0356a01 at 0002, 0003).

268. Dr. Reibstein received his Doctor of Industrial Administration from the Herman C. Krannert Graduate School of Industrial Administration at Purdue University with a major in marketing and a minor in behavioral science. (Reibstein, Tr. 2481). Dr. Reibstein's doctoral dissertation was titled, "*An Empirical Study of Brand Choice and Switching Behavior*." (PX0356a01 at 0001). Dr. Reibstein attended the Master of Business Administration Program at the Graduate Business School at Tulane University. (Reibstein, Tr. 2480-81; PX0356a01 at 0001). Dr. David Reibstein received a B.S. in Business Administration and a B.S. in Statistics and Political Science from the University of Kansas. (Reibstein, Tr. 2480; PX0356a01 at 0001). Dr. Reibstein has been awarded an Honorary Master of Science by The Wharton School at the University of Pennsylvania. (PX0356a01 at 0001).

269. Dr. Reibstein was the Executive Director for the Marketing Science Institute, an organization of 72 company-members. The Marketing Science Institute works closely with its members to identify the major marketing issues confronting them. The Marketing Science Institute prepares reports on various marketing issues which are disseminated to its members and the general business community. The Marketing Science Institute sets the research agenda for marketing academia globally. (Reibstein, Tr. 2483-84; PX0356a01 at 0002).

***30** 270. Dr. Reibstein has published extensively in prestigious peer-reviewed marketing journals, including many articles on marketing and marketing research. Those journals include, among others, the Journal of Consumer Research, Journal of Marketing Research, Marketing Science and the Harvard Business Review. (Reibstein, Tr. 2484; PX0356a01 at 0004-07).

271. Dr. Reibstein has written over seven books and numerous chapters in books on marketing and marketing research. (Reibstein, Tr. 2484; PX0356 (Reibstein, Dep. at 14; (PX0356a01 at 0007, 0008)). Dr. Reibstein authored the book "Marketing Metrics: 50+ Metrics Every Executive Should Master (2006)" which was named as the "Best Business Book: Marketing" by Strategy & Business in 2007. (PX0356a01 at 0004).

272. Dr. Reibstein has provided management education in the field of marketing to more than 300 companies. He has designed, executed, and supervised hundreds of market research studies for over 30 years, including surveys concerning consumer behavior. (Reibstein, Tr. 2485-86).

273. Dr. Reibstein has performed consulting research for a variety of companies where his work focuses on understanding the reasons that customers buy, what motivates customers to buy, and the interface with customer behavior and a company's marketing activities, price, product, place, and promotion. (Reibstein, Tr. 2484-85; PX0356 (Reibstein, Dep. at 14-15)). Dr. Reibstein's consulting work for companies involves collecting and processing information to better inform the company about what has or might influence customers to make the purchase decisions they do, and in the manner they do to reduce uncertainty in the decisions they make. Dr. Reibstein's consulting work also involves determining the messages consumers take from certain advertising. (PX0356 (Reibstein, Dep. at 16)). Dr. Reibstein has also provided extensive management education in the field of marketing to more than 300 companies over his career. (Reibstein, Tr. 2485).

274. Dr. Reibstein serves on the board of the Marketing Accountability Standards Board. This board sets the standards on what are the most important marketing metrics and how to measure them both in the United States and globally. (Reibstein, Tr. 2485).

275. Dr. Reibstein was accepted as an expert witness in marketing and marketing research. (Reibstein, Tr. 2485).

276. Dr. Reibstein prepared for Respondents a survey analysis titled, Survey of POM Wonderful 100% Pomegranate Juice Users ("Reibstein Survey") to understand the underlying motivations that consumers had for purchasing pomegranate juice and what those motivations might have been. (PX0356 (Reibstein, Dep. at 11, 39); Reibstein, Tr. 2487).

277. As stated in the Reibstein Survey, the primary objective of the survey was to evaluate the main factors driving the purchasing decision for POM Wonderful 100% Pomegranate juice buyers, including whether and to what extent POM Wonderful 100% Pomegranate juice buyers purchase the product based on their belief that the product cures or prevents a particular disease. Dr. Reibstein's finding and opinion is that there is a very small percentage of people that bought, would buy again, or would recommend to a friend POM Wonderful Pomegranate Juice because they believed it was beneficial to any disease. (PX0223 at 0003).

***31** 278. Dr. Reibstein also reviewed the Bovitz Survey and the OTX Attitudes & Usages ("A&U") Study. (*See* Section II.J, *infra*). Dr. Reibstein opined that these studies have methodological flaws, cannot be relied on, and do not invalidate the results of the Reibstein Survey. (Reibstein, Tr. 2517; PX0223 at 0003).

3. Complaint Counsel's rebuttal experts

a. Dr. Michael Mazis

279. Dr. Michael Mazis is a Professor Emeritus of Marketing at the Kogod School of Business, American University. (PX0296 (Mazis Expert Report at 0002); Mazis Tr. 2653). He was a Professor of Marketing at American University from 1981 to 2008, serving ten years as chair of the Department of Marketing. (PX0296 (Mazis Expert Report at 0002); Mazis, Tr. 2653).

280. Dr. Mazis has served as a paid consultant for numerous federal government agencies, including the FTC, FDA, Consumer Product Safety Commission, Department of Justice, Federal Deposit Insurance Corporation, Bureau of Alcohol, Tobacco and Firearms and U.S. Mint. (Mazis, Tr. 2656, 2697).

281. Dr. Mazis was employed by the FTC from July 1977 through August 1979. During that time, he was Chief of Marketing and Consumer Research in the Office of Policy and Planning. In addition, Dr. Mazis was employed by the FTC one day per week for a period of five or six years, beginning in the mid-1990's. He has also served as the FTC's principal marketing witness in several cases. Dr. Mazis has been a testifying expert witness in at least 24 legal proceedings during the last four years. (PX096a001 at 0001; Mazis, Tr. 2653, 2696-98; PX0296 (Mazis Expert Report at 0002-03, 0012); PX0359 (Mazis, Dep. at 22-24)).

282. Dr. Mazis is a former director of the Association for Consumer Research. He was Editor of the Journal of Public Policy & Marketing from 1992 to 1995 and Associate Editor of The Journal of Consumer Affairs from 1998 to 2001. (PX0296 (Mazis Expert Report at 0002); Mazis, Tr. 2654). Among his duties as an editor and associate editor, Dr. Mazis would review and critique survey research. (Mazis, Tr. 2655-56). Dr. Mazis has conducted

hundreds of surveys and research studies, including over one hundred surveys for use in legal proceedings. (Mazis, Tr. 2657).

283. Dr. Mazis was called as an expert rebuttal witness in marketing and marketing research to rebut the expert testimony of Dr. Reibstein. (Mazis, Tr. 2659; CX1297 (Mazis Expert Report at 0002)).

284. Dr. Mazis opinioned that the Reibstein Survey contains substantial defects in its design and interpretation and that, as a result of these flaws, no reliable conclusions can be drawn from the Reibstein Survey, with regard either to the materiality of any of the challenged claims or to whether any of the challenged advertisements communicate any of the challenged claims. (CX1297 (Mazis Expert Report at 0004)).

b. Dr. David Stewart

285. Dr. David W. Stewart is a full Professor of Marketing in the A. Gary Anderson Graduate School of Management, University of California at Riverside, where he served as dean of the business school for four years before being asked to step down. (PX0295a01 at 0002, 0041; Stewart, Tr. 3161, 3224-25; CX1295 (Stewart Expert Report at 0002)). During his academic career, Dr. Stewart has taught a variety of graduate and undergraduate level courses related to advertising, consumer behavior, marketing research, and marketing strategy. (PX0295a01 at 0050-51; Stewart, Tr. 3160-61; CX1295 (Stewart Expert Report at 0003-04)).

***32** 286. Dr. Stewart has authored or co-authored eight books on advertising related issues and has written over 125 articles which have been accepted in peer-reviewed academic journals. (Stewart, Tr. 3162-63; PX0295a01 at 0002, 0005, 0008-17; CX1295 (Stewart Expert Report at 0002)). Dr. Stewart has served as the editor, associate editor, or member of the editorial board of numerous academic journals. (PX0295a01 at 0043-47; CX1295 (Stewart Expert Report at 0002); Stewart, Tr. 3161). Dr. Stewart has served as the President of the Academic Council of the American Marketing Association and chairman of the Section on Statistics in Marketing of the American Statistical Association. (Stewart, Tr. 3161-62; PX0295a01 at 0002, 0043). He is a past president of the Society of Consumer Psychology of the American Psychological Association. (Stewart, Tr. 3162; PX0295a01 at 0002, 0045; CX1295 (Stewart Expert Report at 0003)).

287. Dr. Stewart was accepted as an expert in advertising, marketing, consumer behavior, and survey methodology. (Stewart, Tr. 3168).

288. Dr. Stewart was called as a rebuttal witness to respond to Respondents' expert, Dr. Butters. (Stewart, Tr. 3168).

289. Dr. Stewart opined that Dr. Butters' conclusions are inconsistent with the extant literature on consumer response to advertising, POM Wonderful's own internal planning documents, and empirical evidence, and thus Dr. Butters' conclusions have no merit with regard to the determination of what claims are communicated by any challenged POM Wonderful advertisement. (CX1295 (Stewart Expert Report at 0017-18)).

E. Alleged Advertising Claims

1. Facial analysis

a. Alleged “clinically proven” claims

i. Print advertisements

(a) CX0016 ("Drink and be healthy" print advertisement)

290. CX0016 is a POM Juice advertisement with a headline "Drink and be healthy." CX0016 is reprinted in the Appendix to this Initial Decision. (Appendix at 1). (CX0016 at 0001).

291. CX0016 ran once in the Chicago Tribune on October 12, 2003. (CX0016 at 0002).

292. CX0016 ran in 2003 as part of the original launch of the POM Juice product and has not been disseminated since 2003. It was one of the first advertisements Respondents ever ran. (Tupper, Tr. 2995; L. Resnick, Tr. 157).

293. Based on the overall, common-sense, net impression of the advertisement, including the statements and representations set forth below, a significant minority of consumers, acting reasonably under the circumstances, would interpret CX0016 to contain the message that it is clinically proven that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease, by reducing arterial plaque. (CX0016 at 0002; F. 294-296).

294. CX0016 draws a clear and direct connection between consumption of POM Juice and prevention or reduction of risk for heart disease by juxtaposing statements and representations that (a) POM Juice has more antioxidants than other drinks, (b) antioxidants protect against free radicals, (c) free radicals can cause "heart disease," (d) "medical studies have shown" that consumption of POM Juice "minimizes factors that lead to atherosclerosis," which the advertisement defines for the reader as "plaque buildup in the arteries," and (e) such plaque buildup is "a major cause of heart disease." (CX0016 at 0001).

***33** 295. The statement in the advertisement that "[m]edical studies have shown that drinking 8 oz. of POM Wonderful pomegranate juice daily minimizes factors that lead to atherosclerosis (plaque buildup in the arteries), a major cause of heart disease" uses definitive and unambiguous language. This language draws a clear and direct connection between the referenced proof and the claimed effect on heart disease. (CX0016 at 0001 (emphasis added)).

296. In the context of CX0016, the elements of the advertisement communicating that POM is a food product, including the large image of the pomegranate fruit, the reference to POM Juice as "delicious" and "refreshing," and the reference to POM being "[i]n the refrigerated produce section of your grocer[,]" do not materially alter the message conveyed, described in F. 293. (CX0016 at 0001).

(b) CX0029 ("10 OUT OF 10 PEOPLE DON'T WANT TO DIE" print advertisement)

297. The advertisement for POM Juice identified as CX0029 is a POM Juice advertisement with a headline "10 OUT OF 10 PEOPLE DON'T WANT TO DIE" that ran in *Prevention* magazine in or about November 2004 and January 2005. The advertisement also ran in *Martha Stewart Living* magazine in or about May 2005. (CX0029 at 0001-03).

298. CX0029 is reprinted in the Appendix to this Initial Decision. (Appendix at 2-3).

299. Based on the overall, common-sense, net impression of the advertisement, including the statements and representations set forth below, a significant minority of consumers, acting reasonably under the circumstances, would interpret CX0029 to contain the message that drinking eight ounces of POM Juice daily treats, prevents,

or reduces the risk of heart disease, and is clinically proven to do so, by reducing arterial plaque. (CX0029 at 0001-02; F. 300-305).

300. There are elements in CX0029 that weigh against the interpretation described in F. 299. These include an irreverent and/or humorous headline, “10 OUT OF 10 PEOPLE DON'T WANT TO DIE,” the bold notation on the first page indicating that POM Juice is found “in the refrigerated produce section of your grocer,” the image of the pomegranate, the reference to a study as a “pilot” study, and the language in the last paragraph which refers to keeping “your heart healthy” with regular exercise and a healthy diet, in addition to drinking POM Juice. (CX0029 at 0001-02).

301. Notwithstanding the elements described in F. 300, other elements in CX0029 dominate the communication, and result in the overall net impression that consuming POM Juice prevents, reduces the risk of, or treats heart disease, and is clinically proven to do so by reducing arterial plaque. These elements include statements and representations that: (1) free radicals “lead to” “heart disease”; (2) antioxidants “neutralize” free radicals; (3) “scientific research shows” that POM Juice has a superior ability to prevent LDL oxidation and a “clinical pilot study shows that” consuming an “8 oz. glass” of POM Juice “daily” “reduces plaque in the arteries up to 30%” with a footnoted citation to a study by Dr. Aviram published in *Clinical Nutrition* in 2004; (4) “heart attacks are due to ... plaque in the arteries”; and (5) “heart disease” is America's number one killer. The language used is affirmative and non-qualified. (CX0029 at 0001-02).

***34** 302. Interspersed with the language described in F. 301 are an image of a human heart and an image of a graph asserting POM Juice's superior abilities to prevent oxidation of LDL, which the advertisement defines as “bad cholesterol” that “clogs arteries.” In the context of this advertisement, these images reinforce the message conveyed by the language described in F. 301. (CX0029 at 0001-02).

303. Through the language and images described in F. 301 and F. 302, the advertisement draws a clear connection between the consumption of POM Juice and prevention, treatment or reduction of the risk of heart disease. The advertisement also draws a clear connection for the reader between reduced arterial plaque, as shown by the referenced study, and prevention of heart disease. (CX0029 at 0001-02).

304. Notwithstanding the irreverent or humorous headline, “10 OUT OF 10 PEOPLE DON'T WANT TO DIE,” the overall tone of the advertisement is serious. In addition, the advertisement resembles a news article. (CX0029 at 0001-02).

305. In the context of the language and images described in F. 301 and F. 302, the fact that the advertisement pertains to a food product does not materially alter the message conveyed. (CX0029 at 0001-02).

(c) CX0314; CX0372; CX0379; CX0380 (“Magazine Wrap” Advertisements)

306. A “magazine wrap” is a type of advertisement that covers, or wraps, the actual magazine cover. (CX1357 at 87 (Kuyoomjian, Dep. at 86)).

307. POM disseminated a *New York Times* “magazine wrap” advertisement, identified as CX0314, in fall 2008, which included the headline, “Drink to prostate health[]” with an image of the POM Juice bottle on the cover. (CX0314 at 0003).

308. CX0372, CX0379, and CX0380 are *Time* magazine wraps, disseminated in August 2009 (CX0379) and September 2009 (CX0372 and CX0380). The cover of each of these magazine wraps uses the image of the POM

bottle "speaking" the headline, "Lucky I have super Health Powers!" The body copy of each advertisement, CX0372, CX0379, and CX0380, is virtually identical to the body copy of CX0314. (CX0372 at 0001-04; CX0379 at 0001-04; CX0380 at 0001-06).

309. CX0314, CX0372, CX0379 and CX0380 are reprinted in the Appendix to this Initial Decision. (Appendix at 4-26).

310. Based on the overall, common-sense, net impression of these advertisements, including the statements and representations set forth below, a significant minority of consumers, acting reasonably under the circumstances, would interpret CX0314, CX0372, CX0379, and CX0380 to contain the message that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of prostate cancer, by slowing PSA doubling times, and that these effects have been demonstrated in clinical testing. (CX0314; CX0372; CX0379; CX0380; F. 307-308, 311-319).

311. The text on the inside front cover of each of these magazine wrap advertisements describes the results of a published study involving POM Juice, which "followed 46 men previously treated for prostate cancer ...." "After drinking eight ounces of POM Wonderful 100% Pomegranate Juice daily for at least two years, these men experienced significantly slower" "PSA doubling times." The text then draws for the viewer a clear link between PSA levels and prostate cancer by immediately informing the viewer that "PSA (Prostate-Specific Antigen) is a biomarker that indicates the presence of prostate cancer. 'PSA doubling time' is a measure of how long it takes for PSA levels to double. A longer doubling time may indicate slower progression of the disease." (CX0314 at 0004; CX0372 at 0002; CX0379 at 0002; CX0380 at 0002).

***35** 312. CX0314 further states: "In addition, in-vitro testing using blood serum from the patients who drank pomegranate juice showed a 17% increase in prostate cancer cell death and a 12% decrease in cancer cell growth." This language does not materially detract from the overall net impression that the efficacy of POM Juice has been demonstrated in clinical testing; however, the language does represent that the degree of clinical proof is not fully conclusive. (CX0314 at 0004).

313. The magazine wrap further states: "Backed by Science. Only POM is backed by $25 million in medical research conducted at the world's leading universities." The page on which these claims appeared was titled, "The proof is in the POM." In the context of this advertisement, these statements contribute to and reinforce an overall net impression that efficacy for prostate cancer has been demonstrated by clinical testing. (CX0314 at 0005).

314. The text on the inside front cover of each of these magazine wrap advertisements quotes Dr. Allan Pantuck, "lead author" of the study referenced in F. 311, as stating: "This is a big increase." This language bolsters the strength and authoritative nature of the study referenced in the advertisements. (CX0314 at 0004; CX0372 at 0002; CX0379 at 0002; CX0380 at 0002).

315. The inside front cover of each of the magazine wraps states in part, "Results from this study were so promising that many of the original patients continued to drink pomegranate juice daily, and their PSA doubling times remained suppressed." This statement further bolsters the strength of the referenced PSA study. Moreover, the additional statements in this paragraph that the "[r]esearch [c]ontinues" and that "[t]hree more clinical studies are now underway to further investigate the effects of POM on prostate health" do not materially detract from the overall net impression that the claimed efficacy of POM Juice for prostate cancer is based upon clinically testing. (CX0314 at 0004; CX0372 at 0002; CX0379 at 0002; CX0380 at 0002).

316. Amid the text on the inside front cover of each of these magazine wrap advertisements is the "caduceus" symbol, showing snakes curling around a staff. In the context of this advertisement, the symbol, considered to be

a symbol of medicine or medical practice, creates a "medical" tone and contributes to the overall net impression described in F. 310. (CX0314 at 0004; CX0372 at 0002; CX0379 at 0002; CX0380 at 0002; *see also* F. 541).

317. The overall tone of each of the magazine wraps is serious. With respect to the relationship between POM Juice and prostate cancer, the language of the advertisements is clear and affirmative, and not meaningfully qualified. (CX0314; CX0372; CX0379; CX0380).

318. The italicized statements in the middle of the inside front cover of each magazine wrap, that "[p]rostate cancer is the most commonly diagnosed cancer in men in the United States. After lung cancer, it's the second leading cause of cancer death in men," further reinforce the already serious tone of the advertisement. (CX0314 at 0004; CX0372 at 0002; CX0379 at 0002; CX0380 at 0002).

***36** 319. There are elements of these magazine wraps which, in a different context, could militate against the message described in F. 310. These include: (1) generalized references to "health," "prostate health," and (2) general descriptions of POM's antioxidant characteristics and relationship to free radicals. In the context of these advertisements, however, these elements do not materially detract from the message described in F. 310. Similarly, in the context of these advertisements, the reference to POM Juice being "available in your supermarket produce section" does not materially alter the overall net impression described in F. 310. (CX0314 at 0004-05; CX0372 at 0002-03; CX0379 at 0002-03; CX0380 at 0002-03).

320. In the context of these advertisements, the use of humor and/or hyperbole, such as (1) the image of the POM bottle dressed as a caped superhero (CX0314 at 0006); and (2) the POM bottle announcing "Lucky I have super HEALTH POWERS!" "HOLY HEALTH" and "100% PURE pomegranate juice to the rescue!" (CX0372 at 0001-02, 0004; CX0379 at 0001- 02; CX0380 at 0001-02, 0005-06) does not materially detract from the message described in F. 310.

(d) CX0351/CX0355 ("The Only Antioxidant Supplement Rated X" print advertisement)

321. The advertisements identified as CX0351 and CX0355, with the headline, "The Only Antioxidant Supplement Rated X," were disseminated, respectively, in the publication the *Advocate* on or about June 1, 2010, and in *Playboy* magazine on or about July 1, 2010. (CX0351 at 0001-02; CX0355 at 0001-02). These advertisements are reprinted in the Appendix to this Initial Decision. (Appendix at 27-28).

322. The imagery and advertisements in CX0351 and CX0355 are substantially identical to each other. (CX0351 at 0001; CX0355 at 0001).

323. These advertisements state and represent (1) antioxidants keep you healthy by protecting against free radicals, which "emerging science suggests" can damage the body; (2) POMx Pills give you in supplement form "super-potent," and the best available, antioxidants, that are the same antioxidants contained in POM Juice; (3) POMx is "backed by" millions of dollars in research, showing unique and superior antioxidant power and also revealing "promising results for" "prostate, cardiovascular and erectile health." (CX0351 at 0001; CX0355 at 0001).

324. These advertisements further state that "[i]n a preliminary study on erectile function, men who consumed POM Juice reported a 50% greater likelihood of improved erections as compared to placebo. 'As a powerful antioxidant, enhancing the actions of nitric oxide in vascular endothelial cells, POM has potential in the management of ED ... further studies are warranted'. *International Journal of Impotence Research*, '07." (CX0351 at 0001; CX0355 at 0001).

325. Based on the overall, common-sense net impression of CX0351 and CX0355, a significant minority of consumers, acting reasonably under the circumstances, would interpret these advertisements as claiming that a clinical study has shown that taking one POMx Pill daily treats, prevents or reduces the risk of, erectile dysfunction. The advertisements specifically reference "improved erections" and "ED" and draw a direct connection between taking POMx Pills and "improved erections" and "managing" "ED." (CX0351 at 0001; CX0355 at 0001; F. 323-324).

***37** 326. In the context of these advertisements, the use of the phrase "erectile health" or "erectile function," rather than the express term, "erectile dysfunction" is insufficient to alter the overall net impression that the advertisement is conveying a message about erectile dysfunction. (CX0351 at 0001; CX0355 at 0001; *see also* F. 537).

327. The headline (F. 321), and the sub-headlines "[a]lways use protection," "[s]uper-potent just like you" and "[w]e're not just playing doctor," although humorous or irreverent, in the context of these advertisements, fail to detract from the overall, net impression described in F. 325. (CX0351 at 0001; CX0355 at 0001).

(e) CX1426 at 00038-42/Compl. Ex. I (POMx "Antioxidant Superpill" Package Insert)

328. CX1426 at 0038-0042 (POMx "Antioxidant Superpill" package insert), which is attached to the Complaint in this matter as Exhibit I, is a brochure that was disseminated by Respondents as a package insert for shipment with POMx Pills, in or about June 2007. (CX1426 at 0038-42 (Compl. Ex. I); Answer ¶ 10; L. Resnick, Tr. 177-78: CX1356 at 180 (Leow, Dep. at 179)).

329. The package insert consists of five pages of text and images. (CX1426 at 0038-42 (Compl. Ex. I)).

330. The package insert is reprinted in the Appendix to this Initial Decision. (Appendix at 29-33).

331. Based on the overall, common-sense, net impression of CX1426 at 0038-42, including the statements and representations set forth below, a significant minority of consumers, acting reasonably under the circumstances, would interpret the package insert to contain a claim that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents, or reduces the risk of prostate cancer, by slowing PSA doubling times, and that these effects have been demonstrated in clinical testing. (CX1426 at 0041 (Compl. Ex. I); F. 332, 334-336).

332. The first page of the package insert features the POMx bottle, with the headline "Antioxidant Superpill" and the sub-headline, "POM in a Pill." The second page of the package insert represents that POMx is safe, has been reviewed for safety by the FDA, and that POMx has the same "polyphenol antioxidants" contained in POM Juice. The third page of the package insert then clearly represents a link between consuming the antioxidants provided by the POM products and prevention or reduction of the risk of disease, specifically including heart disease and cancer, by stating or representing: (1) POMx contains the same antioxidant power as POM Juice; (2) antioxidants fight free radicals, which "emerging science tells us" destroy healthy cells and "may be linked to ... serious health threats like cancer and heart disease"; and (3) antioxidants "neutralize" free radicals, thereby "helping to prevent the damage that can lead to disease." (CX1426 at 0038-40 (Compl. Ex. I)).

333. The fourth page of this package insert begins with a headlined quotation attributed to the July 4, 2006 *New York Times* that findings from a small study suggest that pomegranate juice "may one day prove" an effective weapon against prostate cancer and statements that "new studies are under way to further investigate." This headline does not materially detract from the overall net impression that the efficacy of POMx has been

demonstrated in clinical testing; however, the headline does indicate that the degree of clinical proof is not fully conclusive. (CX1426 at 0041 (Compl. Ex. I)).

38** 334. The fourth page of the package insert states or represents that (1) "Prostate cancer is the most commonly diagnosed cancer ... and the second-leading cause of cancer death" among men in the United States; (2) POMx is a "time pill" because "stable levels of PSA," which is defined for the reader as "prostate-specific antigens," are "critical for men with prostate cancer," "[p]atients with quick PSA doubling times are more likely to die from their cancer," and "[a]ccording to a UCLA study of 46 men age 65 to 70 with advanced prostate cancer, drinking an 8o***z glass of POM Wonderful 100% Pomegranate Juice every day slowed their PSA doubling time by nearly 350%. 83% of those who participated in the study showed a significant decrease in their cancer regrowth rate"; and (3) "basic studies" indicate POMx may have the same effects as POM Juice with respect to "prostate health." (CX1426 at 0041 (Compl. Ex. I)).

335. The package insert expressly refers to "prostate cancer." Moreover, the representations in F. 334, especially in the context of previous representations regarding the effect of POM antioxidants on cancer (F. 332), represent a connection between the consumption of POMx, a slowing of PSA doubling times, and a beneficial effect on the progress of prostate cancer, including avoiding death from prostate cancer. (CX1426 at 0041 (Compl. Ex. I)).

336. In addition, references on the final page of the advertisement to "backed by $20 Million in medical research" and "clinically tested on adults" tend to bolster the nature and amount of clinical research or testing supporting the efficacy of the POM products for prostate cancer. (CX1426 at 0042 (Compl. Ex. I)).

337. In the context of this advertisement, use of the phrase "promote prostate health" is insufficient to alter the overall net impression that the advertisement is conveying a message about prostate cancer. (CX1426 at 0041 (Compl. Ex. I)).

338. Based on the overall, common-sense, net impression of CX1426 at 0038-42, including the statements and representations set forth below, a significant minority of consumers, acting reasonably under the circumstances, would interpret this package insert to contain a claim that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents or reduces the risk, of heart disease, by reducing arterial plaque or improving blood flow to the heart, and that these effects have been demonstrated by clinical testing. (CX1426 at 0038-42 (Compl. Ex. I); F. 339-342).

339. The final page of the package insert begins with a headline, which represents that POMx may have the same "cardiovascular health benefits" as POM Juice, which has been "proven" to "promote cardiovascular health." This page further represents: (1) "groundbreaking" "preliminary studies" showed that "patients" who drank POM Juice "experienced impressive cardiovascular results"; including (2) a "pilot" study on 19 "patients" with "atherosclerosis," which the text defines for the reader as "clogged arteries," showed that "arterial plaque decreased 30%" for those that consumed 8 oz. of POM Juice daily"; (3) an "additional study" of 45 "patients" with "impaired blood flow to the heart" who drank POM Juice daily "experienced a 17% improvement in blood flow"; (4) POMx has "similar promise" for heart health; (5) POMx is high in antioxidants; and (6) "backed by $20 Million in medical research" and "clinically tested on adults." Depicted within these representations is an image captioned as "the heart." (CX1426 at 0042 (Compl. Ex. I)).

***39** 340. The representations regarding "impressive cardiovascular results," a decrease in "clogged arteries" and "improvement in blood flow to the heart" in "patients," appear in the context of preceding representations regarding the effect of POM antioxidants on heart disease. Moreover, the representations of "proven" heart health benefits in the headline are juxtaposed to the descriptions of these study results. (CX1426 at 0042 (Compl. Ex. I); F. 339).

341. The package insert represents a link between consumption of POM-provided antioxidants, the referenced study results, and effectiveness for heart disease. (F. 339-340).

342. In the context of this advertisement, describing studies as "preliminary," (particularly when described as "groundbreaking"), "initial" or "pilot" is insufficient to modify the overall net impression that the claimed efficacy is based upon clinical testing; however, such language does indicate that the nature of the referenced clinical testing is not fully conclusive. (CX1426 at 0038-42 (Compl. Ex. I); F. 338-341).

ii. Newsletters

343. The advertisements identified as CX1426 at 0046-48, which comprises Exhibit M to the Complaint in this matter, and CX1426 at 0049-51, which comprises Exhibit N to the Complaint, were disseminated by Respondents. (CX1426 at 0046-51; Complaint ¶ 10; Answer ¶ 10). These advertisements are reprinted in the Appendix to this Initial Decision. (Appendix at 34-39).

344. Exhibit M to the Complaint contains a notation, "POMx Heart Newsletter, Pills and Liquid, Monthly, 2nd Continuity Shipment, Summer '07-present (ongoing)" (hereafter, "Heart Newsletter"). Exhibit N to the Complaint contains the notation, "POMx Prostate Newsletter, Pills and Liquid, Monthly, 3rd Continuity Shipment, Fall '07-present (ongoing)" (hereafter, "Prostate Newsletter") (collectively, the "Newsletters"). (CX1426 at 0046, 0049 (Compl. Exs. M, N)).

345. Each Newsletter consists of two pages, and is dense with text. (CX1426 at 0047-48, 0050-51(Compl. Exs. M, N)).

(a) Heart Newsletter

346. Based on the overall, common-sense, net impression of the Heart Newsletter, including the statements and representations in F. 347-349, a significant minority of consumers, acting reasonably in the circumstances, would interpret the Heart Newsletter as claiming that that drinking eight ounces of POM Juice or one POMx Pill taken daily, prevents, treats, or reduces the risk of heart disease, by decreasing arterial plaque, or by improving blood flow to the heart, and that these effects are based upon clinical testing. (CX1426 at 0047-48 (Compl. Ex. M); F. 347-350).

347. The Heart Newsletter begins with the heading "What's New in the Lab by Dr. Mark Dreher" followed by a photograph of Dr. Dreher next to his title: Mark Dreher, PhD, Chief Science Officer, POM Wonderful, LLC. The introductory text, by Dr. Dreher, represents that the purpose of the Heart Newsletter is to advise readers of POM Wonderful's "latest research." This beginning to the Heart Newsletter implies a scientific or medical message. (CX1426 at 0047 (Compl. Ex. M)).

***40** 348. The Heart Newsletter states or represents that (1) "58.8 million Americans suffer from some form of heart disease" and that reducing the risk of "cardiovascular disease" is a core part of lifelong wellness; (2) that diet and exercise are the best weapons against "heart disease", but may not be enough, and that supplementation with antioxidants is "your ally" in fighting "heart disease"; (3) antioxidants fight free radicals and help prevent cell and tissue damage that lead to "disease"; (4) POM Juice and POMx have polyphenol antioxidants, which are unique and superior; and (5) POMx provides antioxidant supplementation without adding the calories of POM Juice.

These representations draw a connection for the reader between POM antioxidants and prevention or reduction of the risk of heart disease. (CX1426 at 0047-48 (Compl. Ex. M)).

349. The Heart Newsletter further states that POM's "scientists have found" that POM Juice "may help counteract factors leading to arterial plaque build up, as well as inhibit a number of factors associated with heart disease." The text then proceeds to describe these findings, from "new research," including (1) a "pilot" study involving 19 "patients" with "clogged arteries" which found a "30% decrease in arterial plaque," among those drinking eight ounces of POM Juice daily; and (2) a study involving 45 "patients" with "impaired blood flow to the heart," showing "17% improved blood flow" among those who consumed eight ounces of POM Juice daily. The Heart Newsletter further states that "the antioxidants in POMx are supported by $20 million in initial scientific research." (CX1426 at 0048 (Compl. Ex. M)).

350. The representations set forth in F. 349, in the context of the representations in F. 348, draw a connection between reducing arterial plaque and treating, preventing, or reducing the risk of heart disease. (CX1426 at 0048 (Compl. Ex. M)).

(b) Prostate Newsletter

351. Based on the overall, common-sense, net impression of the Prostate Newsletter, including the statements and representations described in F. 352 and F. 353, below, a significant minority of consumers, acting reasonably in the circumstances, would interpret the Prostate Newsletter as claiming that drinking eight ounces of POM Juice or one POMx Pill taken daily, prevents, treats, or reduces the risk of prostate cancer, by prolonging PSA doubling time, and that these effects are clinically proven. (CX1426 at 0050-51 (Compl. Ex. N); F. 352-354).

352. The Prostate Newsletter draws a clear link for the reader between antioxidants and reduction of the risk of prostate cancer, including through the following statements or representations: The Prostate Newsletter states prominently "Prostate Cancer Affects 1 Out of Every 6 Men," and that "Prostate cancer is the second leading cause of cancer related death in men in the United States ..." The associated text discusses "risk factors" for prostate cancer, including "diet," and advises a diet that includes, among other things, "fruits rich in antioxidants." (CX1426 at 0050-51 (Compl. Ex. N)).

***41** 353. The Prostate Newsletter draws a connection for the reader between research results showing prolonged PSA doubling time and effectiveness for prostate cancer, including through statements or representations that: early detection, including through a PSA test, increases prostate cancer survival rates; a "preliminary UCLA medical study" on 46 men treated for prostate cancer, showed that a majority of those consuming eight ounces of POM Juice daily "experienced a significantly extended PSA doubling time. Doubling time is an indicator of prostate cancer progression — extended doubling time may indicate slower disease progression"; testing on "patient" blood serum showed a decrease in "cancer cell proliferation," and "increase in cancer cell death"; in another study, "in vitro laboratory testing at UCLA showed that POMx significantly decreased human prostate cancer cell growth and increased cancer cell death" and that POMx has the same active ingredients in POM Juice. (CX1426 at 0050-51 (Compl. Ex. N)).

354. In the context of the Prostate Newsletter, reference to research as "preliminary" or "*in vitro*" is insufficient to modify the claim described in F. 351 that the claimed efficacy is based upon clinical testing, particularly in light of other statements and representations promoting the strength and credibility of the research, as part of $25 million in "world-class research" including "clinical studies published in top peer-reviewed medical journals." Such language does, however, indicate that the degree of proof provided by the referenced studies is not fully conclusive. (CX1426 at 0050-51 (Compl. Ex. N)).

iii. Website advertising

(a) Website background facts

355. POM's websites include pomwonderful.com, pomegranatetruth.com, and pompills.com (collectively, the "websites"). (JX0003 ¶ B.11; Rushton, Tr. 1354-55; Leow, Tr. 433).

356. POM has maintained the pomwonderful.com website since approximately January 2003. (CX0013 at 0004). It has maintained the pomegranatetruth.com website since approximately January 2008. (CX0170 at 0002). POM launched pompills.com in early 2007. (CX1347 (Glovsky, Dep. at 135-36)).

357. Since at least September 2007, POM has had an online department. The online department is part of POM's marketing department and handles anything related to the Internet, including marketing, engagement, interaction, and development. (Rushton, Tr. 1353-54).

358. Jeffrey Rushton was the Director of Marketing for Online for POM Wonderful, from September 2007 through March 2010. (Rushton, Tr. 1353).

359. In approximately 2008, POM converted pomwonderful.com from a traditional static format to a blog format that sought engagement from external sources. (Rushton, Tr. 1354). POM launched this "Community" version of pomwonderful.com in approximately December 2009. (CX0473 (Dec. 2009, pomwonderful.com)).

360. In October 2009, one of the rotating frames on the pomwonderful.com homepage welcomed consumers to its "new community site." (CX0473 (Oct. 2009, pomwonderful.com at 00:25)). The "community" design encouraged website visitors to "participate," including by "Tell[ing] Us Your Health Story." (CX0473 (Oct. 2009, pomwonderful.com at 00:25)).

***42** 361. Testimonials appeared on the POM Wonderful website briefly, for much less than a year. (L. Resnick, Tr. 134).

362. The "Community" section of the pomwonderful.com site also featured blog posts and videos by "POM Experts" like Dr. Aviram, Dr. Heber, and Susan Bowerman, Assistant Director at the UCLA Center for Human Nutrition. (CX0473 (Oct. 2009, pomwonderful.com at 06:52)). POM paid Susan Bowerman to, among other things, write blog posts for pomwonderful.com. (CX0203 at 0001; CX1346 (Rushton, Dep. at 145)).

363. To direct traffic to its website, POM used keyword advertising with search engines. With keyword advertising, marketers can pay for their advertisements to appear on the search results pages of search engines such as Google, Yahoo, Bing, among others, by purchasing keywords that consumers may search for. (Rushton, Tr. 1357-58).

364. Examples of keywords POM has used in its search engine advertising include: "prostate cancer prevention," "prostate cancer info," "prostate cancer research," and "cancer prostate." (CX0427 at 0004-05, 0007-08; Rushton, Tr. 1387-89).

(b) Website claims

365. CX0473 consists of electronically recorded "captures" of Respondents' websites on particular dates, as follows:
Pomwonderful.com — April, October, December, 2009 and January 2010;

Pompills.com — April 2009 and January 2010; and

Pomegranatetruth.com — April 2009

(CX0473).

366. Each website capture reflects an electronic recording of navigation through the pages of the subject website, "clicking" on various hyperlinks to other pages. The web captures total approximately 95 minutes of material, with each capture totaling approximately 15 minutes in length, except for CX0473 Ex. E-1 (pomegranatetruth.com), which is approximately 5 minutes in length. (CX0473).

367. Printouts of those pages referred to in the following findings are reprinted in the Appendix to this Initial Decision. (Appendix at 40-93).

(i) Pomwonderful.com

368. Based on the overall, common-sense, net impression of the pomwonderful.com website, including the "health benefits" or "health" pages and links therefrom, a significant minority of consumers, acting reasonably in the circumstances, would interpret the pomwonderful.com website as claiming that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, prostate cancer, and/or erectile dysfunction, and that these effects are shown in clinical testing, as more fully explained below. (CX0473 (pomwonderful.com website: April 2009 (Compl. Ex. E-2); October 2009, December 2009, January 2010); F. 369-381).

369. In April 2009, the pomwonderful.com homepage included a link to a "health benefits" page. (CX0473 (Compl. Ex. E-2 at 00:04 and 00:15)).

370. In April 2009, the linked "health benefits" webpage displayed a large graphic depicting the POM Juice bottle hanging upside down on a pole, with the juice running through a tube at the bottom of the bottle, in the manner of a hospital intravenous line, while the juxtaposed text refers to POM Juice being "backed by" $25 million in "medical research" and "clinically tested." The page then introduces the "medical results" in separate areas designated "cardiovascular health," "prostate health," and "erectile function" sections. Introductory text in each such section summarizes research, with the cardiovascular section providing a further link to "read more." (CX0473 (Compl. Ex. E-2 at 00:17)).

***43** 371. In April 2009, the "Prostate Health" section of the health benefits webpage described "[a] preliminary UCLA medical study" on "46 men previously treated for prostate cancer," published by "The American Association for Cancer Research," showing that after drinking eight ounces of POM Juice daily for two years, "these men experienced significantly slower PSA doubling times." The description clearly links the significance of this research finding to prostate cancer, stating "PSA is a biomarker for prostate cancer, and slower PSA doubling time may indicate slower disease progression." (CX0473 (Compl. Ex. E-2 at 00:24)).

372. In April 2009, the "Erectile Function" section of the health benefits webpage reported a 2007 "pilot" study, published in the *International Journal of Impotence Research*, involving 61 male subjects with "mild to moderate erectile dysfunction," showing that those men drinking eight ounces of POM Juice daily for four weeks "were 50% more likely to experience improved erections." (CX0473 (Compl. Ex. E-2 at 00:24)).

373. In April 2009, the "Cardiovascular" section of the health benefits webpage described the results of studies as follows: (1) a 2005 study published in the *American Journal of Cardiology*, involving 45 "patients" with "coronary heart disease who had reduced blood flow to the heart," showed that "patients" who drank eight ounces of POM Juice daily had "improved blood flow to the heart," while those who did not drink POM Juice got worse; and (2) a "pilot" study on 19 "patients" with "atherosclerosis," which the text defines for the reader as "clogged arteries," showing that those "patients" who drank eight ounces of POM Juice daily for one year showed a decrease in arterial plaque, while those who did not drink POM Juice got worse. Each of these study descriptions offered a "read more" link. (CX0473 (Compl. Ex. E-2 at 00:24)).

374. In April 2009, the "read more" link from the "Cardiovascular" section of the health benefits webpage took the viewer to a page titled, "Heart Health-Emerging Science." The text advises the reader that "heart disease" is a leading killer of men and women in the United States, that "atherosclerosis," which is defined for the readers as too much "plaque," is a leading factor in "heart attacks" and further describes the role of antioxidants in reducing LDL (defined as "bad" cholesterol) oxidation. The text then invites the reader who wants to learn more about consumption of POM Juice and cardiovascular health, to "click on" the links to a 2005 study on effect of pomegranate on myocardial perfusion published in the *American Journal of Cardiology*; a 2004 study on reduction of carotid intima-media thickness, blood pressure and LDL oxidation, published in the journal, *Clinical Nutrition*; and a 2001 study on reduction of systolic blood pressure, published in the journal, *Atherosclerosis*. This page draws a clear connection for the reader between "heart health" and "heart disease," and between the effects referenced in the studies and effectiveness for heart disease. (CX0473 (Compl. Ex. E-2 at 00:30)).

***44** 375. While the link to the 2005 myocardial perfusion study (F. 374) took the viewer to a reprint of a copy of the actual published study, (CX0473 (Compl. Ex. E-2 at 00:45)), the link to the 2004 study on reduction of carotid intima-media thickness, blood pressure and LDL oxidation (F. 374)) took the viewer to a further description of the study with highlighted commentary by Dr. Aviram and graphs emphasizing the reduced plaque and "anti-atherosclerotic" effects of POM Juice. At the top of this page was a quote attributed to Dr. Aviram that "[t]he present study clearly demonstrates for the first time that pomegranate juice consumption by patients with carotid artery stenosis possesses anti-atherosclerotic properties." (CX0473 (Compl. Ex. E-2 at 01:00, 01:06)).

376. The link to the 2001 study on reduction of systolic blood pressure (F. 374) took the viewer to a further description of the study. The description begins: "This pilot study demonstrates that pomegranate juice lowers blood pressure in patients with hypertension." A quote attributed to Dr. Aviram states that the "potent inhibitory effect on lipid peroxidation" and the "inhibitory effect of pomegranate juice on serum ACE activity" "suggest[] that pomegranate juice consumption may offer wide protection against cardiovascular diseases." The decreased ACE (angiotensin converting enzyme) activity is illustrated by a graph. (CX0473 (Compl. Ex. E-2 at 01:25)).

377. In April 2009, the "Health Benefits" section of pomwonderful.com also included links to other pages, including one titled, "Cancer." (CX0473 (Compl. Ex. E-2 at 01:44)).

378. In April 2009, the linked "Cancer" page stated: "Emerging science has shown that diets rich in fruits and vegetables that contain antioxidants, along with regular exercise, might slow or help prevent the development of cancer. Two great sources of antioxidants are POM Wonderful Pomegranate Juice and POM Tea." The page featured a link to the "Clinical Cancer Research." (CX0473 (Compl. Ex. E-2 at 03:45)).

379. In April 2009, pomwonderful.com included a "Glossary," which was linked to the "Health Benefits" page. A number of definitions reasserted and reinforced the study results referred to F. 374-376. For example, the definitions of "Atherosclerosis," "ACE" (*i.e.*, angiotensin-converting enzyme), and "plaque" provided in the glossary explain for the reader the purported connection between the effects shown by the study results and effects for heart disease. (CX0473 (Compl. Ex. E-2 at 01:44, 04:15-07:08)).

380. Having fully reviewed later versions of the pomwonderful website, captured in October and December in 2009, and January 2010, they are not materially different with respect to linking viewers to text summarizing research results, under the categories of cardiovascular, prostate cancer, and erectile "function," and drawing a connection for the reader between consumption of POM antioxidants, the research results summarized, and the prevention, treatment, or reduction of the risk of diseases associated with the conditions addressed in the research results. Thus, these later versions of the pomwonderful website also convey the claims described in F. 368 as to the April 2009 website. (CX0473; F. 381).

***45** 381. As an example that later versions of the pomwonderful website also convey the claims described in F. 368 as to the April 2009 website, in October 2009, links from the "health" page directed the viewer to a "research study synopses," link, which page further stated *inter alia*: (1) under "cardiovascular," the rate of "CIMT progression" slowed in nearly one-third of the "patients" having "cardiovascular risk factors," (CX0473 (Oct. 2009, pomwonderful.com at 02:43)); (2) under "prostate cancer," that "PSA doubling time increased" among the POM Juice drinkers, and that "PSA doubling time is an indicator of prostate cancer progression, (*Id.*); and (3) under "Erectile Function," that POM Juice drinkers "reported 50% greater likelihood of experiencing improved erections." (*Id.* at 02:52; *see also* CX0473 (January 2010, pomwonderful.com at 00:26; 00:50, "Featured Scientific Studies" page)); CX0473 (December 2009, pomwonderful.com, "Let's Talk about Prostate Cancer" video, in which Dr. Heber states, *inter alia*, that "pomegranate inhibits inflammation in the prostate gland, that it also inhibits prostate cancer growth in animals, both in early prostate cancer and advanced prostate cancer. And in humans, we were able to reduce the rate of rise of PSA in men with prostate cancer"); CX0473 (Dec. 2009, pomwonderful.com at 08:06; CX0473 (Jan. 2010, pomwonderful.com at 00:54, and CX0473 (October 2009 pomwonderful.com at 7:25 (Dr. Aviram stating, regarding "The Unique Antioxidants of Pomegranates," that pomegranates inhibit "atherosclerosis development, ... as well as its consequent cardiovascular events")).

382. The "POM Community" section of pomwonderful.com in December 2009 included consumer testimonials. (CX0336 at 0011-19).

383. Testimonials were in the "POM Community" section of pomwonderful.com for much less than a year. (L. Resnick, Tr. 134).

384. Attached to the expert report of Respondents' linguistic expert, Dr. Butters, is a copy of what Dr. Butters identified as printouts from the pomwonderful.com website in 2011, taken on or before March 25, 2011, the date of Dr. Butters' report. As of that date, the "health" page omits reference to "protective effects," does not refer to any diseases, and does not summarize research results. The linked "glossary" omits the references described in F. 379. (PX0158 (Butters Expert Report at 0042); PX0160 at 0029-36, 0038-53, attachment 3) ("2011 website")).

385. The health page of the 2011 website (F. 384) does provide a link to "view studies" on the POM products, which when activated brings up a disclaimer that the studies are not "intended to make express or implied health or disease claims, ... do not constitute ... advertising for any POM Wonderful product .... Instead they are intended solely for general educational and informational purposes." The linked website is titled "wonderfulpomegranateresearch.com." (PX0158 (Butters Expert Report); PX0160 at 0036-37, attachment 3)).

(ii) Pompills.com

***46** 386. The pompills.com website is an e-commerce site that contains everything from learning about the product to ordering the product. (CX1347 (Glovsky, Dep. at 135)).

387. Based on the overall, common-sense, net impression of the pompills.com website, including the "health benefits" or "medical research" sections and the links to other information included therein, a significant minority of consumers, acting reasonably in the circumstances, would interpret the pompills.com website to be claiming that taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease, prostate cancer, and/or erectile dysfunction, and that these effects are shown in clinical testing, as explained more fully below. (CX0473 (Pompills.com website: April 2009 (Compl. Ex. E-8)), January 2010 (Compl. Ex. E-9); F. 388-410).

388. In April 2009, the menu bar on the home page of pompills.com contained links, *inter alia*, to "POMx Pills," "POMx Liquid," "health benefits" and "Buy Now." In January 2010, the menu bar was the same but the "health benefits" link is replaced by a link to "medical research." (CX0473 (Compl. Ex E-8 at 00:10); CX0473 (Compl. Ex E-9 at 00:04)).

389. A review of the April 2009 and January 2010 web captures show that the pompills.com website made substantially the same representations as those contained in POMx Pill print advertising, described in F. 323 and F. 332, including that POMx Pills provide the same antioxidant "power" as POM Juice, without the calories (CX0473 (Compl. Ex. E8 at 00:15-00:25); CX0473 (Compl. Ex. E-9 at 00:16)); that POMx Pills have the best available, polyphenol antioxidants (CX0473 (Compl. Ex. E-8 at 00:25); CX0473 (Compl. Ex. E-9 at 00:16, 00:30)); and that antioxidants "fight" free radicals which are linked to, among other things, "cancer and heart disease." (CX0473 (Compl. Ex. E-8 at 04:37); CX0473 (Compl. Ex. E-9 at 01:01); *see also* CX0351; CX0355; CX1426 at 0040 (Compl. Ex. I) (POMx package insert)).

390. In April 2009, the POMx Liquid page on pompills.com stated that POMx Liquid is "the most concentrated source of pomegranate antioxidants available," and that "POMx Liquid is a highly concentrated, incredibly powerful blend of all-natural polyphenol antioxidants made from the very same pomegranates in POM Wonderful 100% Pomegranate Juice." The page also depicted the POMx Liquid bottle and teaspoon with the caption, "One teaspoon = the antioxidant power of 8***o***z. of POM Wonderful 100% Pomegranate Juice" and a link to "BUY NOW." The menu bar on the POMx Liquid webpage also included a link to "health benefits." (CX0473 (Compl. Ex. E-8 at 01:00 1:38)).

391. In April 2009, under the subheading "Science, Not Fiction," the POMx Pills page represented, *inter alia*, that POMx is "backed by $25 million in medical research," and is "[c]linically tested." (CX0473 (Compl. Ex. E-8 at 00:35); *see also* January 2010 pompills.com (CX0473 (Compl. Ex. E-9 at 00:16 ($32 million); CX1426 at 0040 (Compl. Ex. I) (POMx package insert ($20 Million in research)).

***47** 392. In April 2009 and January 2010, the POMx Liquid page on pompills.com contained the same language as set forth in F. 392 that appeared on the POMx Pills page. (*Compare* CX0473 (Compl. Ex. E-8 at 00:35) *with* CX0473 (Compl. Ex. E-8 at 01:15); *see also* January 2010 pompills.com (CX0473 (Compl. Ex. E-9 at 00:30) ($32 million in research)).

393. In April 2009, and in January 2010, the "Health Benefits" section of pompills.com offered further links to web pages titled, "Research," "Antioxidant Benefits," "Heart Health," and "Prostate Health." (CX0473 (Compl. Ex. E-8 at 01:38); CX0473 (Compl. Ex. E-9 at 00:36)).

394. In April 2009, and in January 2010, the "Heart Health" section advised the reader that arterial plaque buildup is one of a number of factors "associated with heart disease" that POM Juice consumption may help "counteract." In the context of this webpage, the term, "heart health" implies "heart disease." (CX0473 (Compl. Ex. E-8 at 05:05); CX0473 (Compl. Ex. E-9 at 00:36).

395. In April 2009, the "Learn more" link on the "Heart Health" webpage took the consumer to a page titled "The Heart of The Matter." This page, in April 2009 and in January 2010, noted that atherosclerosis, defined for the reader as "too much plaque in the arteries[]is a leading cause of heart disease" and that "pomegranate antioxidants neutralize free radicals," which "can oxidize LDL (also known as 'bad' cholesterol turning it into plaque that clogs up arteries." This page then summarizes results of the Aviram Carotid Intima-media Thickness/Blood Pressure ("CIIMT/BP") Study and the Ornish Myocardial Perfusion (MP) Study in a manner that is substantially similar to the summaries on pomwonderful.com. (CX0473 (Compl. Ex. E-8 at 05:09-05:10); CX0473 (Compl. Ex. E-9 at 01:22); *see* F. 373-374).

396. In April 2009, and in January 2010, the linked "Heart of The Matter" page on pompills.com displayed a large image of the caduceus symbol, juxtaposed to a subheading "Amaze your cardiologist. Take POMx." This language and imagery convey a medical message. (CX0473 (Compl. Ex. E-8 at 05:09-05:10); CX0473 (Compl. Ex. E-9 at 01:22)).

397. The language on the "Heart of The Matter" page of the pompills.com website that POMx is made from pomegranates "supported by $25 million of initial scientific research" reinforces the message that the efficacy of POMx for heart disease is demonstrated by the results of clinical research. (CX0473 (Compl. Ex. E-8 at 05:09-05:10); *see also* CX0473 (Compl. Ex. E-9 at 01:22 ("supported by $32 million")).

398. In April 2009, the "Antioxidant Benefits" page of the pompills.com website advised the reader that "antioxidants neutralize free radicals," which are "linked to [among other things] cancer and heart disease," and that POMx is made from pomegranates having "$25 million in medical research behind them." This language, which also appears in the January 2010 version of pompills.com ("$32 million"), draws a connection for the viewer between antioxidants and disease, and conveys the message of scientific support for the website's claims. (CX0473 (Compl. Ex. E-8 at 04:37, 04:50); CX0473 (Compl. Ex. E-9 at 01:01)).

***48** 399. In April 2009, the "Research" link on the "Health Benefits" section of pompills.com took the viewer to a list of linked studies, including "Cardiovascular" studies and "Cancer" studies. The text of the links include: "Pomegranate juice improves myocardial perfusion in coronary heart patients," "Pomegranate juice pilot research suggests anti-atherosclerosis benefits," "Pomegranate juice helps promote normal systolic blood pressure." The "Research" page of the January 2010 version of pompills.com contains the same text. (CX0473 (Compl. Ex. E-8 at 01:38); CX0473 (Compl. Ex. E-8 at 01:43-04:23); CX0473 (Compl. Ex. E-9 at 00:55))

400. Some of the linked study titles referred to in F. 399 appear to be paraphrases of the studies' actual titles. (CX0473 (Compl. Ex. E-8 at 01:43-04:23); *see, e.g.*, CX0473 (Compl. Ex. E-8 at 02:10) (study listed as "Pomegranate juice improves myocardial perfusion in coronary heart patients," was published with the title, "*Effects of Pomegranate Juice Consumption on Myocardial Perfusion in Patients with Coronary Heart Disease*"); CX0473 (Compl. Ex. E-8 at 02:45) (study listed as "Pomegranate juice delays PSA doubling time in humans," was published with the title "*Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen following Surgery or Radiation for Prostate Cancer*")).

401. In April 2009, and in January 2010, the "Prostate Health" section of the "Health Benefits" page on pompills.com stated: "A preliminary UCLA medical study on POM Wonderful 100% Pomegranate Juice showed hopeful results for men with prostate cancer who drank an 8***o***z. glass of pomegranate juice daily. And every

POMx capsule provides the antioxidant power of an 8oz. glass of POM Wonderful 100% Pomegranate Juice. Learn more." (CX0473 (Compl. Ex. E-8 at 05:50); CX0473 (Compl. Ex. E-9 at 00:36) (underlined hyperlink in original)). The "Learn more" link took the consumer to a page titled "Pomegranates and Prostate Health." (CX0473 (Compl. Ex. E-8 at 05:55)).

402. Like "The Heart of the Matter" page (F. 397), in April 2009, the "Pomegranates and Prostate Health" page displayed the caduceus symbol. (CX0473 (Compl. Ex. E-8 at 05:55)).

403. In April 2009, on the "Pomegranates and Prostate Health" page of the pompills.com website, the explanatory text under the subheading "Prostate Health" states or represents: "Prostate cancer is the most commonly diagnosed cancer among men in the United States, and the second leading cause of cancer death in men, after lung cancer." In the context of this webpage, the reference to "prostate health" clearly implies "prostate cancer." The text then describes a study in which "A majority of the 46 men participating in the study experienced a significantly extended PSA doubling time .... Before the study of pomegranate juice, the average PSA doubling time for the participants was 15 months. After drinking 8***o***z. of juice daily, the average PSA doubling time increased to 54 months. That's a 350% increase." (CX0473 (Compl. Ex. E-8 at 05:55)).

***49** 404. The April 2009 the "Pomegranates and Prostate Health" page of the pompills.com website further linked the study results showing prolongation of PSA doubling time to the progress of prostate cancer, explaining "PSA (prostate-specific antigen) is a marker that is thought to be associated with the progression of prostate cancer; a slower PSA doubling time may reflect slower progression of the disease." Placing the mouse over the hyperlinked word "doubling time" produced a pop-up text box that reiterated: "The amount of time it takes for the prostate-specific antigen[s] (also called PSA levels) to double in men with prostate cancer may reflect the progression of the disease. A longer doubling time may indicate a slower growing cancer." (CX0473 (Compl. Ex. E-8 at 05:55-05:59, underlined hyperlink in original)).

405. The April 2009 the "Pomegranates and Prostate Health" page further represented that study results for POM Juice should apply to POMx by quoting Dr. Heber, identified as "Director of UCLA's Center for Human Nutrition," as stating: "The most abundant and most active ingredients in Pomegranate Juice are also found in POMx. Basic studies in our laboratory so far indicate that POMx and Pomegranate Juice have the same effect on prostate health." The foregoing text was printed in bold font and was italicized. (CX0473 (Compl. Ex. E-8 at 05:59)).

406. In April 2009, the pompills.com website also featured a "FAQs" page. (CX0473 (Compl. Ex. E-8 at 07:51)).

407. In April 2009, the response to the FAQ "Heart Disease: How does drinking pomegranate juice help the fight against cardiovascular disease?" stated: (1) "Improved Cardiac Blood flow," juxtaposed to the representation that a "published human study ... [on] 45 patients with impaired blood flow to the heart" showed that "[p]atients" who drank eight ounces of POM Juice "daily" experienced "improved blood flow" while the blood flow of the placebo group declined; and (2) "Decrease in Arterial Plaque" juxtaposed to the representation that "[a]nother published human study ... [on] 19 patients with atherosclerosis (clogged arteries) showed that, for those who drank eight ounces of POM Juice "daily," "artery plaque decreased 30%" while the placebo group experienced a worsening of arterial plaque buildup. This page further represented that results for POM Juice are applicable to POMx by quoting Dr. Aviram, identified as "one of the world's preeminent cardiovascular researchers," as commenting: "The results of our pre-clinical studies showed that POMx is as potent an antioxidant as pomegranate juice, and just like pomegranate juice may promote cardiovascular health." The foregoing quotation was italicized. (CX0473 (Compl. Ex. E-8 at 09:05)).

408. In April 2009, the response to the FAQ "Erectile Dysfunction" stated: "Can pomegranate juice benefit men with erectile dysfunction?" stated: "Initial results linking POM Wonderful 100% Pomegranate Juice and erectile

performance are promising. In a soon-to-be-published clinical study on men with erectile dysfunction, the group who consumed 8*oz*. of POM Juice daily experienced better erectile performance than the group who drank a placebo." (CX0473 (Compl. Ex. E-8 at 9:05)).

***50** 409. In April 2009, the response to the FAQ "Prostate Cancer" stated: "There has been promising news on the benefits of pomegranate juice in the fight against prostate cancer. Is this really true?" summarized study results showing the effect of POM Juice on extending PSA doubling times (the Pantuck Phase II Prostate Cancer Study (2006)). (CX0473 (Compl. Ex. E-8 at 09:05)). The answer went on to state that "[a] new study is underway to more fully investigate the potential of POMx to extend PSA doubling time" and quoted Dr. Heber, identified as "Director of UCLA's Center for Human Nutrition," as commenting, "The most abundant and most active ingredients in pomegranate juice are also found in POMx. Basic studies in our laboratory so far indicate that POMx and pomegranate juice may have the same effects." The foregoing quotation was italicized. (CX0473 (Compl. Ex. E-8 at 09:05)).

410. In April 2009, the response to the FAQ, "Dosage: How much POMx should I take?" stated: "Whether you choose pills or liquid, it is important to remember that to reap POMx's full health benefits: you must take it every day." (CX0473 (Compl. Ex. E-8 at 11:03)).

(iii) Pomegranatetruth.com

411. Based on the overall, common-sense, net impression of the pomegranatetruth.com website, including the "backed by science" and "heart health-emerging science" sections and links therefrom, a significant minority of consumers, acting reasonably in the circumstances, would interpret the pomegranatetruth.com website as claiming that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, and that these effects are clinically proven, as explained more fully below. (CX0473 pomegranatetruth.com (Compl. Ex. E-1); F. 412-414)).

412. In April 2009, the home page of pomegranatetruth.com stated or represented that POM is 100% authentic pomegranate juice, obtained through a unique process, and is the only pomegranate juice "backed by $25 million in medical research" including "clinical studies" documenting its benefits, including heart benefits, prostate health, and "better erectile function." Each subsection contained a "read more" link. This page displayed the caduceus symbol next to the "backed by science" reference. (CX0473 (Compl. Ex. E-1 at 00:10)).

413. The linked "Backed By Science" page on the pomegranatetruth.com website proceeded to introduce the "medical results" on POM Juice, dividing into subsections on "Heart Health," "Prostate Health" and "Erectile Dysfunction." The "Heart Health" section provided a "read more" link. (CX0473 (Compl. Ex. E-1 at 01:15)).

414. The linked "heart health" page on the pomegranatetruth.com website contained the headline "Heart Health — Emerging Science." The text advises the reader that "heart disease" is a leading killer of men and women in the United States, that "atherosclerosis," which is defined for the reader as too much "plaque," is a leading factor in "heart attacks" and the role of antioxidants in reducing LDL (defined as "bad" cholesterol) oxidation. The text then invites the reader who wants to learn more about consumption of POM and cardiovascular health to review research studies on the effects of pomegranate on myocardial perfusion, reduction of carotid intima-media thickness, blood pressure, and LDL oxidation; and reducing systolic blood pressure. This page draws a clear connection for the reader between "heart health" and "heart disease," and between the effects shown by the studies and the prevention, treatment or reduction of the risk of heart disease. (CX0473 (Compl. Ex. E-1 at 01:45)).

***51** 415. CX0473 Compl. Ex. E-1 does not show the content of the "prostate" page or the "erectile health" page, referred to in F. 413.

iv. Press releases

(a) January 2003 Press Release (CX0013)

416. POM issued a press release in January 2003 titled "Consumer Demand for POM Wonderful's Refrigerated All-Natural Pomegranate Juice Grows as the Health Benefits of Pomegranate Juice Become Recognized." (CX0013 at 0002-05). A copy of this press release is reprinted in the Appendix to this Initial Decision. (Appendix at 94-97).

417. Based on the overall, common-sense, net impression of CX0013, a significant minority of reasonable consumers would interpret this press release as claiming that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, by reducing arterial plaque, and that the effects have been clinically proven. (CX0013 at 0002-05; F. 418-420).

418. This press release had the subtitle, "Scientific support indicates that drinking pomegranate juice provides the body with an active source of antioxidants and shows promise against cardiovascular disease." (CX0013 at 0002).

419. This press release further states or represents that "cardiovascular diseases rank as America's No. 1 killer," and that 61.8 million Americans have some form of "cardiovascular disease such as diseases of the heart, high blood pressure, and hardening of the arteries." This release further states that "[m]edical research shows that daily consumption" of eight ounces of POM Juice "confers heart health benefits by lessening factors that contribute to atherosclerosis," which is defined for the reader as "plaque in the arteries." (CX0013 at 0002).

420. A paragraph titled "Effects on Heart Health" asserts that "[n]ew research is showing that antioxidants can play a highly beneficial role in reducing one of the major risk factors in heart disease: atherosclerosis (plaque in the arteries)," and explains the connection between "progression of atherosclerosis," "oxidation of LDL cholesterol" and "adhesion of LDL molecules" to the blood vessel. The paragraph further explains that (1) "one human study" showed that drinking eight ounces of POM Juice for two weeks "lowered" LDC oxidation, "clumping and adhesion" and (2) an "additional human study showed that consuming pomegranate juice reduces ... ACE (angiotensin converting enzyme)" which "lessens the progression of atherosclerosis." "Pomegranate juice inhibited ACE by 36% after two weeks of juice consumption" and a "5% decrease in systolic blood pressure ... a known risk factor for atherosclerosis." (CX0013 at 0003).

(b) September 2005 Press Release (CX0044)

421. POM issued a press release in September 2005 titled, "Pomegranate Juice May Affect the Progression of Coronary Heart Disease," which highlighted the results of the Ornish MP Study (2005). (CX0044 at 0001). A copy of this press release is reprinted in the Appendix to this Initial Decision. (Appendix at 98-99).

***52** 422. Based on the overall, common-sense, net impression of CX0044, a significant minority of reasonable consumers would interpret this press release as claiming that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, by improving blood flow to the heart, and that clinical studies prove these effects. (CX0044 at 0001; F. 423-427).

423. This press release stated that "Men and women with coronary heart disease who drink one glass of pomegranate juice daily may improve blood flow to their heart, according to a new study." (CX0044 at 0001).

424. This press release described "the first randomized, double-blind, placebo-controlled trial showing that pomegranate juice may affect the progression of coronary heart disease, which is the #1 cause of death in the U.S. and in most of the world" and that "results ... [would] be published in ... the American Journal of Cardiology, one of the leading peer-reviewed cardiology journals." (CX0044 at 0001).

425. This press release described the study as involving 45 "patients" with "coronary heart disease" having "reduced blood flow to the heart" and reported that the results showed "blood flow to the heart improved" in those drinking a daily glass of pomegranate juice, but showed worsening in the comparison group. (CX0044 at 0001).

426. The press release explained that "[p]omegranate juice from POM Wonderful was used in this study." (CX0044 at 0002).

427. Dr. Ornish, identified as senior author of the referenced study (F. 424), founder of the Preventive Medicine Research Institute, and clinical professor of medicine at UCSF, is quoted as stating that although the study sample was "relatively small," "the strength of the design and the significant improvements in blood flow to the heart observed after only three months suggest that pomegranate juice may have important clinical benefits in those with coronary heart disease" and that "[a]lso, it may help to prevent it." In the context of Dr. Ornish's entire statement, and in the context of the press release as a whole, the reference to a small sample, and use of words "suggest" and "may have" do not materially modify the overall net impression from the press release described in F. 422. (CX0044 at 0002).

(c) July 2006 Press Release (CX0065)

428. POM issued a press release in July 2006 titled, "POMx, a Highly Concentrated Form of Healthy Pomegranate Antioxidants, Becomes Available to Consumers for the First Time." (CX0065 at 0001-02). A copy of this press release is reprinted in the Appendix to this Initial Decision. (Appendix at 100-101).

429. Based on the overall, common-sense, net impression of CX0065, a significant minority of reasonable consumers would interpret this press release as claiming that that drinking eight ounces of POM Juice or taking one POMx Pill daily, treats prostate cancer by prolonging PSADT and that these effects have been demonstrated by clinical studies. (CX0065 at 0001-02; F. 430-431).

***53** 430. This press release discussed research published by the American Association for Cancer Research "indicat[ing] that a daily pomegranate regimen has a positive effect for men with prostate cancer" and that "[s]pecifically, drinking 8 ounces of POM Wonderful pomegranate juice daily prolonged post-prostate surgery PSA doubling time from 15 to 54 months (*Clinical Cancer Research*, July 1, 2006). PSA is a protein marker for prostate cancer and the faster PSA levels increase in the blood of men after treatment, the greater their potential for dying of prostate cancer." (CX0065 at 0002).

431. This press release represented that study results using POM Juice are applicable to POMx, by quoting Dr. Heber, identified as "Professor of Medicine and Director, UCLA Center for Human Nutrition," as stating, "[b]asic studies indicate that the effects of POMx and POM Wonderful pomegranate juice on prostate cancer are the same. The most abundant and most active ingredients in pomegranate juice are also found in POMx." (CX0065 at 0002).

(d) June 2007 Press Release (CX0128)

432. POM issued a press release in June 2007 titled, "POM Wonderful 100% Pomegranate Juice May Improve Mild to Moderate Cases of Erectile Dysfunction, Study Finds." (CX0128 at 0002-04). A copy of this press release is reprinted in the Appendix to this Initial Decision. (Appendix at 102-104).

433. Based on the overall, common-sense, net impression of CX0128, a significant minority of reasonable consumers would interpret this press release as claiming that drinking eight ounces of POM Juice treats erectile dysfunction, and that this effect has been demonstrated by clinical studies. (CX0128 at 0002-04; F. 434-439).

434. This press release stated, "[r]esearch shows 8 ounces a day of POM Wonderful 100% Pomegranate Juice may help the management of erectile dysfunction" and "[a]ccording to a pilot study released in the *International Journal of Impotence Research* (http://www.nature.com/ijir), POM Wonderful 100% Pomegranate Juice was found to have beneficial effects on erectile dysfunction (ED), a disorder that affects 1 in 10 men worldwide and 10 to 30 million men in the United States alone." (CX0128 at 0002).

435. This press release describes the study as a "randomized, placebo-controlled, doubleblind, crossover pilot study" on the "efficacy of pomegranate juice," and notes that "to qualify" for the study, among other things, the "participants had to experience mild to moderate ED for at least 3 months." The press release defined "mild" and "moderate" ED in relation to the extent of the "decreased ability to get and keep an erection." (CX0128 at 0002).

436. This press release reported the results as showing that "[f]orty-seven percent of the subjects reported that their erections improved with POM Wonderful Pomegranate Juice." (CX0128 at 0003).

437. The press release attributed the study results of improved erections to "enhance[d] blood flow," which is an effect of "potent pomegranate antioxidants," noting that in "previously published medical studies, pomegranate juice has been shown to enhance blood flow." (CX0128 at 0003).

***54** 438. The press release disclosed that the "study did not achieve overall statistical significance"; however, in the context of the press release as a whole, this disclosure does not materially modify the overall net impression described in F. 433. (CX0128 at 0002-04).

439. Use of the phrase, "may help," in the overall context of this press release, is insufficient to modify the net impression of the press release as a whole, described in F. 433. (CX0128 at 0002-04).

b. Alleged efficacy claims

(a) CX0031 ("Floss your arteries. Daily")

440. The advertisement identified as CX0031 (Floss your arteries. Daily) was disseminated on or about December 1, 2004. (CX0031at 0001-02).

441. CX0031 is reprinted in the Appendix to this Initial Decision. (Appendix at 105).

442. POM first ran this advertisement in 2004 and stopped running it that same year. The "Floss your arteries" headline, image and body copy have not run as part of any advertisement since 2004. (Tupper, Tr. 2995-96).

443. Based on the overall, common-sense, net impression of the advertisement, a significant minority of consumers, acting reasonably under the circumstances, would interpret CX0031 to contain the message that drinking eight ounces of POM Juice daily treats, prevents or reduces the risk of heart disease, by reducing arterial plaque. (CX0031 at 0001; F. 444-445).

444. This advertisement draws a connection between the consumption of POM Juice and the prevention, treatment or reduction of the risk of heart disease, through statements and/or representations that (1) POM Juice has more antioxidants than other drinks; (2) antioxidants fight free radicals; (3) free radicals cause "artery clogging plaque"; (4) consumption of POM Juice "can reduce plaque by up to 30%!"; and (5) "Clogged arteries lead to heart trouble. It's that simple. That's where we come in." (CX0031 at 0001).

445. The headline, "Floss your arteries. Daily," is clearly an exaggeration which would not be taken literally; however, in the context of this advertisement, the headline contributes to the overall net impression described in F. 433. (CX0031 at 0001).

446. An implied claim that consuming POM Juice is "clinically proven" to prevent, treat, or reduce the risk of heart disease is not reasonably clear or conspicuous on the face of the advertisement. A review of the advertisement alone, considering all its elements, does not lead to a confident conclusion that a significant minority of reasonable consumers would interpret CX0031 as claiming that POM Juice is "clinically proven" to prevent, treat or reduce the risk of "heart disease." (CX0031 at 0001).

447. Among other things, in the context of this advertisement, the language that POM Juice "can" reduce plaque by "up to 30%" is qualified and non-definitive, and the citation to a study appears in a small print footnote, which states: "Aviram, M. Clinical Nutrition, 2004. Based on a clinical pilot study." (CX0031 at 0001).

***55** 448. Having fully examined CX0031 in its totality, and having further considered any extrinsic evidence in the record pertaining thereto (*see* Section II. E. 2, *infra*), the preponderance of the evidence fails to demonstrate that CX0031 conveys a claim that drinking eight ounces of POM Juice daily is "clinically proven" to prevent, treat, or reduce the risk of heart disease. (CX0031 at 0001; F. 446-447).

(b) CX0033 ("Life Support")

449. CX0033 ("Life Support") is an advertisement for POM Juice that was disseminated on or about December 30, 2004 in *Rolling Stone* magazine, and on or about February 1, 2005 in *Details* magazine. (CX0033 at 0001-02).

450. CX0033 is reprinted in the Appendix to this Initial Decision. (Appendix at 106).

451. The advertisement's headline is "Life Support," next to a large image of a POM Juice bottle hanging upside down on a pole, with the juice running through a tube at the bottom of the bottle, in a manner reminiscent of an intravenous line. (CX0033 at 0001).

452. The body copy of this advertisement juxtaposes the statements and representations that (a) POM Juice possesses "more ... antioxidants" than other drinks; (b) antioxidants "fight hard" against free radicals that "can cause heart disease"; and (c) if you drink POM Juice daily, "you'll be on life support — in a good way." (CX0033 at 0001).

453. Through the language and images described in F. 451 and F. 452, CX0033 draws a connection for the reader between consuming POM Juice and efficacy for heart disease. (CX0033 at 0001).

454. In the context of this advertisement, the reference to POM Juice as "refreshing" and "delicious" does not materially alter the overall message conveyed. (CX0033 at 0001; F. 453, 455).

455. Based on the overall, common-sense, net impression of CX033, a significant minority of reasonable consumers, would interpret CX0033 to be claiming that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease. (CX0033 at 0001; F. 451-454).

(c) CX0034 ("Amaze your cardiologist")

456. The POM Juice advertisement identified as CX0034 ("Amaze your cardiologist") was disseminated in *Prevention* magazine in February 2005. (CX0034 at 0001-02).

457. CX0034 is reprinted in the Appendix to this Initial Decision. (Appendix at 107).

458. This advertisement stopped running in 2005. (Tupper, Tr. 2996-97).

459. The headline of the advertisement is "Amaze your cardiologist." The headline is juxtaposed to an image of a POM Juice bottle with electrocardiogram (EKG) leads attached to it, in the manner of a patient having a heart exam. (CX0034 at 0001).

460. The body copy of CX0034 includes the statements or representations: (a) "Ace your EKG: just drink 8 ounces of delicious POM Wonderful Pomegranate Juice a day"; (b) POM Juice has more "antioxidants" than other drinks; (c) antioxidants fight free radicals that "can cause ... artery clogging plaque"; (d) a glass of POM Juice a day "can reduce plaque by up to 30%!"; and (e) "your cardiologist will be amazed." (CX0034 at 0001).

***56** 461. The advertisement draws a clear connection between consumption of POM Juice and reduction of arterial plaque. (CX0034 at 0001).

462. The advertisement draws a further connection between reduction of arterial plaque and effectiveness for heart disease through the juxtaposition of (1) the dressed bottle image undergoing an EKG (F. 459) and (2) the references to pleasing "your cardiologist" with positive EKG results. (CX0034 at 0001).

463. Based on the overall, common-sense, net impression of this advertisement, a significant minority of consumers, acting reasonably under the circumstances, would interpret CX0034 to contain the message that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, by reducing arterial plaque. (CX0034 at 0001; F. 459-462).

464. The depiction of the POM Juice bottle with an EKG, even if itself humorous or not to be taken literally, does not materially alter the message conveyed by the advertisement. (CX0034 at 0001; F. 463).

465. An implied claim that consuming POM Juice is "clinically proven" to prevent, treat, or reduce the risk of heart disease is not reasonably clear or conspicuous on the face of the advertisement. A review of the advertisement alone, considering all its elements, does not lead to a confident conclusion that a significant minority of reasonable consumers, would interpret CX0034 as claiming that POM Juice is "clinically proven" to prevent, treat or reduce the risk of "heart disease." (CX0034 at 0001).

466. Among other things, in the context of this advertisement, the language that POM Juice "can" reduce plaque by "up to 30%" is qualified and non-definitive, and the citation to a study is appears in a small print footnote, which states: "Aviram, M. Clinical Nutrition, 2004. Based on a clinical pilot study." (CX0034 at 0001).

467. In the context of this advertisement, the fact that the advertisement cites studies in connection with the arterial plaque representation is not enough to conclude, based on the face of the advertisement alone, that the advertisement claims POM Juice is clinically proven to prevent, treat, or reduce the risk of heart disease, including by reducing arterial plaque. (CX0034 at 0001).

468. Having fully examined CX0034 in its totality, and having further considered any extrinsic evidence in the record pertaining thereto (*see* Section II.E.2, *infra*), the preponderance of the evidence fails to demonstrate that CX0034 conveys a claim that POM Juice is "clinically proven" to prevent, treat, or reduce the risk of heart disease, including by reducing arterial plaque. (CX0034 at 0001; F. 465-467).

(d) CX0036 ("Cheat Death")

469. In 2005 and 2006, POM disseminated a POM Juice advertisement with the headline, "Cheat Death." The advertisement ran in *Rolling Stone* magazine in March, June, and July 2005; in *Prevention* magazine in May 2005; and in *Fitness* magazine in January 2006. (CX0036 at 0001-02).

***57** 470. CX0036 is reprinted in the Appendix to this Initial Decision. (Appendix at 108).

471. The headline, "Cheat Death," is juxtaposed to a large image of the POM Juice bottle with a noose around the bottle's neck. (CX0036 at 0001).

472. The text of CX0036, which is brief, includes the statement that POM Juice "can help prevent" "heart disease." (CX0036 at 0001).

473. This "Cheat death" advertisement, with the above-quoted body copy that POM "can help prevent" certain diseases stopped running in or around 2005. (Tupper, Tr. 2987-90).

474. Based upon the overall, common-sense, net impression of CX0036, particularly the statement that consumption of POM Juice "can help prevent ... heart disease," CX0036 would convey to a significant minority of reasonable consumers, a claim that that drinking eight ounces of POM Juice daily reduces the risk of heart disease. (CX0036 at 0001; F. 471-473).

475. In the context of this advertisement, use of the qualifying phrase "can help" does not alter the overall, common sense, net impression of CX0036 set forth in F. 474.

476. The headline and noose imagery, even if constituting humor or hyperbole, does not, in the context of the entirety of the advertisement, materially detract from the overall net impression of the advertisement, as described in F. 474.

2. Extrinsic evidence regarding advertisement interpretation

a. Summary of expert opinions

i. Respondents' expert Dr. Butters

477. Dr. Butters offered his opinion as a linguistics expert on the meanings of Respondents' advertisements. (Butters, Tr. 2816-17).

478. Linguistics is the study of human language in all its forms and manifestations. (Butters, Tr. 2813). Linguistics encompasses a number of often intersecting scientific subfields, including semantics, the study of word and sentence meanings; pragmatics, the study of how such meaning is affected by nonlinguistic contexts; and semiotics, the study of extra-linguistic and paralinguistic meaning systems that individuals assign to nonlinguistic signs, such as pictures, colors, visual patterns, and icons. (PX0158 (Butters Expert Report at 0006-07)).

479. To draw his conclusions in this case, Dr. Butters applied all the subdivisions of linguistics, including semantics, pragmatics, and semiotics, and considered the nature of the product advertised, as part of the overall context for the advertisement. (Butters, Tr. 2814-15, 2817-18).

480. Dr. Butters reviewed an extensive number of POM advertisements, including the advertisements included as exhibits to the Complaint and representative samples of other advertisements admitted into evidence. (PX0158 (Butters Expert Report at 0008); Butters, Tr. 2817, 2847).

481. Dr. Butters offered opinions on Respondents' advertising in general, and also offered opinions on the meanings of many of the Challenged Advertisements in this case. (PX0158 (Butters Expert Report)).

482. In summary, Dr. Butters opined that the Challenged Advertisements do not expressly convey or convey by implication that the Challenged Products prevent, reduce the risk of, or treat heart disease, prostate cancer or erectile dysfunction, or that such alleged medical effects or benefits are scientifically established facts. (PX0158 (Butters Expert Report at 0003, 0042)).

***58** 483. In Dr. Butters' opinion, none of Respondents' advertisements that he reviewed stated or implied that POM products treated any disease. (Butters, Tr. 2822, 2825).

484. In linguistic terms, an advertisement “implies” a message if it is the meaning that a reasonable consumer “takes away,” or infers, from the words and context of the advertisement. (Butters, Tr. 2826-2829).

485. Dr. Butters further opined, among other things, that the POM advertisements and POM communications he reviewed, make no definitive health claims, beyond the general accepted notion that consuming fruit products as part of an overall healthy diet is a healthy thing to do, including in order to reduce the risk of various diseases. (PX0158 (Butters Expert Report at 0042)).

486. Dr. Butters expressed his opinion that, at most, Respondents' advertising conveys that pomegranate juice is a healthy beverage; that POM products are high in antioxidants; that antioxidants are believed to fight free radicals and promote health; and that preliminary research performed on POM products indicates potential beneficial properties. (PX0158 (Butters Expert Report at 0003-04, 0043)).

487. In Dr. Butters' opinion, the POM advertisements he reviewed depend upon parody, exaggeration, and humor to bring their message to the potential purchaser. (PX0158 (Butters Expert Report at 0033)).

488. In Dr. Butters' opinion, the use of humor and parody in the advertisements work to “block” any inference that the advertisements are “intended to make definitive health claims” with respect to disease. (PX0158 (Butters Expert Report at 0004)).

489. Dr. Butters opined that hyperbole and humor block literal interpretation of such headings as “I'm off to save prostates” because these are absurd terms which would not be viewed as making disease claims. (Butters, Tr. 2958; PX0158 (Butters Expert Report at 0004)).

490. In drawing his conclusions, Dr. Butters relied, in part, on the use of such words as “promising,” “pilot studies,” or “preliminary results” and that the advertisements generally encourage those reading and hearing the advertisements to investigate the research and draw their own conclusions. (PX0158 (Butters Expert Report at 0003-04, 0043)).

491. In Dr. Butters' opinion, what people might infer with respect to a food product might be different than what they might infer with respect to a drug. (Butters, Tr. 2818).

492. In Dr. Butters' opinion, an advertisement promoting the consumption of food is far less likely to be interpreted by a reasonable consumer as conveying a treatment claim, than an advertisement promoting a drug. (Butters, Tr. 2825; *see also* Butters, Tr. 2818).

493. Dr. Butters analyzed the Challenged Advertisements from the perspective of the ordinary adult user of the English language in America. (Butters, Tr. 2816-17, 2831-32).

494. Dr. Butters did not take into account education or income level of the viewer of an advertisement, or whether the advertisement viewer was concerned about health issues. (Butters, Tr. 2832-34).

***59** 495. Dr. Butters stated that his conclusions about the Challenged Advertisements would be no different if analyzed from the perspective of more educated, affluent people, who are concerned about their health. (Butters, Tr. 2829-30).

496. In Dr. Butters' opinion, the phrase, “I'm off to save prostates” could be interpreted by outliers (*i.e.*, viewers that are not ordinary or reasonable) to mean protect or rescue from disease but that interpretation is unlikely. (Butters, Tr. 2898; PX0350 (Butters, Dep. at 125)).

497. Dr. Butters stated that use of the term “may” would not cause a reasonable person to believe that the product will produce that result. (Butters, Tr. 2822-23).

498. In Dr. Butters' opinion the representation that POM Juice will “fight for” “cardiovascular, prostate, erectile health” does not imply that the product will “treat cardiovascular, prostate, and erectile disease, or even give you cardiovascular, prostate, and erectile health.” Dr. Butters further opined that a closer possible inference is that pomegranate juice “improves your odds of maintaining” health in those areas, in a general way like any other food that is good for you, and to this extent, the language implies some kind of health benefit. (Butters, Tr. 2885-86, 2888; *see also* Butters, Tr. 2893 (phrase “fight for” “doesn't necessarily mean that you are going to win it”).

499. Dr. Butters acknowledged that a reasonable viewer could take away from CX0016 (“Drink and be healthy”) that pomegranate juice, in general, and POM Wonderful, in particular, can help to reduce the risk of heart disease. (Butters, Tr. 2929-30).

500. According to Dr. Butters, a reasonable viewer could not take away from the entire advertisement comprising CX0016 “Drink and be healthy” that pomegranate juice, in general, and POM Wonderful in particular, will treat atherosclerosis. (Butters, Tr. 2930).

501. In Dr. Butters' opinion, CX0274/1426 Ex. C ("I'm off to save PROSTATES"), could communicate to viewers, among other things, that POM Juice is protecting or defending prostates from disease. (Butters, Tr. 2899-2901).

502. Regarding CX0274/1426 Ex. C ("I'm off to save PROSTATES"), Dr. Butters opined that "the parodic method of presentation [use of parody] is so frivolous that no definite or clear claims will be understood, beyond the general notion that pomegranate juice is a good source of [anti]oxidants, and a healthy drink to include in one's diet." Dr. Butters has the same opinion with respect to CX0034 ("Amaze Your Cardiologist"); CX0031 ("Floss Your Arteries") and CX0351/CX0355 ("The Only Antioxidant supplement Rated X"). (PX0158 (Butters Expert Report at 0019-22)).

503. Regarding CX0034 Dr. Butters opined that the headline, "Amaze Your Cardiologist" is hyperbolic and cannot be taken literally. According to Dr. Butters, this language serves to "make explicit the theme of the importance of heart health using advertising-cliché language." (CX0034; PX0158 (Butters Expert Report at 0019-20)).

***60** 504. Dr. Butters opined that CX0351 and CX0355 (both having the title, "The Only Antioxidant Supplement Rated X"), convey the message that preliminary initial studies suggest that pomegranate extract, a strong source of antioxidants, could help alleviate erectile dysfunction. (Butters, Tr. 2943).

505. Regarding CX0351 and CX0355 ("The Only Antioxidant Supplement Rated X"), Dr. Butters opined that the advertisement only suggests that emerging science suggests that antioxidants are "critically important," and that "preliminary ... initial studies" suggest that pomegranate extract, a strong source of antioxidants, could help alleviate erectile dysfunction. (Butters, Tr. 2943).

506. Regarding CX0260 ("Drink to Prostate Health"), Dr. Butters acknowledged that one inference that would be drawn is that POM Juice might be beneficial for people who have had prostate cancer, because this is what has been found in the preliminary medical study referenced in the advertisement. (Butters, Tr. 2943-44; PX0158 (Butters Expert Report at 0024); PX0350 (Butters, Dep. at 121-22)).

507. Regarding CX0260 ("Drink to Prostate Health"), Dr. Butters expressed the opinion that ordinary consumers would not find that the advertisement communicates that POM Juice could treat, prevent, or reduce the risk of disease. Dr. Butters further testified that there may be some outliers who may interpret the advertisement to make such claims, but those outliers would, by definition, not be ordinary or normal. (PX0350 (Butters, Dep. at 121-25)).

508. Regarding CX0036 ("Cheat Death"), Dr. Butters opined that based on use of the words and phrases "can" and "help" with respect to heart disease, which words have intrinsic meaning in the English language, reasonable consumers would not interpret this advertisement to communicate that drinking eight ounces of POM Juice prevents or reduces the risk of heart disease. (PX0350 (Butters, Dep. at 102-05)).

509. Regarding CX0103 ("Decompress"), Dr. Butters testified that it would be a gross exaggeration for anybody to think that the image of a blood pressure cuff around the POM Juice bottle and the headline "Decompress" could literally mean drink a glass of pomegranate juice and your blood pressure will go down. (Butters, Tr. 2933).

510. According to Dr. Butters, the headline "Decompress," juxtaposed to the "blood pressure cuff" dressed bottle image, and a sub-headline "the antioxidant power of pomegranate juice, would not likely communicate that drinking POM Juice lowers blood pressure, and it would be far-fetched to interpret this text and imagery as making a medical claim. (PX0350 (Butters, Dep. at 148-50)).

511. Regarding CX0348 and CX0350 ("24 Scientific Studies"), Dr. Butters testified that a viewer of the "24 Scientific Studies" advertisement would find it reasonable to believe that the headline is accurate and that there must be 24 scientific studies on POMx. (Butters, Tr. 2940).

ii. Complaint Counsel's rebuttal expert Dr. Stewart

***61** 512. Complaint Counsel offered Professor David Stewart as a rebuttal witness to Dr. Butters. Dr. Stewart's area of expertise is advertising, marketing, consumer behavior, and survey methodology. Dr. Stewart is not an expert in linguistics, the subject of Dr. Butters' testimony. (Stewart, Tr. 3168-69).

513. Dr. Stewart was not asked by Complaint Counsel to conduct a facial analysis of the Challenged Advertisements to opine on what the advertisements meant. Dr. Stewart was asked to read and critique Dr. Butters' report, and to reach a conclusion as to whether or not he agreed with Dr. Butters' conclusions, and why. (Stewart, Tr. 3169, 3226).

514. Dr. Stewart opined that "[I]t is not possible to determine that an advertisement does or does not communicate certain implied messages simply from linguistic analysis." (CX1295 (Stewart Expert Report at 0006)).

515. According to Dr. Stewart, linguistic analysis fails to take into account the individual characteristics of the viewer and how that consumer processes information; it looks only at the advertisement stimulus. (Stewart, Tr. 3171-73).

516. According to Dr. Stewart, Dr. Butters' analysis ignores research related to how consumers use information, process advertising messages, and make decisions in the market place. (CX1295 (Stewart Expert Report at 0006); Stewart, Tr. 3170-71).

517. According to Dr. Stewart, well-educated, affluent, health-conscious consumers are more likely to be more attentive to health claims and more likely to draw pragmatic inferences about the benefits of POM products. (CX1295 (Stewart Expert Report at 0012-13)). However, Dr. Stewart defined a "pragmatic" inference as a meaning that is neither express, nor implied by the advertisement, and may or may not even follow, logically. (Stewart, Tr. 3227-28).

518. Dr. Stewart disagreed with Dr. Butters that a typical consumer would necessarily discern a difference between "can" and "will." According to Dr. Stewart, when viewing an advertisement the typical consumer is looking at the totality of the advertisement including: the illustration, the headline, the text, and carrying away a net impression based on all of that information. The potential meaning of "can" versus "will" is defined by its context, according to Dr. Stewart. (Stewart, Tr. 3190-91).

519. Dr. Stewart disagreed with Dr. Butters over the effect of such words as "initial" or "pilot." In Dr. Stewart's opinion, the typical consumer would likely have little understanding of what "initial" or "pilot" means, particularly in the context of being referred to as having been published in a major journal. In such circumstances, according to Dr. Stewart, juxtaposing terms such as "initial" or "pilot" with mentions of a well-respected medical school (UCLA), "leading universities," reference to professional journals in which support of the claims is found, reference to a Nobel laureate, and reference to the sum of money spent on research that is represented as supporting the advertising claims (*e.g.*, $25 million), have the effect of establishing the credibility of claims for the POM products. (CX1295 (Stewart Expert Report at 0016-17); Stewart, Tr. 3191).

***62** 520. Dr. Stewart opined that the Bovitz Study (*see* subsection c, *infra*), which studied headlines from billboard advertisements, contradicts the notion that humorous headlines, such as "Amaze your cardiologist" and "Floss your arteries," do not communicate any claims, as Dr. Butters concluded. (Stewart, Tr. 3202, 3204-06, 3230-31; *see* F. 497-489, 502-503).

b. Findings of fact regarding advertising interpretation, based upon testimony of Dr. Butters and Dr. Stewart

521. More educated, affluent people, who are concerned about their health, are likely to be more discerning and careful readers of an advertisement. (Butters, Tr. 2829-30).

522. Better educated people are more likely to better understand an advertisement. (Stewart, Tr. 3240).

523. According to the New Oxford Dictionary ("NOAD") the meaning of "defend" (*see* CX0274/1426 Ex. C), includes to "resist an attack made on (someone or something) and protect from harm or danger." (Butters, Tr. 2899-2901).

524. In linguistic terms, "I'm off to save prostates" would not imply that a product will protect or rescue from disease. (Butters, Tr. 2898; PX0350 (Butters, Dep. at 125)).

525. In linguistics terms, the word "may" is a shortened way of saying "may or may not." (Butters, Tr. 2822-23).

526. According to an ordinary desktop dictionary, "can" does not mean "will." (Butters, Tr. 2915).

527. Whether a consumer will discern a difference between "can" and "will" depends on the context and the totality of the advertisement. (Stewart, Tr. 3190-91).

528. Some academic literature indicates that the use of qualifiers, such as "can," "could," "might," or "up to" "encourage the audience of the advertisements to infer that a stronger claim is intended than the one that is actually entailed." Dr. Butters disagrees with this assertion. (Butters, Tr. 2916-19; *see also* CX1295 (Stewart Expert Report at 0016-17) (discussing study finding use of the word "may" rather than the stronger term "will" created greater credence for the claim)).

529. In linguistic terms, to "prevent" a disease means to keep the disease from happening. (Butters, Tr. 2818).

530. In linguistic terms, the word "treat" means medical treatment. (Butters, Tr. 2825).

531. In linguistic terms, the phrase, "backed by research" totaling a certain dollar amount, such as used in CX0475/1426 Ex. A, could be interpreted to mean there has been completed research with some results, or that there has been a certain dollar amount of research done so far and that research is ongoing. (Butters, Tr. 2876-78).

532. In the field of linguistics, hyperbole is a term used to refer to extreme exaggeration, and is not meant literally. (Butters, Tr. 2824).

533. Readers discount puffery and hyperbole because an advertisement using either, on its face, is an exaggeration; however, the fact that puffery and hyperbole are not to be taken literally does not mean that they cannot convey a claim that is serious. (Butters, Tr. 2824; Stewart, Tr. 3230).

***63** 534. Parody and humor have the effect of capturing the attention of the advertisement viewer, to help them connect with the message in the printed portion of the advertisement. (Butters, Tr. 2866).

535. Humor can induce further processing of an advertisement and a search for further information. (Stewart, Tr. 3229-30).

536. Contemporary speakers of American English would include "heart disease" within their understanding of the meaning of "heart trouble." (Butters, Tr. 2850-51).

537. Contemporary speakers of American English could interpret the phrase "erectile function" to relate to the ability of men to achieve and maintain erections. Erectile function and the absence of erectile dysfunction are closely related. (Butters, Tr. 2851 (discussing CX0351 and CX0355).

538. Contemporary speakers of American English could interpret the phrase "prostate health" to include the condition of not being diseased. (Butters, Tr. 2851).

539. Contemporary speakers of American English could interpret the phrase "heart health" to include the condition of not being diseased. (Butters, Tr. 2851).

540. In the proper context, a visual of an intravenous drip bottle could be a symbol for drugs and medicine. (Butters, Tr. 2947).

541. The caduceus symbol, showing snakes curling around a staff, is a symbol that people associate with medicine. (Butters, Tr. 2944). [3]

542. Academic marketing and psychology literature indicate that the meaning of a particular communication really resides in the recipient, not in the actual stimulus. Consumers are not simply passive recipients of messages but are active processors. (Stewart, Tr. 3170).

543. To determine what a consumer would take away from the POM advertising, it is very important to know the characteristics of the viewer of the advertisements, including prior beliefs and prior knowledge, and how the consumer would process the information, and generally what the consumer brings to the viewing situation — all of which are really important in understanding the totality of what people will take away from an advertising message. (Stewart, Tr. 3171-73).

c. Bovitz Billboard Survey

544. In March 2009, at the request of Ms. Resnick, POM engaged the Bovitz Research Group ("Bovitz") to design a consumer survey to evaluate the relative effectiveness of the then-running "Super Hero" advertising campaign compared to POM's earlier "Dressed Bottle" advertising campaign. (CX0286; CX1378 at 0049 (Kuyoomjian, Ocean Spray Dep. at 191-92)).

545. The target POM consumer for purposes of the survey was identified for Bovitz as "Higher HH income $75k +", 25 to 64, concerned about their health and willing to buy premium, health products." In recruiting participants, the survey eliminated individuals with incomes below $75,000. Individuals who did not score high on a scale measuring certain attitudes and lifestyle choices related to health and diet were also disqualified from participation. (CX0286 at 0002-03; CX0369 at 0003).

***64** 546. The Bovitz Survey used a forced exposure methodology (*i.e.*, showing the advertisement for which one wants to ascertain the consumer takeaway, to the survey respondents) which, although not the typical, natural way that consumers are exposed to advertising, is a valid method for a survey measuring advertising communication. (CX0369 at 0004-07; Mazis, Tr. 2693-95; Reibstein, Tr. 2509-10).

547. The Bovitz Survey exposed survey respondents only to POM's billboard advertising. (Reibstein, Tr. 2572-73, 2575; Stewart, Tr. 3207, 3209; PX0295a15 at 0005-06).

548. The Bovitz Survey compared consumers' perceptions of the following ten billboard advertisements from POM's Super Hero and Dressed Bottle advertising campaigns (hereinafter, “Bovitz Stimuli”), as follows:
Super Hero campaign advertisements:

Holy Health! $25 million in medical research.

I'm off to save PROSTATES!

100% PURE pomegranate juice to the rescue!

BACK OFF ... impostor juices!

Risk your health in this economy? NEVER!

Dressed Bottle campaign advertisements:

Cheat Death.

The Antioxidant Superpower.

Decompress.

Heart therapy.

Forever young.

(PX0295a15 at 0010-11).

549. The billboard advertisements from the Dressed Bottle campaign use humorous headlines and images. (Stewart, Tr. 3205).

550. Each of the Bovitz Stimuli also included a tagline related to antioxidants, such as “The Antioxidant Superpower” and the “The antioxidant power of pomegranate juice.” The Bovitz Stimuli contained no additional text. (PX0225 at 0005-06).

551. In the Bovitz Survey, a total of 150 target consumers and 100 existing POM users were exposed to the billboard advertisements from each campaign, identified in F. 544. (PX0225 at 0003-04).

552. Four of the billboard advertisements described in F. 548 (*i.e.*, "Heart therapy," "Decompress," "Cheat death" and "I'm off to save prostates") share headlines and imagery that appear in certain of the Challenged Advertisements in this case. (*See* CX0109 at 0001 and CX0463 ("Heart therapy banner advertisement"), CX0103 at 0001 ("Decompress"), CX0036 at 0001 and CX0188 at 0001 ("Cheat death"), and CX0274 at 0001 and CX0466 ("I'm off to save PROSTATES!" banner advertisement)).

553. The headline of one test billboard included a reference to "$25 million in ... medical research," (F. 548), which reference appears in some of the Challenged Advertisements. (*See, e.g.*, CX0274).

554. The participants were shown various advertisements, in a variety of configurations, and asked a series of questions, including: "Other than trying to get you to buy the product, what do you think is the main idea" that the advertisement "is trying to get across to you?" (CX0369 at 0005-11).

555. Fourteen percent of the general target audience and seventeen percent of POM Juice users in the Bovitz Survey, when shown an advertisement picturing a POM Juice bottle inside a blood pressure cuff, with the headline "Decompress" and a sub-headline "POM Wonderful Pomegranate Juice. The Antioxidant Superpower," said the ad's main idea was "helps/lowers blood pressure." (PX0295a15 at 0011, 0018, 0046; Stewart, Tr. 3213-14).

***65** 556. Other "main ideas" identified in the Bovitz Survey by those shown the billboard advertisement picturing a POM Juice bottle inside a blood pressure cuff, with the headline "Decompress" and a sub-headline "POM Wonderful Pomegranate Juice. The Antioxidant Superpower," include: (1) 64% of the general population and 73% of the POM population stated that the "main idea" of the billboard was "healthy/health benefits/juice is good for you"; (2) 16% of the general population and 20% of the POM population responded "antioxidants"; and (3) 6% of the general population and 13% of the POM population said "calming/relieves stress/relaxing." (PX0295a15 at 0018, 0046).

557. Forty-three percent of the general target audience and forty-eight percent of POM Juice users in the Bovitz Survey, when shown an advertisement picturing a POM Juice bottle saying, "I'm off to save PROSTATES!" and a sub-headline "The Antioxidant Superpower," said the advertisement's main idea was "good for prostates." (PX0295a15 at 0010, 0017, 0045).

558. Other "main ideas" identified in the Bovitz Survey by those shown the billboard advertisement picturing a POM Juice bottle saying, "I'm off to save PROSTATES!" and a sub-headline "The Antioxidant Superpower," include: (1) 31% of the general population and 48% of the POM population said the "main idea" of the "I'm off to save PROSTATES!" billboard was "healthy/health benefits/juice is good for you" and (2) 12% of the general population and 28% of the POM population said "antioxidants." (PX0295a15 at 0017, 0045).

559. Twenty-two percent of the general target audience and thirty-one percent of POM Juice users in the Bovitz Survey, who were shown an advertisement picturing a POM Juice bottle saying, "HOLY HEALTH! $25 million in medical research" and a sub-headline "The Antioxidant Superpower," said the advertisement's main idea was "$25 million spent on research/research based." (PX0295a15 at 0010, 0017, 0045).

560. Other "main ideas" identified in the Bovitz Survey by those shown the "HOLY HEALTH!" billboard advertisements were: (1) 57% of the general population and 46% of the POM population said "healthy/health benefits/juice is good for you;" (2) 12% of the general population and 9% of the POM population responded "antioxidants." (PX0295a15 at 0017, 0045).

561. According to Dr. Stewart, a test of headlines and images in the context of a billboard advertisement provides some insight into understanding what messages were communicated by the image and the headline. Other text that

is added to a lengthier print advertisement might modify the messages communicated by the image and headline. (Stewart, Tr. 3205-06).

562. Bovitz Survey respondents were also exposed to all five tested advertisements from the "Super Hero" campaign or all five tested advertisements from the "Dressed Bottle" campaign and asked: "Based on the ads you just saw, what are the specific benefits, if any, of drinking POM Wonderful?" (CX0369 at 0008-09; Stewart, Tr. 3214-16).

***66** 563. Professor Reibstein testified that the question posed in F. 562 was a leading, biased question because it directed the survey participants to select a "specific benefit" which pressures them to identify a "specific benefit" even if they had not perceived a particular benefit. (Reibstein, Tr. 2515-16). Dr. Stewart testified that this question was open-ended and not leading. (Stewart, Tr. 3216).

564. Of the survey respondents exposed to the five "Dressed Bottle" advertisements, which included the images and headlines of the "Decompress" print advertisement (CX0103) and the "Heart Therapy" print and banner advertisements (CX0109; CX0463), 38% of the general target audience said that a benefit of drinking POM Juice was "good for your heart" and 21% said a benefit was "helps/lowers blood pressure." (PX0225 at 0014; Stewart, Tr. 3216-17).

565. Bovitz Survey respondents who were exposed to the five "Super Hero" advertisements, which included an advertisement picturing a POM Juice bottle saying, "HOLY HEALTH! $25 million in medical research," were asked a close-ended question, "Based on the ads you just saw, which of the following do you think are true about POM Wonderful?" Survey respondents were provided a multiple-choice list and told to select as many or as few that applied. (CX0369 at 0010-11). Specifically, question 16 provided the following choices:
1. Backed by medical research

2. Is good for cardiovascular health

3. 100% pure pomegranate juice

4. Contains all natural ingredients

5. Is good for prostate health

6. Like "health in a bottle"

7. Contains naturally occurring antioxidants

8. Is the original pomegranate juice

9. Is good for you

10. Will help you stay healthy

11. Will help you live longer

12. Is better than other pomegranate juices

13. Has proven health benefits

14. Tastes good

566. In response to Question 16, 63% of the general population and 78% of POM Juice users included the choice, "has proven health benefits." (PX0295a15 at 0033, 0034).

567. Complaint Counsel's expert, Dr. Stewart, acknowledged that because Question 16 was a closed-ended question, there is the possibility of yea-saying, *i.e.*, the tendency to give a yes or more socially desirable response in an effort to be agreeable. (Stewart, Tr. 3218-19).

568. According to Dr. Reibstein, by providing respondents with a list of choices in response to Question 16 of the Bovitz Survey, survey respondents were cued to select from attributes that they may not otherwise have thought of, and do not have the option of attributes that do not appear on the list. This tends to inflate results. (Reibstein, Tr. 2518-19).

569. According to Dr. Reibstein, the Bovitz Survey is methodologically flawed and unreliable because it had no control and, thus survey respondents might have had preconceived perceptions about pomegranate juice before being exposed to POM's billboard advertisements. (Reibstein, Tr. at 2510-11).

***67** 570. Dr. Stewart testified he was "comfortable" with open-ended questions without a control, although he also testified that, without a control, you cannot draw a firm inference that an advertisement had a particular effect. (Stewart, Tr. 3241-42).

571. Dr. Reibstein opined that the Bovitz Survey is methodologically flawed and unreliable because the sample size of only 100 POM users and 150 target consumers exposed to each category of advertisements was too small to reach statistical significance at the 95% confidence level. (Reibstein, Tr. 2512-13).

572. None of the survey respondents in the Bovitz Survey answered that the main idea of the billboard advertisements was prevention, risk reduction, or treatment of any specific disease. The most common "main idea" communicated (at least 90%) was that POM Juice had general health benefits. (Reibstein, Tr. 2516-17; PX0225 at 0012-13).

573. Dr. Reibstein testified that the Bovitz Survey is methodologically flawed and unreliable because Question E (F. 574), which asked about health-related beliefs, resulted in accepting only recruits who were extremely health-focused, rather than merely healthoriented. According to Dr. Reibstein, such respondents would be more inclined to find health-oriented messages, particularly in light of the methodology of forced exposure and copy test questions cueing health. (Reibstein, Tr. 2511-12).

574. Question E of the Bovitz Survey stated as follows:

Listed below are some statements that may or may not describe you. Using the scale provided, please indicate the extent to which each of the following statements describes you.

(RANDOMIZE ROWS)	Describes me perfectly	Describes me well	Describes me somewhat	Describes me a little	Does not describe me at all

I use my diet to manage my health	5	4	3	2	1
High fiber foods are a regular part of my diet	5	4	3	2	1
I regularly work out to stay fit	5	4	3	2	1
I try to include plenty of fruits and vegetables in my diet	5	4	3	2	1
I believe that what I eat can directly affect my health	5	4	3	2	1
I am the first of my friends to try new gadgets and technology	5	4	3	2	1
I prefer to watch movies at home instead of a theater	5	4	3	2	1
I am adjusting my lifestyle to be conscious of the environment	5	4	3	2	1
I enjoy cooking and trying new recipes that I find online	5	4	3	2	1
I like to stay up on current events	5	4	3	2	1

***68** To qualify for participation in the survey, respondents had to respond with a "5" or a "4" on the rating scale with respect to at least three of the five health-related statements (*i.e.*, Questions 1 through 5). (CX0369 at 0002).

3. Television interviews

575. On November 20, 2008, Mrs. Resnick appeared on NBC's *The Martha Stewart Show*. Martha Stewart invited Mrs. Resnick to be interviewed on *The Martha Stewart Show*. (CX1426, Ex. E-6; L. Resnick, Tr. 137).

576. On February 19, 2009, Mrs. Resnick appeared on CBS' *The Early Show* in a segment on Cashing in on Ideas. (CX472 at 0003).

577. On March 20, 2009, *Newsweek* published on its website two pages of excerpts from an interview with Mrs. Resnick titled, "*Striking Out On Your Own. Is now a good time to start a company?*" (CX1426, Ex. F).

578. On June 17, 2008, Mr. Tupper provided a television interview on the Fox Network Business Channel. (CX1426, Ex. E-7; Tupper, Tr. 919). [4]

4. Summary of findings on advertising claims

579. In determining whether Respondents disseminated advertisements and promotional materials making the claims alleged in the Complaint, each of the Challenged Advertisements has been reviewed. Extrinsic evidence as to how the Challenged Advertisements would be interpreted by a reasonable consumer has also been considered.

580. Respondents disseminated advertisements and promotional materials that impliedly represented either that drinking eight ounces of POM Juice daily, taking one POMx Pill daily, and/or taking one teaspoon of POMx Liquid daily, is clinically proven to treat, prevent, or reduce the risk of heart disease, by reducing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart, as alleged in paragraph 12 of the Complaint. The following advertisements and promotional materials contain one or more of the foregoing representations:
• CX0016 (print advertisement) (prevent/reduce the risk only) (F. 293);

• CX0029 (print advertisement) (F. 299);

• CX1426 (Compl. Ex. I) (package insert) (F. 338);

• CX1426 (Compl. Ex. M) (POMx Heart Newsletter)(F. 346);

• CX0473 (Pomwonderful.com website: April 2009 (Compl. Ex. E-2); October 2009, December 2009 and January 2010 (F. 368, 380); Pompills.com website: April 2009 (Compl. Ex. E-8), January 2010 (Compl. Ex. E-9) (F. 387); pomegranatetruth.com website (Compl. Ex. E-1)(F. 411));

• CX0013 (press release) (F. 417); and

• CX0044 (press release) (F. 422).

581. Respondents disseminated advertisements and promotional materials that impliedly represented either that drinking eight ounces of POM Juice daily, taking one POMx Pill daily, and/or taking one teaspoon of POMx Liquid daily, is clinically proven to treat, prevent or reduce the risk of prostate cancer by prolonging prostate-specific antigen ("PSA") doubling time, as alleged in paragraph 14 of the Complaint. The following advertisements and promotional materials contain one or more of the foregoing representations:
***69** • CX0314 (magazine wrap) (F.310);

• CX0372 (magazine wrap) (F. 310);

• CX0379 (magazine wrap) (F. 310);

• CX0380 (magazine wrap) (F. 310);

• CX1426 (Compl. Ex. N) (POMx Prostate Newsletter) (F. 351);

• CX1426 (Compl. Ex. I) (package insert) (F. 331);

• CX0473 (Pomwonderful.com website: April 2009 (Compl. Ex. E-2); October 2009, December 2009, and January 2010 (F 368, 380); Pompills.com website: April 2009 (Compl. Ex. E-8), January 2010 (Compl. Ex. E-9) (F. 387)); and

• CX0065 (press release) (F. 429).

582. Respondents disseminated advertisements and promotional materials that impliedly represented either that drinking eight ounces of POM Juice daily, taking one POMx Pill daily, and/or taking one teaspoon of POMx Liquid daily, is clinically proven to treat, prevent or reduce the risk of erectile dysfunction, as alleged in paragraph 16 of the Complaint. The following advertisements and promotional materials contain one or more of the foregoing representations:
• CX0351 (print advertisement) (F. 325);

• CX0355 (print advertisement) (F. 325);

• CX0473 (Pomwonderful.com website: April 2009 (Compl. Ex. E-2); October 2009, December 2009, and January 2010 (F. 368, 380); Pompills.com website: April 2009 (Compl. Ex. E-8), January 2010 (Compl. Ex. E-9) (F. 387)); and

• CX0128 (press release) (treatment only) (F. 433).

583. Respondents disseminated advertisements and promotional materials that impliedly represented either that drinking eight ounces of POM Juice daily, taking one POMx Pill daily, and/or taking one teaspoon of POMx Liquid daily, treats, prevents or reduces the risk of heart disease, by reducing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart, without also representing clinical proof of these effects, as alleged in paragraph 19 of the Complaint. The following advertisements contain one or more of the foregoing representations:
• CX0031 (print advertisement) (F. 443);

• CX0033 (print advertisement) (F. 455);

• CX0034 (print advertisement) (F. 463); and

• CX0036 (print advertisement) (F. 474).

584. The findings described in F. 580-583 are based upon the overall, common-sense, net impression of the advertisements themselves, and full consideration of any applicable extrinsic evidence. As to advertisements cited in F. 580-583, the weight of the applicable extrinsic evidence fails to sufficiently contradict the overall, common-sense, net impression gleaned from the advertisements themselves.

585. The following Challenged Advertisements were found to have made claims alleged in the Complaint, but the preponderance of the evidence fails to prove that these advertisements made all the claims asserted by Complaint Counsel. *See* Appendix A to Complaint Counsel's Post-hearing Brief. These advertisements and claims are: CX0031 ("clinically proven" claim not found); CX0034 ("clinically proven" claim not found); CX0065 (press release) (heart disease claim not found); CX0351 and CX0355 (prostate cancer and heart disease claims not found). It is not reasonably clear from the face of the advertisements alone that a significant minority of consumers, acting reasonably under the circumstances, would interpret these advertisements as making the identified claims. A review of each of these advertisements, considering the interplay of all the elements of each such advertisement, failed to allow a confident conclusion that a significant minority of reasonable consumers would interpret the advertisements as making the identified claims. Among other reasons, the foregoing advertisements: do not mention heart disease, prostate cancer, or erectile dysfunction; use vague, nonspecific, substantially qualified, and/or otherwise non-definitive language; use language and/or images that, in the context of the advertisement, are inconsistent with the alleged claim; and/or do not draw a sufficiently clear connection for the reader, such as through associated explanatory text, between the health effects or study results referred to in the advertisements and the diseases alleged in the Complaint. Moreover, applicable extrinsic evidence fails to demonstrate that these advertisements make the identified claims.

***70** 586. Based on a thorough review of all the Challenged Advertisements, none expressly (*i.e.*, unequivocally and directly) states that "drinking eight ounces of POM Juice daily" or "taking one POMx Pill daily," or "taking one teaspoon of POMx Liquid daily"(1) "treats," "prevents," or "reduces the risk" of "heart disease," including by reducing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart, or that these effects are "clinically proven"; (2) "treats," "prevents" or "reduces the risk" of "prostate cancer," including by prolonging prostate-specific antigen doubling time, or that these effects are "clinically proven"; or (3) "treats," "prevents," or "reduces the risk" of erectile dysfunction, or that these effects are "clinically proven."

587. As to the Challenged Advertisements not identified in F. 580-583 as making the representations alleged in the Complaint, after a thorough review it is not reasonably clear from the face of these advertisements that a significant minority of consumers, acting reasonably under the circumstances, would interpret these advertisements as making the claims alleged in the Complaint. A review of these advertisements, considering the interplay of all the elements of each such advertisement, failed to allow a confident conclusion that a significant minority of reasonable consumers would interpret these advertisements as making the claims alleged in the Complaint. These advertisements, which are all print advertisements except where noted, are: CX0103; CX0109; CX0188, CX0192; CX0260; CX0274; CX0475; CX0120; CX0122; CX0169; CX0180; CX0279; CX0280; CX0328; CX0331; CX0337; CX0342; CX0348; CX0350; CX0353; CX0463 (banner advertisement) and CX0466 (banner advertisement).

588. Among other reasons, the advertisements identified in F. 587: use language that is vague, non-specific, substantially qualified, and/or otherwise non-definitive; use language and/or imagery that in the context of the advertisements is inconsistent with the alleged claims; fail to mention specific diseases; and/or fail to draw a sufficiently clear connection for the reader, such as through associated explanatory text, between health effects or study results referred to in the advertisements and the diseases alleged in the Complaint.

589. As to the advertisements identified in F. 587, the weight of the applicable extrinsic evidence (*see* Section II.E.2, *infra*) fails to demonstrate that these advertisements make the claims alleged in the Complaint.

590. Having fully considered each of the advertisements identified in F. 587, as well as any extrinsic evidence pertaining thereto (*see* Section II.E.2, *infra*), the preponderance of the evidence fails to demonstrate that a

significant minority of reasonable consumers would interpret these advertisements as making the claims alleged in the Complaint.

***71** 591. The evidence fails to show that CX0473 (pomegranatetruth.com website) made the prostate cancer and erectile dysfunction claims alleged in the Complaint because the web capture of this website did not include content pertaining to such claims. (F. 415).

F. Level of Required Substantiation

1. Types of studies

592. There are four study types for examining the relation between a food or nutrient and a disease outcome: (a) *in vitro* studies; (b) animal studies; (c) human observational studies; and (d) human clinical studies. (CX1293 (Stampfer Expert Report at 0008)).

593. "Basic science" refers to test-tube, animal studies, and preclinical research. (Dreher, Tr. 528).

a. *In vitro* studies

594. *In vitro* studies are those where blood elements or cells are removed from the body and tested in a controlled laboratory environment, such as a test tube. They are used to identify potential biologic mechanisms and generate hypotheses for studies in humans. (CX1293 (Stampfer Expert Report at 0008); CX1291 (Sacks Expert Report at 0015-16); *see* Melman, Tr. 1112). Human metabolism and disease processes are very complicated and cannot be replicated in a petri dish, and therefore, many *in vitro* studies produce results that cannot be replicated in humans. (CX1291 (Sacks Expert Report at 0015-16); Sacks, Tr. 1450; *see also* Stampfer, Tr. 725-26; deKernion, Tr. 3063-64).

b. Animal studies

595. Animal studies are tools for identifying potential treatments, mechanisms, and side effects. Animals are not the same as humans, either biologically or psychologically, and therefore, many findings of dietary or drug effects in animals are not confirmed in human testing. (CX1291 (Sacks Expert Report at 0016); Sacks, Tr. 1451; Melman, Tr. 1112-13; CX1289 (Melman Expert Report at 0011); *see* PX0355 (Ornish, Dep. at 66)).

596. Animal studies alone are not sufficient to show that a tested product will prevent or treat human disease. (Sacks, Tr. 1451-52; Melman, Tr. 1112-13; CX1289 (Melman Expert Report at 0011); Goldstein, Tr. 2644; PX0349 (Burnett, Dep. at 57, 112-13)).

597. Animal studies are very informative and provide for some clinical insights. (PX0349 (Burnett, Dep. at 111); PX0352 (Goldstein, Dep. at 122-24); Goldstein, Tr. 2644; Heber, Tr. 2086, 2149; CX1352 (Heber, Dep. at 243); Heber, Tr. 2086; 2149, 2182; PX0192 (Heber Expert Report at 0015, 0041-42, 0051-59). In an animal study, researchers can isolate mechanisms of action and accomplish toxicity or safety testing, as well as examine specific mechanisms by taking out their organs and cells, which cannot be done in humans. (PX0361 (Sacks, Dep. at 89-91). Results from such animal studies have potential for benefit of therapy at the human level. (PX0206 (Miller Expert Report at 10-11, 13); Miller Tr. 2194; PX0349 (Burnett, Dep. at 112); Burnett, Tr. 2262-63; Heber, Tr.

2086, 2149; CX1352 (Heber, Dep. at 243); Heber, Tr. 2086; 2149, 2182; PX0192 (Heber Expert Report at 0015, 0041-42, 0051-59).

***72** 598. Although there are limitations to extrapolating from animal studies to human studies, studies on animals have value in determining therapeutic efficacy. (PX0025 (Ornish Expert Report at 0007)).

599. Dr. Sacks, Complaint Counsel's cardiology expert, testified that he considers all levels of science in issuing national guidelines for the prevention or treatment of cardiovascular disease. (PX0361 (Sacks Dep. at 71)). Similarly, Complaint Counsel's erectile dysfunction expert, Dr. Melman, testified that based on the results of his gene therapy erectile dysfunction product in an animal model, he was "personally satisfied" that it would also work in humans. (PX0360 (Melman, Dep. at 56-57)).

c. Human observational studies

600. Human observational studies are large human studies that compare intake of various levels of nutrients (for example, low vitamin C versus high vitamin C) with various endpoints, such as disease outcomes, over time. (CX1293 (Stampfer Expert Report at 0008); Stampfer, Tr. 719; *see* Heber, Tr. 2168).

601. Human observational studies can support a conclusion that there is an association between a nutrient and a disease of interest, but generally do not prove causation, due to the potential, even in well-designed studies, for unidentified biases or inadequately controlled confounding factors. (CX1293 (Stampfer Expert Report at 0008-09); Stampfer, Tr. 720-21; *see* Sacks, Tr. 1418-19).

d. Human clinical studies

602. Human clinical studies are those in which investigators assign the exposure level to participant — meaning that the investigators tell the subjects how much of a particular nutrient to consume, in contrast to observational studies, where the investigators study existing exposure levels within a particular population. (CX1293 (Stampfer Expert Report at 0009)).

603. There is a typical progression in human clinical studies, from exploratory research to randomized clinical trials. (PX0025 (Ornish Expert Report at 0010, 0024) ("Science usually progresses when someone publishes a study of a series of patients with a nonrandomized control group that shows an unprecedented finding which is then replicated by one or more subsequent randomized controlled trials[;]" "[t]here is a logical progression in science which often begins with a pilot study that has no control group")).

604. Some researchers describe the progression of research in terms of "phases," where: a Phase I trial tests treatments in a small number of patients to find a safe dose; a Phase II trial tests the intervention in a larger number of people to identify specific effects; a Phase III trial tests the treatment in a larger number of people, to compare it to "standard treatment"; and a Phase IV trial tests a treatment in several hundred to thousands of people to assess long-term safety and effectiveness. (CX1287 (Eastham Expert Report at 0009); CX1341 (Pantuck, Dep. at 28-29); *see also* Burnett, Tr. 2262).

***73** 605. Typically, researchers conduct pilot or exploratory studies. A pilot study is designed to investigate whether there is any evidence of a treatment effect. Such research can reveal potential changes from an intervention, allows the researchers to see if people can tolerate the intervention or if it causes unexpected side

effects, and paves the way for more definitive research. (CX1338 (Padma-Nathan, Dep. at 87-88, 155); CX1193 at 0001; Melman, Tr. 1116; Stampfer, Tr. 747-48; CX1342 (Hill, Dep. at 45-48)).

606. Pilot studies are generally considered by scientists and clinicians in the scientific community to be valid, accurate, and reliable studies. (CX1336 (Davidson, Dep. at 232-33); CX1342 (Hill, Dep. at 48-49, 53); CX1339 (Ornish, Dep. at 23); CX1358 (Aviram, Dep. at 17)).

607. A "pilot" study does not mean that it is not as scientifically valid as a larger study. (CX1339 (Ornish, Dep. at 23, 119-20)). A small number of participants do not weaken the importance of the results, especially if they are in agreement with *in vitro*, mechanistical studies and in animal models. (CX1358 (Aviram, Dep. at 18)).

608. A reason a researcher conducts a "pilot" study is because he or she is not certain how many subjects it will take to adequately power the study. If there is no effect shown, then this allows the investigators to address any concerns regarding the study. (CX1342 (Hill, Dep. at 46-48)).

2. Randomized clinical trials

609. Well-designed, well-conducted, randomized, double-blinded, placebo-controlled human clinical studies are referred to by experts in the field of clinical testing as "RCTs." (CX1291 (Sacks Expert Report at 10)).

610. It is standard practice, in human research, to begin with a *protocol*. (Stampfer, Tr. 760; Sacks, Tr. 1436-37; Heber, Tr. 2044-45). A protocol describes the key features of a study, such as objectives, methodology, statistical analysis plan, the definition of the *p* value (probability), and primary outcome variables (endpoints). (Sacks, Tr. 1436-37; Stampfer, Tr. 760; *see* Ornish, Tr. 2367). The purpose of identifying the primary outcomes in advance is to prevent a researcher from using positive results and ignoring negative ones, resulting in bias. (Sacks, Tr. 1475; CX1291 (Sacks Expert Report at 0021)).

611. A *controlled* study is one that includes a group of patients receiving the purported treatment ("treatment" or "active" group) and a control group ("placebo" or "control" group). (CX1291 (Sacks Expert Report at 0011)). A control group provides a standard by which results observed in the treatment group can be evaluated. (CX1287 (Eastham Expert Report at 0013)). A control group allows investigators to distinguish between real effects from the intervention, and other changes, including those due to the mere act of being treated ("placebo effect"), the passage of time, change in seasons, other environmental changes, and equipment changes (such as calibration changes). (CX1291 (Sacks Expert Report at 0011); Burnett, Tr. 2265; Eastham, Tr. 1268; *see* CX1293 (Stampfer Expert Report at 0009); Ornish, Tr. 2367). The control group should be approximately the same size and meet the same criteria as the treatment group. (Eastham, Tr. 1268-69; CX1287 (Eastham Expert Report at 0013); CX1291 (Sacks Expert Report at 0011); Melman, Tr. 1095; CX1289 (Melman Expert Report at 0009)). It also should receive the same measurements and attention from the researchers as the treatment group. (CX1291 (Sacks Expert Report at 0011)).

***74** 612. *Randomization* means assigning subjects to the active product group or the control group in a random fashion, whether using a computer program, random number table, or coin toss. It is another way to control for bias. (Burnett, Tr. 2264-65; CX1291 (Sacks Expert Report at 0011); CX1339 (Ornish, Dep. at 20); Eastham, Tr. 1266; Melman, Tr. 1096). It increases the likelihood that the treatment and control groups are similar in relevant characteristics, so that any difference in the outcome between the two groups can be attributed to the treatment. (CX1291 (Sacks Expert Report at 0011-12); CX1293 (Stampfer Expert Report at 0009); CX1287 (Eastham Expert Report at 0012-13); CX1339 (Ornish, Dep. at 20) ("[B]y randomizing people, if there were some unknown factor that was biasing your outcomes, it would be likely to be distributed across both groups")). It also prevents the

investigator from deciding who gets which treatment, which can introduce bias into the study. (CX1345 (deGroof, Dep. at 62); Melman, Tr. 1096).

613. A *placebo* is an inactive product or treatment given to the control group, in lieu of the intervention being tested. (Stampfer, Tr. 708; Eastham, Tr. 1267-68; Melman, Tr. 1094-95). For example, in a study of a pill, the placebo would be a pill that looks like the intervention, but does not contain the active ingredient. (Stampfer, Tr. 708). A placebo should be identical, in all ways possible, to the active treatment. (CX1291 (Sacks Expert Report at 0011); Melman, Tr. 1095). A double blind study, *see* F. 614, blinds participants and investigators as to whether study participants are in the active or placebo group. (CX1293 (Stampfer Expert Report at 0009); Melman, Tr. 1095-96).

614. *Blinding* refers to steps taken to ensure that neither the study participants nor the researchers conducting the outcome measurements are aware of whether a patient is in the active group or the control group. (CX1291 (Sacks Expert Report at 0012); Melman, Tr. 1097).

615. *Double-blinding*, that is, blinding of both the patients and investigators, is optimal to prevent bias arising from actions of the patients or investigators. (CX1293 (Stampfer Expert Report at 0009); Stampfer Tr. 708-09; Eastham, Tr. 1267; Melman, Tr. 1098; CX1287 (Eastham Expert Report at 0013); *see also* Heber, Tr. 2044). In some instances, the blinding of patients is not possible. A study that is unblinded can still have value. (Sacks, Tr. 1435-36; PX0361 (Sacks, Dep. at 104-05); Ornish, Tr. 2345; Eastham, Tr. 1327, 1339).

616. Once a randomized controlled trial is completed and all the data is collected, data for the control and active treatment groups is compared through use of appropriate *statistical analyses*. (Eastham, Tr. 1272; CX1287 (Eastham Expert Report at 0014); CX1291 (Sacks Expert Report at 0012-13)). If the results of the treatment group are *statistically significant* from those of the control group at the end of the trial, it can be concluded that the tested product is effective. This analysis is called a *between-group analysis*. (CX1291 (Sacks Expert Report at 0012-13); Burnett, Tr. 2269).

***75** 617. A *within-group* analysis, where a researcher compares the treatment group participants' "before" data to their "after" data, has much less scientific value, because it relies on the assumption that without the intervention there would have been no change in the study participants' condition. (Stampfer, Tr. 714).

618. Evaluating data from a clinical trial for *statistical significance* is the standard practice to demonstrate that a study's hypothesis has been proven. (Burnett, Tr. 2269; CX1287 (Eastham Expert Report at 0014)). *Statistical significance* is recognized as being attained if the statistical test for probability, referred to as the "*p*" value, is less than or equal to 0.05 ($p \# 0.05$), which means that there is only a 5 percent or less chance that the difference between the treatment and placebo groups is due to chance. (CX1291 (Sacks Expert Report at 0012); Eastham, Tr. 1273; Ornish, Tr. 2368; Melman, Tr. 1102-03; CX1289 (Melman Expert Report at 0010)). It eans that the results demonstrated would occur no more than one time out of 20, and therefore, other causes of the result, such as chance, are less likely as an explanation. (Stampfer, Tr. 710-11).

619. Statistical significance is an arbitrary convention in the context of studying a whole food. (Ornish, Tr. 2340, 2368; Goldstein, Tr. 2598-99 (choosing a significance level is technically an arbitrary task, and "in specific situations a different value could be utilized")).

620. Results that do not have a *p*-value of less than 0.05 can still evidence a clinically meaningful benefit that is scientifically supportable. (PX0352 (Goldstein, Dep. at 108-09); Goldstein, Tr. 2599; PX0189 (Goldstein Expert Report at 0013); PX0349 (Burnett, Dep. at 67, 138-39); Burnett, Tr. 2270-71; CX1350 (Liker, Dep. at 190-91); PX0361 (Sacks, Dep. at 109); Sacks, Tr. 1608-09).

621. *Validated* endpoints or surrogate markers are those outcomes that, while not direct endpoints, have been shown to be so closely linked to a direct endpoint that a change in the surrogate marker is confidently predictive of a change in the disease. (*See* CX1291 (Sacks Expert Report at 0013); *see* CX1287 (Eastham Expert Report at 0010) ("Changes in a surrogate are expected to reflect changes in a clinically meaningful endpoint")). *Validated* measures or assessment tools are those that have been established as reliable through rigorous assessments involving a large number of individuals. (Burnett Tr. 2266-67; Melman, Tr. 1100).

622. Certain validated measures, like the International Index of Erectile Function ("IIEF"), were originally intended for pharmaceutical products and "not necessarily designed for a nutraceutical [a food product that provides medical or health benefits]." (PX0352 (Goldstein, Dep. at 67-69); Goldstein, Tr. 2603-04, 2633).

623. Certain non-validated measures are very "informative and ... valuable to use in clinical studies." (Burnett, Tr. 2294).

***76** 624. *Clinical significance* means that the treatment makes a real difference in a patient's life. (Melman, Tr. 1103; Eastham, Tr. 1274; PX0361 (Sacks, Dep. at 109)). A result may also be clinically significant even if it did not reach statistical significance. (PX0352 (Goldstein, Dep. 108-09); Goldstein, Tr. 2599; PX0189 (Goldstein Expert Report at 0013); PX0349 (Burnett, Dep. at 67, 138-39); Burnett, Tr. 2270-71; CX1350 (Liker, Dep. at 190-91). A result may be statistically significant, but not clinically significant. (Melman, Tr. 1104; Eastham, Tr. 1274).

625. *Replication* is intended to ensure that the results obtained in one study are not due to chance. Even with the safeguards contained in an RCT, the results contained in any one study may be due to chance or may not be generalizable due to uniqueness of the study sample. (Sacks, Tr. 1446; CX1291 (Sacks Expert Report at 0014-15)).

3. Testimony from Complaint Counsel's experts on whether RCTs are required

a. Dr. Meir Stampfer

626. Dr. Stampfer provided the following opinion regarding the appropriate level of evidence of substantiation: randomized, double blind, placebo-controlled trials are needed for nutrient supplements when they are used as medical interventions to prevent or treat diseases. (CX1293 (Stampfer Expert Report at 0029)).

627. Dr. Stampfer testified that if there is a claim that a cause and effect relationship (causal link) between a nutrient or food and a disease has been established, then one has to have evidence to back it up. (Stampfer, Tr. 830-31).

628. Dr. Stampfer testified that the level of scientific evidence required to support a claim depends on the claim being made. (Stampfer, Tr. 830-31).

629. Dr. Stampfer explained that it is an efficacy claim to say that a product reduces the risk of a disease, but it is not an efficacy claim to say that users of a product have a lower incidence of a particular disease. To state that users of a product have a lower incidence does not mean that use of the product caused them to have a lower incidence. (Stampfer, Tr. 798).

630. Dr. Stampfer further testified that a statement that studies indicate that a product lowers the risk of heart disease and diabetes does not imply that a causal link is established. (Stampfer, Tr. 817).

631. Dr. Stampfer testified that if the claim does not imply a causal link, for example, if the claim is that there is some evidence to suggest the possibility that nuts may reduce the risk of diabetes, then evidence short of RCTs can support that claim. (Stampfer, Tr. 830-31; CX1293 (Stampfer Expert Report at 0029-30) (it may be appropriate to use evidence short of randomized clinical trials for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, because everyone eats and the public should be given advice based on the best evidence available. This advice should distinguish between recommendations based on good evidence of a causal relation from those that are based on evidence that is suggestive but falls short of a firm casual conclusion.)).

***77** 632. Dr. Stampfer further testified that in a nutritional context, a hypothesis about disease causation can, rarely, if ever, be directly tested in humans using the RCT design. (Stampfer, Tr. 831-32; PX0362 (Stampfer, Dep. at 73, 99); CX1293 (Stampfer Expert Report at 0030) (long term trials of diet and disease outcomes are often unfeasible due to the financial and participant burden required to perform such studies, but it is indisputable the randomized clinical trial is the best study design that permits strong causal inference concerning the relationship between an administered agent (whether drug or nutrient) and any specific outcome)).

633. Dr. Stampfer also testified, that the failure to act, in the absence of conclusive RCT evidence, increases the risk of forgoing benefits to the public that might have been achieved with little risk and little cost and that one should "definitely" make that potential benefit available to the public rather than withhold it. (Stampfer, Tr. 837-38).

634. In a recently published article titled "*Evidence-based criteria in the nutritional context*," Dr. Stampfer opined that the general principles of evidence-based nutrition "can provide a sufficient foundation for establishing nutrient requirements and dietary guidelines in the absence of RCTs for every nutrient and food group." (Stampfer, Tr. 831; RX5007 at 483). Dr. Stampfer also opined that because RCT study designs may not be "available" (economically or scientifically) for nutrients, "nutrient related decisions could be made at a level of certainty somewhat below that required for drugs." (RX5007 at 481).

635. Dr. Stampfer also stated in the article "*Evidence-based criteria in the nutritional context*" that some of the intellectual fathers of evidence based medicine "stressed" that evidence based medicine was "not restricted to randomized trials and meta-analyses." (RX5007 at 483). Dr. Stampfer further stated that "certain features of [evidence-based medicine] seem ill-suited to the nutrition context." (RX5007 at 479). He also opined that "to fail to act in the absence of conclusive RCT evidence increases the risk of forgoing benefits that might have been achieved with little risk and at low cost." (RX5007 at 481).

636. In the article "*Evidence-based criteria in the nutritional context*," Dr. Stampfer noted that some of the differences between the evaluation of drugs and nutrients are: "(i) medical interventions are designed to cure a disease *not* produced by their absence, while nutrients prevent dysfunction that would result from their inadequate intake; (ii) it is usually not plausible to summon clinical equipoise for basic nutrient effects, thus creating ethical impediments to many trials; (iii) drug effects are generally intended to be large and with limited scope of action, while nutrient effects are typically polyvalent in scope and, in effect size, are typically within the "noise" range of biological variability; (iv) drug effects tend to be monotonic, with response varying in proportion to dose, while nutrient effects are often of a sigmoid character, with useful response occurring only across a portion of the intake range; (v) drug effects can be tested against a nonexposed (placebo) contrast group, whereas it is impossible and/or unethical to attempt a zero intake group for nutrients; and (vi) therapeutic drugs are intended to be efficacious within a relatively short term while the impact of nutrients on the reduction of risk of chronic disease may require decades to demonstrate — a difference with significant implications for the feasibility of conducting pertinent RCTs." '28RX5007 at 479; PX0362 (Stampfer, Dep. at 78)).

***78** 637. Dr. Stampfer admitted that he has made public health recommendations about foods that were not supported by RCTs. (Stampfer, Tr. 810, 813-14; PX0362 (Stampfer, Dep. at 173)).

b. Dr. Frank Sacks

638. Dr. Sacks provided the following opinion regarding the appropriate level of evidence of substantiation: appropriately analyzed results of well-designed, well-conducted, randomized, double-blinded, controlled human clinical studies, demonstrating significant changes in valid surrogate markers of cardiovascular health would be necessary (a) to substantiate that a product, including a conventional food or dietary supplement, can treat, prevent or reduce the risk of heart disease and/or (b) to support a claim that clinical studies, research, or trials prove that a product treats, prevents or reduces the risk of heart disease. In addition, Dr. Sacks opined that at least two well-designed studies, conducted by different researchers, and each showing strong results, are needed to constitute reliable evidence. (CX1291 (Sacks Expert Report at 0010-11, 0014-15)).

639. Dr. Sacks testified that most scientists in the fields of nutrition, epidemiology and the prevention of disease believe that at least two well-designed RCTs, conducted by independent researchers, and each showing strong results, are needed to constitute reliable evidence that an intervention causes a result. (Sacks, Tr. 1446; CX1291 (Sacks Expert Report at 0014-15)).

640. Dr. Sacks testified that pomegranate juice has not been proven for safety and that double-blinded, placebo-controlled tests would be necessary to prove pomegranate juice to be safe. (Sack, Tr. 1534).

641. Dr. Sacks acknowledges that in some instances, such as studies on foods, the blinding of patients is not possible, and that if a study becomes unblinded or does not have a placebo, it can still have value. (Sacks, Tr. 1435; PX0361 (Sacks, Dep. at 104-105, 111, 137)).

642. In an article titled "*The Importance of Population-Wide Sodium Reduction as a Means to Prevent Cardiovascular Disease and Stroke: A Call to Action From the American Heart Association*" published in their journal (Circulation. 2011 Mar 15;123(10):1138-43), Dr. Sacks, as one of the authors, wrote: "Some scientists still question the evidence supporting population-wide sodium reduction. Common arguments include the absence of a major trial with hard clinical outcomes. It is well-known, however, that such trials are not feasible because of logistic, financial, and often ethical considerations." (Sacks, Tr. 1561; PX0361a03). In writing about "financial considerations" in this article, Dr. Sacks conceded that he meant the cost of conducting a major trial. (Sacks, Tr. 1561).

643. Dr. Sacks has never researched whether a single fruit, such as the pomegranate, has health benefits, but instead has only studied "fruits and vegetables as a category." (PX0361 (Sacks, Dep. at 54, 56)).

644. Dr. Sacks served as the Chairman of the Design and Analysis Committee for the DASH ("Dietary Approaches to Stop Hypertension") diet sponsored by the National Heart, Lung and Blood Institute, part of the National Institute of Health. The DASH study was a multi-center study to look at the effect of fruits and vegetables in lowering blood pressure and the effect of a total dietary approach in lowering blood pressure, including the reduction of sodium intake. The DASH diet showed that diets high in fruits and vegetables, among other things, substantially lowered blood pressure in subjects compared to the control group. (PX0361a03 at 002; PX0361 (Sacks, Dep. at 48-49); Sacks, Tr. 1417-18).

***79** 645. Dr. Sacks testified that you do not need RCTs to test the benefit of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. However, Dr. Sacks also opined that you do need two RCTs to test pomegranate juice. (Sacks, Tr. 1546-47).

646. Dr. Sacks also testified that *in vitro* studies can be competent and reliable evidence of an agent's effect on a particular mechanism. (Sacks, Tr. 1578; PX0361 (Sacks, Dep. at 123-24)).

647. Dr. Sacks further testified that there are common clinical recommendations today that have not been proven by RCTs and that major trials with hard clinical outcomes are often not feasible because of the costs of conducting them. (Sacks, Tr. 1559-61).

c. Dr. James Eastham

648. Dr. Eastham provided the following opinion regarding the appropriate level of evidence of substantiation: qualified experts in the field of urology, including the prevention and treatment of prostate cancer, and in the field of clinical testing relating to the prevention and treatment of prostate cancer, would require claims that the POM Products treat, prevent, or reduce the risk of prostate cancer, or are clinically proven to do so, to be supported by at least one well-conducted, randomized, double-blind, placebo-controlled clinical trial involving an appropriate sample population and with an appropriate endpoint. (CX1287 (Eastham Expert Report at 006, 012)).

649. Dr. Eastham testified that even if a product is safe and might create a benefit, like a fruit juice, he would still require an RCT to justify claims that Respondents are charged with making. (Eastham, Tr. 1325-31).

650. Dr. Eastham testified that studies of disease prevention should involve 10,000 to 30,000 men and that such studies are “incredibly expensive” and in the range of $600 million. (Eastham, Tr. 1328).

651. Dr. Eastham testified additionally that animal or *in vitro* studies alone do not provide sufficient scientific evidence to support a claim that a product prevents or treats prostate cancer, even where the agent being tested is nontoxic. (Eastham, Tr. 1284-85).

652. Dr. Eastham has performed over 200 radical prostatectomies per year for a number of years before there were any RCTs showing that they worked. (Eastham Tr. 1331-32; PX0358 (Eastham, Dep. at 154-55)). Dr. Eastham performed these radical operations without RCTs despite the fact that the side-effects of this operation are significant and include impotence, incontinence, bleeding, embolisms, and infection, plus risks of general anesthetic. (Eastham, Tr. 1331-32).

653. Dr. Eastham testified that he has removed hundreds of prostates despite all the above stated risks and without RCT substantiation, yet he would not consider the use of pomegranate juice to treat, prevent or reduce the risk of prostate cancer unless supported by RCTs. (Eastham, Tr. 1332).

d. Dr. Arnold Melman

654. Dr. Melman provided the following opinion regarding the appropriate level of evidence of substantiation: to constitute competent and reliable scientific evidence demonstrating efficacy in preventing, reducing the risk of, or treating erectile dysfunction, experts in the field of erectile dysfunction would require at least one clinical trial, involving several investigatory sites, which is well-designed, randomized, placebo-controlled, and double-blinded. (CX1289 (Melman Expert Report at 0004-05)).

***80** 655. Dr. Melman testified that the only kind of science to support claims that a product helps with erectile dysfunction are two double-blind placebo based randomized trials, conducted in two separate institutions, with a group large enough to produce a statistically significant ($p < 0.05$) result. Dr. Melman testified that you cannot properly make public claims that a product helps with erectile dysfunction in absence of such trials. (Melman, Tr. 1135, 1138-39; CX1289 (Melman Expert Report at 0008-11)).

656. Dr. Melman also testified that the men's sexual partners must also confirm the result; that for a study to claim any improvement in participants, the men must have reached orgasm; and that the sexual partner must achieve sexual satisfaction. (Melman, Tr. 1139-43).

657. Dr. Melman testified that "pomegranate juice is a drug," and therefore the FDA standard for pharmaceutical drugs should apply. (PX0360 (Melman, Dep. at 17-19); Melman, Tr. 1141).

658. Dr. Melman conceded that he has never conducted any clinical work on a food product, including pomegranates. (Melman, Tr. 1164-65).

659. Dr. Melman is developing a gene-transfer therapy for erectile dysfunction called hMaxi-K which is injected into the penis. (Melman, Tr. 1148, 1192). Dr. Melman announced to the public, in an interview with the *New York Observer*, that his hMaxi-K produced spontaneous normal erections in men suffering from erectile dysfunction. (Melman, Tr. 1154). Dr. Melman acknowledged that people have died or gotten very sick from gene-transfer therapy. (Melman, Tr. 1158).

660. While Dr. Melman testified that Respondents must have at least one clinical trial, involving several investigatory sites, which is well-designed, randomized, placebo-controlled, and double-blinded before they can publicize the positive effects of pomegranate juice on men with erectile dysfunction, Dr. Melman publicized preliminary results of studies on his gene-transfer therapy based only on the results of an animal study. (Melman, Tr. 1149-55).

4. Testimony from Respondents' experts on whether RCTs are required

a. Dr. Denis Miller

661. Dr. Miller provided the following opinion regarding the appropriate level of evidence of substantiation: because pomegranates are a food, an appropriate level of scientific substantiation regarding the health benefit claims of pomegranates should be flexible, and consider several factors (including the risk of harm) with the desirability of getting information to the public, the validity of the science, costs of the science, and the nature of the claim. (PX0206 (Miller Expert Report at 15)).

662. Dr. Miller opined that the standard for substantiating claims for pure foods which are clearly safe need not be as rigorous as that for a new drug or anticancer agent, but should be based on reliable and competent scientific data that confirm its safety, and support a relevant and beneficial effect; and that valid, scientifically conducted basic science could be enough to support a claim, depending on the claim, so long as the product is not claimed to be a substitute for conventional drug therapies or medical care. (PX0206 (Miller Expert Report at 15); Miller, Tr. 2194).

***81** 663. Dr. Miller opined that if the product is a whole food or a derivative of a whole food and it is obviously safe, there should be a cost benefit analysis to determine whether it makes sense to report possible, or probable

benefits of consumption, and to err on the side of giving more information to the public and medical community, so long as the claim does not suggest (by use of absolutes or in other ways) that an individual forgo conventional medical care or treatment based on the consumption of the product and/or suggest that the underlying science is valid. (PX0206 (Miller Expert Report at 7-8)).

664. Dr. Miller opined that retrospective or prospective observational cohort or case-control studies are not feasible to study the benefits of a food and that a double-blind, placebo controlled trial evaluating POM Products as prostate cancer protective agents would take decades and thousands of patients and would have to control for other naturally occurring, dietary antioxidants, anti-inflammatory, and anticancer agents as well as life-style activities (*e.g.*, exercise, smoking, alcohol use), genetic predisposition, racial and ethnic factors, benign prostatic hypertrophy, and other factors that might have an effect on carcinogenesis of prostate cancer. (PX0206 (Miller Expert Report at 0014)).

665. Dr. Miller opined that the claim being made about a product is relevant to the level of substantiation required. (Miller, Tr. 2195, 2210).

666. Dr. Miller opined that even if a food were marketed for the treatment or prevention of a disease, the level needed to substantiate claims about a food is more relaxed or less rigorous than it would be for a drug because with a drug, one would have to consider the safety of the agent, the efficacy of the agent, and the risk-benefit ratio. (Miller, Tr. 2210-11).

667. Dr. Miller testified that if one were claiming a fruit juice prevents prostate cancer, and there was reliable scientific data to support that claim, one could make that claim without an RCT. (Miller, Tr. 2201).

668. Dr. Miller testified that you do not need to go through the process of clinical testing and randomized clinical trials to establish the safety and efficacy of a food when there is already reliable scientific evidence supporting that. (Miller, Tr. 2205-06).

669. Dr. Miller opined that if a dietary supplement is derived from a pure food it should require the same level of substantiation as a food. In the alternative, if a dietary supplement is "a mixture of fifty different minerals and elements and vitamins," then it is different than a food and would require a different level of substantiation. (Miller, Tr. 2213).

670. Dr. Miller testified that because a food is not patentable, it is not reasonable to require the maker of a potentially beneficial foodstuff to conduct a prohibitively expensive RCT to claim that it is beneficial to health. (PX0206 (Miller Expert Report at 16)).

b. Dr. David Heber

***82** 671. Dr. Heber provided the following opinions regarding the appropriate level of evidence of substantiation: (1) double-blind placebo-controlled trials have limited usefulness for nutritional research; (2) the nutritional complexity of pomegranate juice and extract makes controlled studies less suitable for researching the health benefits of pomegranate juice and extract; (3) prospective randomized controlled trials demand that a nutrient act like a drug and that is an unreasonable requirement for nutritional studies because nutrients occur in a food matrix; and (4) the prospective randomized trial cannot practically be imposed as a requirement for nutritional science. (PX0192 (Heber Expert Report at 0013-16)).

672. Dr. Heber testified that most experts in the field of nutrition consider competent and reliable science to support health claims for pomegranate juice based upon the totality of evidence, which does not necessarily include RCTs. (Heber, Tr. 2166, 2182).

673. Dr. Heber testified that in dealing with nutrients, RCTs are often infeasible and too expensive; that the drug standard should not be applied to nutrients; and that most experts in the field of nutrition believe that RCTs have some significant drawbacks when it comes to the study of nutrient substances like pomegranates. (Heber, Tr. 1948-50).

c. Dr. Dean Ornish

674. Dr. Ornish provided the following opinion regarding the appropriate level of evidence of substantiation: it is important to carefully examine the totality of scientific evidence in determining whether or not pomegranate juice in its various forms is beneficial and that in a nutritional context, *in vitro* and animal studies may be more effective in testing the efficacy of a nutrient. (PX0025 (Ornish Expert Report at 0005); Ornish, Tr. 2327-31).

675. Dr. Ornish testified that new drugs, which always have toxicities and side effects, need to be held to a higher standard than a juice that is derived from a fruit that has been around for thousands of years. (Ornish, Tr. 2324-25, 2340, 2381).

676. Dr. Ornish testified that if a fruit or beverage is held to the standard required of drugs, no one would be able to meet that standard. No manufacturer would spend billions of dollars to test a fruit unless it is a drug like Lipitor, where one could make billions of dollars a year and it would be worthwhile to make such an investment. (Ornish, Tr. 2324-25).

677. Dr. Ornish opined that there is a world of difference between offering juice as a healthy lifestyle choice or as an *adjunct* to conventional treatments versus offering it as a replacement for conventional medical care. (PX0025 (Ornish Expert Report at 0008)).

678. Dr. Ornish also opined that "it is an extreme position to state that the therapeutic efficacy of a fruit juice or extract of pomegranate juice should be held to the same standard of evidence as a new drug." Dr. Ornish further opined that the study of pomegranates or pomegranate juice is different than studying a new drug, in which harmful side-effects, both short-term and long-term, are the rule rather than the exception. (PX0025 (Ornish Expert Report at 0008)).

***83** 679. Dr. Ornish opined that RCTs, even when conducted perfectly, do not control for all sources of bias and may inject new ones unique to RCTs. For example, in studying a fruit or food, it is hard to do double-blind, randomized, placebo-controlled trials. Once a participant is assigned to the control group, and they know what the intervention is, they can consume the food or juice anyway, whereas one would not be able to do so with an experimental drug. (PX0025 (Ornish Expert Report at 0008); Ornish, Tr. 2328-29, 2356).

680. Dr. Ornish also testified that RCTs have shown that angioplasties and stents do not prevent heart attacks or prolong life, yet the number of these procedures performed is greater than ever. (PX0025 (Ornish Expert Report at 0007); Ornish, Tr. 2380-81).

681. Dr. Ornish opined that while there are limitations to extrapolating from *in vitro* and animal studies to human studies, it is false to say this research has no value in determining therapeutic efficacy. (PX0025 (Ornish Expert Report at 0007)).

d. Dr. Jean deKernion

682. Dr. deKernion provided the following opinion regarding the appropriate level of evidence of substantiation: if you have a drug with toxicities, it is extremely important to have a test with a placebo group, because it gives one a valid measure of the toxicity of the drug. But in the case of something like fruit juice, that has low or no toxicity at all, is it not necessary to use an RCT or placebo-controlled kind of test. (deKernion, Tr. 3060).

e. Dr. Arthur Burnett

683. Dr. Burnett provided the following opinion regarding the appropriate level of evidence of substantiation: (1) because pomegranate juice is a harmless fruit product that creates no material risk of harm and assuming that drinking pomegranate juice is not advocated as an alternative to following medical advice, information of pomegranate juice's likely benefit may be communicated to consumers; and (2) studies such as double blinded, placebo-based tests are not required before permitting this information to be given to the public. (Burnett, Tr. 2272-74; PX0149 (Burnett Expert Report at 0006-07)).

684. Dr. Burnett testified that the standard of substantiation is different for a product that is directly associated as a treatment for erectile dysfunction and for a product that claims to have helpful benefits for or improves one's erectile function. (Burnett, Tr. 2260-62, 2303).

f. Dr. Irwin Goldstein

685. Dr. Goldstein provided the following opinion regarding the appropriate level of evidence of substantiation: health care practitioners who treat patients concerned with erectile health would not hold pomegranate juice to the standards of safety and efficacy traditionally required by the FDA for approval of a pharmaceutical (including performance of large, double-blind, placebo-controlled pivotal clinical trials) before recommending pomegranate juice to their patients. (PX0189 (Goldstein Expert Report at 0003, 0014)).

***84** 686. Dr. Goldstein testified that when studying pomegranate juice and its effect on erectile function, RCT studies are not necessary because the safety of natural fruit juice is not questionable. Furthermore, Dr. Goldstein questioned whether one could make a placebo pomegranate juice. By contrast, Dr. Goldstein testified that RCTs are needed for pharmaceutical drugs, which are unnatural and developed in laboratories, to assess safety and efficacy. (Goldstein, Tr. 2599-01, 2619).

687. Dr. Goldstein testified that an article he co-authored stated that RCTs are considered the criterion standard for determining causality, but that that article was written in the context of the pharmaceutical industry and pharmaceutical drugs like Viagra, Levitra and Cialis that have been studied with randomized clinical trials for determination of their safety and efficacy. Dr. Goldstein further testified that it would be ideal if there could be randomized clinical control data for nutraceuticals, but that in reality, that is not going to happen or it is not possible. (Goldstein, Tr. 2613-14).

5. Determinations on the required level of substantiation

a. Type of claims

688. The level of scientific evidence required to support a claim depends on the claim being made. (Stampfer, Tr. 830-31; Miller, Tr. 2195, 2210).

689. Claims of efficacy can be made only when a causal relation with human disease is established. (CX1293 (Stampfer Expert Report at 0030)).

690. A claim that users of a product have a lower incidence of disease is not the same thing as a claim that use of the product caused them to have a lower incidence of disease. (Stampfer, Tr. 798).

691. A claim that studies indicate that a product lowers the risk of heart disease and diabetes does not imply that a causal link is established, *i.e.*, that the product caused users to have lower risk of heart disease and diabetes. (Stampfer, Tr. 817).

692. If the claim does not imply a causal link, for example, if the claim is that there is some evidence to suggest the possibility that nuts may reduce the risk of diabetes, then evidence short of RCTs can support that claim. (Stampfer, Tr. 830-31; CX1293 (Stampfer Expert Report at 0029-30)).

693. If the claim does not suggest (by use of absolutes or in other ways) that an individual should forgo conventional medical care or treatment based on the consumption of a safe product, one can relax the requirement for an RCT. (Miller, Tr. 2201-02; PX0206 (Miller Expert Report 7-8)).

b. Type of product

694. The level of scientific evidence required to support a claim depends on the product being promoted. (Miller, Tr. 2196, 2198; PX0206 (Miller Expert Report at 8)).

695. The potential risk of the product must be weighed against the potential benefit and harm of keeping information from the public. (Sacks, Tr. 1559; PX0361 (Sacks, Dep. at 137)). In recommending a food or drug, you have to take into account the risk of harm from the product. (Stampfer, Tr. 829).

***85** 696. RCTs are needed for pharmaceutical drugs to assess safety and efficacy because pharmaceutical drugs are unnatural, developed in laboratories, and have toxicities. (Goldstein, Tr. 2600-01, 2620; deKernion, Tr. 3060).

697. Pharmaceutical drugs, which are not known to be safe and always have toxicities and side effects, are held to a higher standard than a juice that is derived from a fruit that has been around for thousands of years. (Ornish, Tr. 2324-25, 2340, 2381; PX0025 (Ornish Expert Report at 0008); Goldstein, Tr. 2600-01, 2620; deKernion, Tr. 3060).

698. The standard applied to new drugs should not be applied to nutrients as long as the product is not claimed to be a substitute for conventional drug therapies or medical care. (PX0206 (Miller Expert Report at 15); Miller, Tr. 2194; Heber, Tr. 1948-50; PX0025 (Ornish Expert Report at 0008)).

699. Pomegranate juice is a natural fruit product with health promoting characteristics. The safety of pomegranate juice is not in doubt. (Miller, Tr. 2194, 2201; PX0206 (Miller Expert Report at 10); Heber, Tr. 1948-50; PX0025 (Ornish Expert Report at 0007)).

c. Feasibility of RCTs

700. RCTs can be beneficial, but they are not perfect and, when dealing with nutrition, they have their own set of limitations as well. (Ornish, Tr. 2329).

701. In a nutritional context, a hypothesis about disease causation can rarely, if ever, be directly tested in humans using the RCT design. (Stampfer, Tr. 832-33; PX0362 (Stampfer, Dep. at 73, 98); CX1293 (Stampfer Expert Report at 0029-30); PX0361 (Sacks, Dep. at 111, 137); PX0192 (Heber Expert Report at 0009-12)).

702. In studying a drug, RCTs are possible because placebos can be used and subjects, therefore, do not know if they are getting a drug or not. (Ornish, Tr. 2328).

703. In studying a fruit or food, it is difficult to do double-blind, randomized, placebo-controlled trials because the subjects know what they are consuming. Once a participant is assigned to the control group, and they know what the intervention is, the participant can consume the food or juice anyway, whereas one would not be able to do so with an experimental drug. (PX0025 (Ornish Expert Report at 0008); Ornish, Tr. 2328-29, 2356; Goldstein, Tr. 2600-01, 2620).

704. In a nutritional context, RCTs are extremely expensive and often not feasible because of the costs of conducting them. (Sacks, Tr. 1559-61; Stampfer, Tr. 810, 813-14; Heber, Tr. 1948-50; PX0192 (Heber Expert Report at 0013-16); Goldstein, Tr. 2613-14; (Eastham, Tr. 1328) (the standard studies for chemoprevention should involve 10,000 to 30,000 and are “incredibly expensive,” costing in the range of $600 million)).

705. Because a food, unlike a pharmaceutical drug, is not patentable, it is not reasonable to require the maker of a potentially beneficial foodstuff to conduct an RCT to claim that it is beneficial to health. (PX0206 (Miller Expert Report at 16)). No manufacturer would spend billions of dollars to test a fruit unless it is a drug where one could make billions of dollars a year and was worthwhile to make such an investment. (Ornish, Tr. 2324-25).

d. Conditions where RCTs are necessary

***86** 706. RCTs are needed for a nutrient supplement if one makes a claim that the product causes the effect of treating, preventing, or reducing the risk of a disease and offers the nutrient supplement as a replacement to medical care to prevent, treat or reduce the risk of disease. (PX0206 (Miller Expert Report at 15); Miller, Tr. 2194; PX0025 (Ornish Expert Report at 0008); *see also* CX1293 (Stampfer Expert Report at 0029); Stampfer, Tr. 830-31).

707. RCTs are not required to convey information about a food or nutrient supplement where: the safety of the product is known; the product creates no material risk of harm; and the product is not being advocated as an alternative to following medical advice. (PX0149 (Burnett Expert Report at 0006-07); deKernion, Tr. 3060; Goldstein, Tr. 2600-01, 2620; PX0025 (Ornish Expert Report at 0008)).

e. Necessary substantiation

708. If a dietary supplement is derived from a pure food, it should require the same level of substantiation as a food. By contrast, if a dietary supplement is “a mixture of fifty different minerals and elements and vitamins,” then it is different than a food and requires a different level of substantiation. (Miller, Tr. 2213).

709. Because pomegranate juice is a food, the appropriate level of scientific substantiation regarding health benefit claims of pomegranate juice in its various forms should be flexible, and consider several factors, including the risk of harm, the validity of the science, costs of the science, and the nature of the claim, including whether it is offered as a substitute or replacement for a conventional therapy. (Miller, Tr. at 2201; PX0206 (Miller Expert Report at 11, 15). *See also* PX0025 (Ornish Expert Report at 0005); Ornish, Tr. 2329-31).

G. Substantiation for Respondents' Heart Disease Claims

1. Substantiation standard for heart disease claims

710. Experts in the field of cardiovascular health would not require RCTs to substantiate health benefit claims for harmless pure fruit products like pomegranate juice. (Ornish, Tr. 2327-30; *see also* Miller, Tr. 2194, 2201; *but see* Sacks, Tr. 1545-48) (testifying that RCT trials are not necessary to test the benefit of food categories that are included in a diet that has already been tested, like the DASH diet; that pomegranates are in the fruit category and, thus, do not need to be tested with RCTs; but that pomegranate juice is different from pomegranates and thus held to a higher standard).

711. Experts in the field of cardiovascular health would require that a product be scientifically evaluated through rigorous scientific and clinical studies, which does not necessarily include RCTs, to make claims that the product can treat, prevent or reduce the risk of heart disease. (Heber, Tr. 1948-49, 2058, 2085, 2166, 2182 (food products must be evaluated on the totality of the scientific evidence that is competently performed, which includes *in vitro* animal studies and human studies, along with basic science about nutritional uptake on metabolism). *But see* Sacks CX1291 (Sacks Expert Report at 0010) (requiring "well-designed, well-conducted, randomized, double-blinded, controlled human clinical studies" with strong "*p*" values)).

***87** 712. To substantiate a claim that a food or a diet supplement can treat heart disease, one needs appropriately analyzed data showing significant changes in valid surrogate markers of cardiovascular health and the study subjects must have established cardiovascular disease ("CVD") or coronary heart disease ("CHD"). To substantiate a claim that a food or a diet supplement can prevent or reduce the risk of heart disease, the study subjects may be persons with *or* without CVD or CHD. (*See* CX1291 (Sacks Expert Report at 0010-11 (also stating requirement of RCTs)).

713. The same level of evidence stated in F. 711-712 is needed to show that clinical studies, research, or trials prove that a product treats heart disease. (*See* CX1291 (Sacks Expert Report at 0011).

714. There must be a sufficient number and diversity of subjects tested in a study to conclude that the measured effect of a product on heart disease can be generalized to a larger population. The study also must be of sufficient duration to show that the effect will last. (CX1291 (Sacks Expert Report at 0014)).

2. Overview of cardiovascular disease

715. A heart attack occurs when there is a sudden rupture of inflamed plaque which covers about 50 percent of the inner surface (lumen) of a coronary vessel. (Heber, Tr. 1959).

716. Plaque is the end result of decades of damage to the blood vessel, which begins with oxidation. The process of plaque formation begins when a protein called low-density lipoprotein ("LDL") or so-called "bad cholesterol," which circulates through the blood, becomes oxidized. (Heber, Tr. 1959).

717. When the LDL cholesterol gets oxidized, the chemical nature of the protein changes, causing the protein to reside and deposit in the wall of the blood vessel, where it accumulates. (Heber, Tr. 1959; CX1358 (Aviram, Dep. at 5)).

718. Regular cholesterol passes in and out of the arteries, but the oxidized cholesterol remains there. (Heber, Tr. 1959-60).

719. Macrophages (white blood cells that respond to inflammation by digesting cellular debris) come in and they eat up this oxidized cholesterol. (Heber, Tr. 1960).

720. Macrophages have ravenous appetites which do not stop, and they continue to accumulate until they become what are called foam cells, which are full of cholesterol and actually burst into the area, bringing in more cells and more inflammation. (Heber, Tr. 1960).

721. Oxidation is followed by inflammation, which is followed by damage to the interior of the blood vessel. This damage is detected as yellow streaks in the coronary arteries. As this process progresses, plaque forms and begins to fill those lumen. (Heber, Tr. 1960).

722. Plaque can have different characteristics; it can be stable or unstable. Unstable plaque is full of oxidized cholesterol and macrophages, reft with inflammation. (Heber, Tr. 1960).

723. By blocking inflammation and oxidation, it is possible to stabilize plaque. (Heber, Tr. 1960; PX0192 (Heber Expert Report at 0033)).

***88** 724. Inhibitors of the oxidation process are called antioxidants. (CX1358 (Aviram, Dep. at 5)). Punicalagin, an ellagitannin, is the most abundant polyphenol that accounts for more than 50% of the antioxidant activity. (PX0025 (Ornish Expert Report at 0008)).

725. Several studies have indicated that pomegranate juice has antioxidant and anti-atherosclerotic properties due to the presence of multiple polyphenols such as tannins, flavonols, anthocyanins and ellagic acid. (PX0025 (Ornish Expert Report at 0008)).

726. Antioxidants are well known to enhance the biological actions of nitric oxide ("NO") by virtue of their capacity to improve endothelial NO synthase ("eNOS"). (PX0055 at 0002; PX0056).

727. Antioxidants are well known to increase and prolong cellular concentrations of NO by protecting it from oxidation. Antioxidants accomplish this task by neutralizing free radicals. (PX0055 at 0002; PX0056 at 0002; PX0057; PX0059 at 0001, 0004; PX0190 at 0006).

728. The negative effects on NO caused by shear stress (the force of friction caused by perturbed blood flow around atherosclerosis) and on the expression of oxidation-sensitive genes can be mitigated by antioxidants. (PX0055 at 0002; PX0056).

729. Dr. Louis Ignarro demonstrated that POM Juice and POMx were able to attenuate the effects of perturbed shear stress and atherogenisis. However, POMx was significantly more effective at enhancing the expression of endothelial nitric oxide synthase (eNOS — an enzyme necessary for cellular NO production), decreasing oxygen-sensitive gene expression, and reducing lesion size. (PX0056).

730. Antioxidants enhance the bioavailability of NO. (Heber, Tr. 1816; CX0908 at 0001, 0002; PX0058).

731. NO helps maintain healthy blood vessels, which improves blood flow to almost every organ in the body, including the heart. (Heber, Tr. 1816, 1969).

3. Respondents' basic science studies

732. Respondents have sponsored many published studies in cellular and animal models evaluating the effects of pomegranate juice and/or its extracts on cardiovascular function. (PX0007; PX0008; PX0010; PX0015; CX0543; PX0017; PX0022; PX0055; PX0056, PX0057; PX0058; PX0059; CX0053).

a. Dr. Aviram's *in vitro* and *in vivo* studies

733. The earliest heart studies on pomegranate juice were carried out by Dr. Aviram at the Technion Institute in Israel. (Heber, Tr. 1957).

734. Dr. Aviram is a professor and head of the Lipid Research Laboratory at the Technion Faculty of Medicine, Rappaport Institute for Research in the Medical Sciences and Rambam Medical Center, in Haifa, Israel. (CX1116 at 0001).

735. Dr. Aviram is considered an internationally renowned researcher, pioneer, and one the leading experts in the world on cholesterol, lipid oxidation and the protective role of dietary antioxidants related to cardiovascular disease. (Heber, Tr. 1957-58).

736. Dr. Frank Sacks, Complaint Counsel's expert on cardiovascular health, acknowledges that Dr. Aviram's basic science is good and that Technion is a good research institution. (Sacks, Tr. 1571).

***89** 737. For the last 30 years, Dr. Aviram's major research focus has been on dietary antioxidants and antioxidants in general, especially their role in cardiovascular disease. (CX1358 (Aviram, Dep. at 5)).

738. Before studying pomegranates, Dr. Aviram examined a number of antioxidants from plants, including lycopene from tomatoes, green tea, citrus fruits, and red wine. (Heber, Tr. 1958).

739. Dr. Aviram published a red-wine study, which explained partially the “French paradox,” that people in France, even though they eat fatty foods like people in Finland, they do not get heart attacks in France compared to Finland. It was shown epidemiologically that it has to do with drinking red wine, because red wine contains antioxidants from the skin of the grape. (CX1358 (Aviram, Dep. at 5)).

740. Dr. Aviram was approached by POM and asked to do the same type of study that he did for red wine, and other fruits and vegetables, but now for pomegranates. (CX1358 (Aviram, Dep. at 6)).

741. After a year of studying in 1998 or 1999, Dr. Aviram concluded that pomegranate juice had greater antioxidant potencies than red wine. (CX1358 (Aviram, Dep. at 6)).

742. High-density lipoprotein cholesterol (“HDL” or so-called “good cholesterol”) contains an antioxidant enzyme, called “paraoxonase” or “PON1” which acts to protect the body against oxygen radicals. (Heber, Tr. 1961).

743. Dr. Aviram found that pomegranate juice benefits the activity of paraoxonase or PON1 by increasing its binding to HDL cholesterol. (Heber, Tr. 1961).

744. Beginning in 2000 and continuing until as recently as 2010, Dr. Aviram's *in vitro* and *in vivo* research on pomegranate juice and/or POMx pills showed reduction in oxidation of LDL cholesterol; lessening the uptake of oxidized and native LDL cholesterol by macrophage foam cells; diminishing the size of atherosclerotic lesions and foam cells; inhibition of macrophage cholesterol biosynthesis; decrease in macrophage oxidative stress; protection against cellular lipid peroxidation; reduction of serum lipids and glucose levels; improvement of PON1; and lessening of platelet aggregation. (PX0007; PX0008; PX0010; PX0015; CX0543; PX0017; PX0022; CX0053).

745. Dr. Sacks acknowledges that some of Respondents' *in vitro* studies have shown pomegranate juice's favorable effects on the mechanisms involved in cardiovascular disease and that *in vitro* studies, like Dr. Aviram's, can be competent and reliable evidence of an agent's effect on a particular mechanism. (Sacks, Tr. 1578).

746. Dr. Sacks agrees that Dr. Aviram's *in vitro* studies showed that pomegranate juice inhibits macrophage uptake of oxidized LDL, which is one component of atherosclerosis, and a significant reduction in atherosclerotic vessels, but that changes in macrophage levels are not a reliable surrogate marker of heart health. (Sacks, Tr. 1572, 1579, 1622).

b. *In vitro* and *in vivo* studies on nitric oxide

***90** 747. Respondents have also sponsored research in the area of nitric oxide and understanding its role in cardiovascular health. (PX0055; PX0056; PX0057; PX0058; PX0059).

748. Respondents have sponsored *in vitro* and *in vivo* research by Dr. deNigris, Dr. Napoli, and, Dr. Ignarro to conduct basic research on the effects of pomegranate juice on nitric oxide in the human body. (PX0055; PX0056; PX0057; PX0058; PX0059).

749. Nitric oxide is produced by the cells lining the heart blood vessels and by the cells lining the blood vessels of many organs around the body. Nitric oxide opens up tiny blood vessels and helps, among other things, preserve blood flow to the heart. (Heber, Tr. 1966-68).

750. Nitric oxide is beneficial in that it improves blood flow to almost every organ in the body that is dependent upon blood flow. (Heber, Tr. 1969-70).

751. In their *in vitro* and *in vivo* studies, Dr. deNigris, Dr. Napoli, Dr. Ignarro, and others found that pomegranate juice and/or POMx pills demonstrated: increasing and preserving levels of nitric oxide and decreasing expression of genes associated with stress and progression of atherosclerosis; reducing LDL oxidation, size of atherosclerotic plaques, and formation of foam cells; reversing effects of shear stress, which can damage the endothelial cells or thin layer of cells that line the interior of blood vessels; decreasing cellular production and release of oxygen radicals in the vascular wall; inhibiting activation of oxidation-sensitive genes; and improving biological activity of nitric oxide. (PX0055; PX0056; PX0057; PX0058; PX0059).

c. Experts' analysis on Respondents' basic research

752. Complaint Counsel's expert witness, Dr. Sacks, opined the following regarding Respondents' basic research:

• *in vitro* studies do not provide reliable scientific evidence of what effects a treatment will have inside the human body;

• animal studies cannot be generalized to describe what effects a treatment has on human subjects and, thus, do not provide reliable scientific evidence on whether an agent can treat, prevent or reduce the risk of cardiovascular disease in humans;

• *in vitro* and animal studies need to be replicated in humans to show an effect on preventing or treating a disease; and

• there is value in conducting *in vitro* and animal studies because it is possible to isolate mechanisms of action and accomplish toxicity or safety testing.

(CX1291 (Sacks Expert Report at 0015-16); PX0361 (Sacks, Dep. at 91)).

753. Respondents' expert witness, Dr. Ornish, opined the following regarding Respondents' basic research:
• *in vitro* and animal studies are important in considering the totality of evidence in determining whether or not pomegranate juice in its various forms is beneficial; and

• *in vitro* and animal studies have value in determining therapeutic value, but there are limitations to extrapolating from *in vitro* and animal studies to humans.

***91** (PX0025 (Ornish Expert Report at 005, 007)).

d. Determinations on Respondents' basic research

754. Respondents' basic and animal science shows that pomegranate juice and/or its extract may be beneficial toward cardiovascular health by, among other things, reducing the oxidation of LDL cholesterol and its uptake, diminishing the size and scope of atherosclerotic legions, macrophages, and foam cells, lessening platelet aggregation, and enhancing the presence of nitric oxide. (PX0007, PX0008, PX0010, PX0015, CX0543, PX0017, PX0022, CX0053, PX0055, PX0056, PX0057, PX0058, PX0059).

755. The basic research relied upon by Respondents is part of the totality of evidence that must be examined in evaluating the effects of the POM Products, but *in vitro* and animal studies need to be replicated in humans to show an effect on preventing or treating a disease. F. 752-753.

4. Overview of Respondents' clinical trials and surrogate markers in clinical studies on heart disease

756. Respondents have sponsored approximately ten published studies on humans evaluating the effect of pomegranate juice and/or its extracts on cardiovascular health. (PX0004; PX0005; CX0611; PX0014; PX0020; PX0021; PX0023; PX0038; PX0127; PX0139). Two of these published human studies, the Davidson CIMT Study and the Ornish MP Study (discussed below), were designed as RCTs. In addition, Respondents conducted several unpublished human studies on POM Juice and POMx Pills related to cardiovascular health, also discussed below.

757. Respondents worked with Dr. Aviram and two other pre-eminent research scientists in the field of cardiovascular health to evaluate the potential benefits of pomegranate juice and/or its derivatives in humans: Dr. Dean Ornish and Dr. Michael Davidson. (PX0014; PX0023).

758. The qualifications of Dr. Ornish, who also testified as an expert for Respondents, are set forth in F. 227-230.

759. Dr. Davidson is the Clinical Professor of Medicine and Director of Preventive Cardiology at the University of Chicago Medical Center, Medical Director of Radiant Research, Chicago, and a practicing physician who typically treats patients with cholesterol abnormalities, coronary artery disease, or clinical atherosclerosis. Dr. Davidson has been involved, in some manner, in over 700 clinical studies over the past 25 years. (JX0003 at 0004; CX1134 at 0001; CX1336 (Davidson, Dep. at 218-21)).

760. Dr. Sacks regards Dr. Davidson as one of the foremost clinical researchers in the cardiovascular field with a superb reputation for top-quality clinical trial research in cardiovascular disease. (Sacks, Tr. 1490).

761. In considering whether a study shows a benefit to cardiovascular disease, it is important to look at what endpoints have been measured. There are two kinds of endpoints: direct endpoints and surrogate markers. (CX1291 (Sacks Expert Report at 0013)).

762. In the case of heart disease, direct endpoints are heart attack, unstable angina, or the need for coronary artery bypass or angioplasty. Surrogate markers are measurements that are closely linked to the disease process such that a change in a surrogate marker can confidently be predictive of a change in the disease. (CX1291 (Sacks Expert Report at 0013)).

***92** 763. Blood pressure and LDL cholesterol are recognized as valid surrogate markers of cardiovascular health in clinical guidelines and by the FDA. (Ornish, Tr. 2334; Sacks, Tr. 1441; CX1291 (Sacks Expert Report at 0013)).

764. LDL cholesterol is a risk factor for heart disease, but is not actually heart disease. For that reason, Dr. Ornish testified, LDL cholesterol cannot be a valid surrogate. (Ornish, Tr. 2334). Dr. Heber further explained, when a person has a biomarker such as high LDL cholesterol which increases his or her risk, it is very distal or far away from the actual event of a heart attack which may be affected by many other factors, such as inflammation and oxidation. (Heber, Tr. 1974). There are a number of people who have low cholesterol levels, but get heart disease. (Ornish, Tr. 2334-35). About 50 percent of the people who die from a heart attack actually have cholesterol in the normal range. (Heber, Tr. 1974). There are people who have high cholesterol levels who do not have heart disease, and the same is true with high blood pressure. (Ornish, Tr. 2334-35).

765. While the FDA, for the purposes of drug registration and testing, only accepts a limited number of surrogate markers, the number of indicators that physicians and scientists use is much greater and indicators can be at many points along the pathway of heart disease. (Heber, Tr. 1973).

766. Most experts (but not all) also recognize C-reactive protein, HDL cholesterol, and triglycerides as valid surrogate markers. (Sacks, Tr. 1441; CX1291 (Sacks Expert Report at 0013)).

767. Carotid intima media thickness, or “CIMT,” testing measures the combination of the vessel muscle and atherosclerosis (arterial plaque). There is a moderate connection between a reduction in the intima-media thickness and a reduction in atherosclerosis. (CX1291 (Sacks Expert Report at 0013); Sacks, Tr. 1442-43)).

768. Dr. Sacks acknowledged that the CIMT test is "a worthy test" and is relevant to cardiovascular health, but noted there is disagreement among experts on the prognostic value of CIMT. (Sacks, Tr. 1589-90; CX1291 (Sacks Expert Report at 0013)).

769. Dr. Sacks opined that if CIMT measures show consistent improvement, this would be an indicator that a treatment may be beneficial, but that he would be reluctant to rely on CIMT improvements alone, if these were the only evidence that an intervention treated heart disease. Dr. Sacks referenced a recent article in a leading cardiology journal that analyzed CIMT in relation to cardiovascular events and found that among a metaanalysis of 41 randomized trials, "there was no significant relationship between IMT regression and CHD [coronary heart disease] ... events ... CBV [cerebrovascular] events ... and for all-cause death." From this, Dr. Sacks opined, there is broad consensus that at least two types of imaging studies must be obtained to make inferences on benefit to cardiovascular disease. (CX1291 (Sacks Expert Report at 0014)).

***93** 770. Myocardial perfusion (MP) is a measure of blood flow to the heart. Dr. Sacks opined that change in MP is not recognized as a surrogate marker of therapeutic effects on CHD. Even where blood flow is shown to be improved, it will not necessarily result in improved cardiovascular health, such as reductions in heart attack and stroke. (CX1291 (Sacks Expert Report at 0020-21)).

771. Dr. Ornish opined that when researchers measure myocardial perfusion, researchers are actually measuring what matters most. How much blood flow the heart receives is really the "bottom line" in coronary heart disease. (PX0025 (Ornish Expert Report at 0012); Ornish, Tr. 2334-35).

5. Cardiovascular studies sponsored by Respondents

a. Aviram 2000 Study

772. In 2000, in a study titled, "*Pomegranate juice consumption reduces oxidative stress, atherogenic modifications to LDL, and platelet aggregation: studies in humans and in atherosclerotic apolipoprotein E-deficient mice*" by Aviram M, Dornfeld L, Rosenblat M, Volkova N, Kaplan M, Coleman R, Hayek T, Presser D, and Fuhrman B (Am. J. Clin. Nutr. 2000: 71;1062-76), ("Aviram 2000 Study"), Dr. Aviram and his colleagues examined the effect of pomegranate juice consumption on the atherogensis process (the development of fatty plaques in the walls of arteries) in humans, animal models, and cells.

773. The Aviram 2000 Study consisted of two human studies: one involving 13 subjects who consumed pomegranate juice daily for two weeks; and one involving 3 subjects who consumed increasing doses for 10 weeks. The authors concluded that the study "showed the antiatherogenic capabilities of PJ [pomegranate juice] in 3 related components of atherosclerosis, plasma lipoproteins, arterial macrophages, and blood platelets. The potent antioxidative capacity of PJ against lipid peroxidation may be the central link for the antiatherogenic effects of PJ on lipoproteins, macrophages, and platelets." (PX0004 at 0001-02, 0004-05, 0014).

b. Aviram ACE/BP Study

i. About the Aviram ACE/BP Study

774. In 2001, in a study titled, "*Pomegranate juice consumption inhibits serum angiotensin converting enzyme activity and reduces systolic blood pressure*" by Aviram M and Dornfeld L, (Atherosclerosis 158 (2001) 195-198) ("Aviram ACE/BP Study"), Dr. Aviram and his co-workers conducted a study with ten elderly, hypertensive

patients who drank 50 ml. of pomegranate concentrate daily, for two weeks. (CX0542 at 0002; CX1358 (Aviram, Dep. at 21)).

775. The Aviram ACE/BP Study measured angiotensin converting enzyme ("ACE") activity and blood pressure. (CX0542 at 0001). ACE is an enzyme that alters the function of angiotensin, which relates to blood pressure for each patient. (Stampfer, Tr. 742).

776. The Aviram ACE/BP Study was unblinded and had no control group; instead, each patient's "before" measures were compared to his or her "after" measures. (CX1358 (Aviram, Dep. at 22-24); CX0025 at 0012).

***94** 777. According to the Aviram ACE/BP Study, seven of the ten patients experienced a statistically significant 36% reduction in serum ACE activity from their baseline measure. (CX0542 at 0001). The article does not reveal what happened to the ACE levels of the other three patients or analyze the overall results in all ten patients. (CX1291 (Sacks Expert Report at 0016-17); CX0542 at 0002-03; *see also* Stampfer, Tr. 741-42; CX1293 (Stampfer Expert Report at 0017-18)). Dr. Aviram testified that there was "no effect" from pomegranate juice on the other three patients' ACE levels. (CX1358 (Aviram, Dep. at 23)).

778. The Aviram ACE/BP Study reports that all ten patients experienced a statistically significant 5% reduction in systolic blood pressure from their baseline blood pressure measure. (CX0542 at 0002-03; CX1291 (Sacks Expert Report at 0016-17)).

779. The Aviram ACE/BP Study concludes that, "pomegranate juice consumption can offer a wide protection against cardiovascular disease." (CX0542 at 0003).

ii. Experts' analysis on the Aviram ACE/BP Study

780. Complaint Counsel's experts criticized the Aviram ACE/BP Study on the following grounds:
• the sample size of ten patients is too small to provide reliable evidence that the observed effects would be generally applicable to a larger population

• the two-week period of the study was too short to provide reliable evidence that the reported improvement in ACE activity and blood pressure would be enduring; and

• ACE (one of the study endpoints) is not a recognized surrogate marker of cardiovascular disease.

(CX1291 (Sacks Expert Report at 0017); *see also* Stampfer, Tr. 748).

781. Complaint Counsel's experts also testified that although blood pressure reduction is a validated surrogate for heart disease, the Aviram ACE/BP Study does not provide competent and reliable evidence to support a claim of effectiveness for heart disease because it was not a blinded, placebo-controlled study. According to these experts, given the lack of a control group, it is not possible to conclude what caused the reported improvements in the subjects' blood pressure levels; and without a control group, this study was simply an observational study on patients given pomegranate juice concentrate. (CX1291 (Sacks Expert Report at 0017); Sacks, Tr. at 1452-54; *see also* Stampfer, Tr. 748, 771; CX1293 (Stampfer Expert Report at 0019)).

782. Dr. Ornish's response to Complaint Counsels' experts' criticism (F. 780-781) is that the Aviram ACE/BP Study should be viewed in the larger context of other studies in this area, as its findings are congruent with, and supportive of, other research. (PX0025 (Ornish Expert Report at 0009)).

783. Dr. Ornish testified that there is a common misconception that a larger study is a better study, but the opposite can be argued. When a study has a smaller number of patients, the treatment has to be that much more powerful and that much more consistent for it to be statistically significant. (Ornish, Tr. 2362-63; CX1339 (Ornish, Dep. at 22-23)).

***95** 784. Dr. Aviram explains that comparing the statistics from each patient after treatment to his or her own statistics before treatment is a valid method to conduct a study. (CX1348 (Aviram, Dep. at 12-13)).

785. A study with a small number of subjects or conducted without a placebo does not weaken the importance of the result, especially if the results are in agreement with previously published findings conducted through *in vitro*, mechanistic, and animal models. (CX1348 (Aviram, Dep. at 18)).

iii. Determination on the Aviram ACE/BP Study

786. The Aviram ACE/BP Study does not provide competent and reliable scientific evidence to support claims that the POM Products treat, prevent or reduce the risk of heart disease. (*See* F. 774-785).

c. Aviram CIMT/BP Study

i. About the Aviram CIMT/BP Study

787. The carotid arteries are located on each side of the neck and provide the main blood supply to the brain. Carotid artery stenosis ("CAS") is a narrowing or constriction of the inner surface (lumen) of the carotid artery, usually caused by atherosclerosis. (JX0003 at 0001).

788. Stenosis occurs when a person has more than a 50 percent blockage in one of the carotid arteries. To remove a blockage in the carotid artery, a person undergoes an operation called an endarterectomy, where the buildup is removed and a graft is placed in the artery. CAS is a risk factor for heart disease. (Heber, Tr. 1963).

789. In 2004, Dr. Aviram and his co-workers investigated, among other things, the effects of pomegranate juice consumption by patients with CAS in a study titled, "*Pomegranate juice consumption for 3 years by patients with carotid artery stenosis reduces common carotid intima-media thickness, blood pressure and LDL oxidation*" by Aviram M, Rosenblat M, Gaitini D, Nitecki S, Hoffman A, Dornfeld L, Volkova N, Presser D, Attias J, Liker H, and Hayek T, (Clin Nutr. 2004; 23:423-33), ("Aviram CIMT/BP Study"). (CX0611).

790. In the Aviram CIMT/BP Study, a group of ten patients with severe CAS consumed 50 ml. of concentrated pomegranate juice daily for one year and five of them continued for up to three years. A second group of nine patients who did not consume pomegranate juice acted as a control. (CX0611 at 0001-02).

791. In the Aviram CIMT/BP Study, in the control group that did not consume pomegranate juice, the patients' carotid intima-media thickness increased by 9% during one year, whereas, pomegranate juice consumption resulted in a significant CIMT reduction, by up to 30%, after one year. (CX0611).

792. In the Aviram CIMT/BP Study, in two out of the ten patients on pomegranate juice (after 3 and 12 months) due to clinical deterioration, carotid endartherectomy surgery was performed. Their carotid lesions were analyzed and compared to lesions obtained from seven patients that did not consume pomegranate juice (not the patients of the placebo group). The cholesterol content in carotid lesions from the two patients that consumed pomegranate juice was lower by 58% and 20%, respectively, in comparison to lesions obtained from CAS patients that did not consume pomegranate juice. The lipid peroxides content in lesions obtained from the patients after pomegranate juice consumption for 3 or 12 months was significantly reduced by 61% or 44%, respectively, as compared to lesions from patients that did not consume pomegranate juice. (PX0025 (Ornish Expert Report at 0011)).

***96** 793. Dr. Ornish testified that the findings in the Aviram CIMT/BP Study suggest that oxidative stress, including oxidation of LDL to a form that makes it more likely to cause arterial blockages and cause foam cell production in macrophages (macrophage-derived foam cells play integral roles in all stages of atherosclerosis) may have been reduced by pomegranate juice consumption in these patients. (PX0025 (Ornish Expert Report at 0011)).

794. The Aviram CIMT/BP Study reports that the pomegranate juice group members' systolic blood pressure was significantly ($p < 0.05$) reduced by 12% after one year of pomegranate juice consumption compared to their baseline values. In the group that did not consume pomegranate juice, blood pressure was unchanged. (CX0611 at 0005).

795. The CIMT and blood pressure changes described in the Aviram CIMT/BP Study are *within-group* analyses. The Study did not provide any *between-group* statistical analysis, that is, analysis of changes in CIMT and blood pressure between the active and control groups at the end of the study. (Sacks, Tr. 1456-57; CX0163 at 0017 (stating that between group analysis was not performed for any of the outcomes)). Dr. Aviram explained that each subject in the study served as his or her own control. (CX1358 (Aviram, Dep. at 27-28, 32)).

796. The Aviram CIMT/BP Study concluded: “pomegranate juice consumption (by patients with carotid artery stenosis) possess anti-atherosclerotic properties, as it substantially decreased serum oxidative stress and, in parallel, reduced common carotid intima-media thickness.” (CX0611 at 0009).

797. The Aviram CIMT/BP Study also concluded that the “results of the present study thus suggest that PJ [pomegranate juice] consumption by patients with CAS decreases carotid IMT and systolic blood pressure and these effects could be related to the potent antioxidant characteristics of PJ polyphenols.” (CX0611 at 0002).

ii. Experts' analysis on the Aviram CIMT/BP Study

798. Dr. Sacks testified that a qualified scientist would not be able to conclude with any credibility that the Aviram CIMT/BP Study's reported improvements in the treatment group were caused by their consumption of pomegranate juice and not some other factor because of: the lack of a randomized, placebo-controlled group; the fact that the patients in the active and control groups received different treatment; the small sample size, and the lack of any between-group statistical analysis. (Sacks, Tr. at 1459, 1585; CX1291 (Sacks Expert Report at 0019)).

799. Dr. Sacks concedes that he has no basis to disagree with Dr. Aviram's numbers. (Sacks, Tr. 1589-90).

800. Dr. Stampfer concluded the Aviram CIMT/BP Study does not support Respondents' heart disease prevention and treatment claims or their lower blood pressure claims. (CX1293 (Stampfer Expert Report at 0018)).

801. Dr. Ornish responds to Complaint Counsels' experts' criticism (F. 798-800) that the Aviram CIMT/BP Study should be viewed in the larger context of other studies in this area, as its findings are congruent with and supportive of other research. (PX0025 (Ornish Expert Report at 0010-11)).

***97** 802. Dr. Ornish agreed that the Aviram CIMT/BP Study was limited in scope and opined: "Thus, while not at all conclusive, the study suggests a benefit." He further testified that the Aviram CIMT/BP Study (2004) was "very provocative and interesting and laid the groundwork for even more conclusive studies." (PX0025 (Ornish Expert Report at 0010-11); PX0355 (Ornish, Dep. at 107)).

803. Dr. Heber also testified that small studies can be more informative than large studies. (Heber, Tr. 1963).

iii. Determination on the Aviram CIMT/BP Study

804. The Aviram CIMT/BP Study does not provide competent and reliable scientific evidence to support claims that the POM Products treat, prevent or reduce the risk of heart disease. (*See* F. 789-803).

d. Ornish MP Study

805. Dr. Dean Ornish and the Preventative Medicine Research Institute ("PMRI") conducted two studies for Respondents: (1) Sumner M, et al., *Effects of Pomegranate Juice Consumption on Myocardial Perfusion in Patients with Coronary Heart Disease*, 96 Am. J. Cardiology 810 (2005) ("Ornish MP Study") (CX1198; *see* JX0003 ¶ B.16); and (2) the Ornish CIMT Study (unpublished, 2005). (CX0754; *see* JX0003 ¶ B.16).

806. These studies (F. 805) were the only studies ever conducted by Dr. Ornish to consider whether a single food product has health benefits. (Ornish, Tr. 2464).

807. The contract setting forth the terms of the two studies conducted by Dr. Ornish (F. 805) was a September 19, 2003, letter agreement between the Resnicks, as Trustees of the Stewart and Linda Resnick Revocable Trust, and Dr. Ornish's organization, PMRI. (CX0613 at 0001). Attached to the letter agreement were protocols for the two studies. Although the Ornish MP Study budget was $708,436, and the CIMT Study budget was $496,390, the funding of these studies was cut short. (Ornish, Tr. 2431-35, 2436, 2441, 2454).

i. About the Ornish MP Study

808. In the Ornish MP Study, Dr. Ornish and his colleagues investigated whether the daily consumption of pomegranate juice for three months would affect myocardial perfusion (or blood flow) in 45 patients who had coronary heart disease and myocardial ischemia (narrowing of the arteries) in a randomized, placebo-controlled, double-blind study. (PX0023 at 0001; Ornish, Tr. 2336).

809. In the Ornish MP Study, patients were randomly assigned into one or two groups: a pomegranate juice group (240 ml./day, approximately 8 ounces) or a placebo group that drank a beverage of similar caloric content, amount, flavor, and color. (PX0023 at 0001-02).

810. The Ornish MP Study provides data on three imaging measures at baseline and three months for myocardial perfusion: the summed rest score, or "SRS" (imaging results before the pharmacologic or exercise challenge), the summed stress score, or "SSS" (imaging results after the pharmacologic or exercise challenge) and the summed

difference score, "SDS" (calculated by subtracting the SRS from the SSS). (CX1198 at 0003 (Table 2); CX1291 (Sacks Expert Report at 0020)).

***98** 811. The Ornish MP Study indicated that after three months there was a significant ($p = 0.05$) improvement of 17% in the SDS score in the POM Juice group, as compared to an average worsening of 18% in the control group. The comparative benefit of the pomegranate juice group to the placebo group in the Ornish MP Study was about 35 percent. (PX0023 at 0001; Ornish, Tr. 2337-38; Heber, Tr. 1972).

812. Those differences (F. 811) were statistically significant and the results were published in the *American Journal of Cardiology*. (PX0023; Ornish, Tr. 2337-39; Heber, Tr. 1971-72).

813. The Ornish MP Study also indicated that there were no statistically significant differences between the two groups in SSS and SRS, and no significant changes in blood pressure, cholesterol, LDL, HDL, or triglycerides. (CX1198 at 0003-04, Table 3 (notation below table); CX1291 (Sacks Expert Report at 0024)).

814. A conclusion of the Ornish MP Study was that "[t]he results of this study demonstrate, for the first time, that daily consumption of pomegranate juice for 3 months may decrease myocardial ischemia and improve myocardial perfusion in patients who have ischemic CHD [coronary heart disease] as measured by the SOS." (PX0023 at 0004).

815. Another conclusion of the Ornish MP Study was that "[a]lthough the sample in this study was relatively small, the strength of the design and the clinically significant and statistically significant improvements in myocardial perfusion observed in the experimental group over a rather short period suggest that daily consumption of pomegranate juice may have important clinical benefits in this population. (PX0023 at 0004).

816. The American Heart Association ("AHA") rejected the Ornish MP Study abstract in August 2004. Dr. Ornish asked the AHA's chairman of scientific sessions to reconsider, but the chairman responded that "[m]ultiple qualified, blinded graders scored this abstract below acceptable range." (CX0672, CX0680).

817. In November 2004, the *Journal of the American Medical Association* ("JAMA") rejected the Ornish MP Study manuscript. In response to Dr. Ornish's request for feedback, the Deputy Editor of JAMA responded that "the study appears very preliminary, with small sample size, apparent baseline imbalances between groups, use of an intermediate endpoint as main outcome measure, and modest differences with large variability." (CX0699 at 0001-02).

818. Dr. Ornish then submitted the Ornish MP Study manuscript to the *American Journal of Cardiology*. The editor accepted it without external peer-reviews. (CX1339 (Ornish, Dep. at 200); CX0715).

ii. Experts' analysis on the Ornish MP Study

819. In trial testimony and in his expert report, Dr. Ornish acknowledged that "some problems" occurred during the Ornish MP Study that were not "optimal." (Ornish, Tr. 2394; PX0025 (Ornish Expert Report at 0016)).

820. In the Ornish MP Study, although 41 patients completed the study, the published report provided data on only 39 patients. Complaint Counsel's experts opined that alterations in the original sample size may be critical when there is a borderline "*p*" value. (CX1291 (Sacks Expert Report at 0022); Sacks Tr. 1478-79; Ornish, Tr. 2394; *see* CX1198 at 0003 (Table 2); CX0664 at 0001).

***99** 821. Dr. Ornish agrees that a mistake was made in the Ornish MP Study in not reporting data on 41 patients, but opined that when data on all 41 patients was analyzed, the difference in SDS remained statistically significant and, therefore, the conclusions of the study remain valid. If anything, according to Dr. Ornish, the results were more statistically significant and even stronger because the sample size was slightly larger. (PX0025 (Ornish Expert Report at 0015); Ornish, Tr. 2347-48; 2394).

822. Dr. Sacks criticized the Ornish MP Study because two subjects in the placebo group did not receive a placebo treatment. They were tested at baseline and three months, with no intervention, and their data was included in the final study results. (Sacks, Tr. 1475-77; CX1339 (Ornish, Dep. at 168-70); CX0580 (patients' names *in camera*)).

823. Dr. Ornish explained that, initially, the two patients had been randomized to the control group in the Ornish MP Study and their measurements taken at baseline. As a result of funding issues, however, the study was put on hold. Three months later, the myocardial perfusion study resumed. Because these patients were already in the control group and their measurements taken at baseline, the decision was made to include them in the control group. Dr. Ornish explained his rationale for doing so as follows: “effectively, having nothing is the same as having a placebo beverage. I think it is probably worth putting in context that in any study there are things that are not optimal because you are dealing with human beings and all the vagaries of that and particularly in a study where the funding was changed midstream .... But the question is whether those things are considered likely to have impacted the validity of the study, including in this case the answer is no.” (CX1339 (Ornish, Dep. at 169-71); PX0025 (Ornish Expert Report at 0016)).

824. Complaint Counsel's experts criticize the Ornish MP Study on the additional ground that that six patients were unblinded before their three-month test dates — meaning the study patients discovered which beverage they were consuming. Dr. Ornish testified that the unblinding of the patients did not undermine the validity of the study or its conclusions. Dr. Ornish further testified that the expectation that an intervention is beneficial has the potential for confounding the outcome of a study, but such an outcome was unlikely to have occurred in this study because at the time that the study was conducted, there was not an awareness in the general population that pomegranate juice was beneficial or even that the subjects were drinking pomegranate juice (the study was titled a “beverage study”). (Ornish, Tr. 2345-46, 2403-09; (CX1339 (Ornish, Dep. at 146-49); PX0025 (Ornish Expert Report at 0016)).

825. Drs. Sacks and Stampfer testified that the Ornish MP Study did not use a recognized surrogate marker of heart disease. (CX1291 (Sacks Expert Report at 0020-21); Sacks, Tr. 1464 (myocardial perfusion, a measure of blood flow, is not used as the primary outcome in studies of treatment efficacy for coronary heart disease); Stampfer, Tr. 771-72 (blood flow is a research tool but not a recognized surrogate marker)). Even where blood flow is shown to have been improved, it will not necessarily result in improved cardiovascular health, such as reductions in heart attack and stroke. (CX1291 (Sacks Expert Report at 0020-21)).

***100** 826. Dr. Sacks also testified that proper blood flow from the coronary artery and to the heart is fundamental to lowering the risk of cardiovascular disease. (Sacks, Tr. 1593).

827. Dr. Ornish opined that blood flow is essential to life, an important measure of heart disease, and the “bottom line” in coronary heart disease (along with how well the heart is pumping blood) and, thus, when researchers measure myocardial perfusion, researchers are actually measuring what matters most. (PX0025 (Ornish Expert Report at 0012); Ornish, Tr. 2331-35).

828. Dr. Ornish further explained: Blood carries oxygen and nutrients that feed the heart. If the blood flow the heart (perfusion) is reduced, then the heart is no longer receiving enough blood flow to maintain itself. Coronary heart disease, which is the most common form of heart disease, occurs when the heart does not get enough blood to fuel itself and blood carries oxygen, which is the fuel for the heart. If the reduction in blood flow is temporary,

then the person often experiences angina, or chest pain. If this reduction in blood to the heart lasts more than a few hours, then that portion of the heart that is underperfused may die and turn in to scar tissue — this is commonly referred to as a "heart attack." (PX0025-0012; Ornish, Tr. 2331-35).

829. Respondents' experts testified that in comparing myocardial perfusion and LDL cholesterol, myocardial perfusion is more closely connected as a surrogate marker for cardiovascular disease. When a person has a biomarker like high LDL cholesterol which increases his or her risk, that is far away from the actual event of a heart attack, which may be affected by many other factors, such as inflammation and oxidation. There are a number of people who have low cholesterol levels, but get heart disease. About 50 percent of the people who die from a heart attack actually have cholesterol in the normal range. There are people who have high cholesterol levels who do not have heart disease, and the same is true for blood pressure. When measuring myocardial perfusion, researchers are actually measuring what matters most, which is how much blood flow the heart is receiving. (Ornish, Tr. 2334-35; Heber, Tr. 1974).

830. Dr. Ornish also opined that the degree of blockage is only one of several mechanisms that affect perfusion, or blood flow to the heart. Other mechanisms include changes in vasomotor tone (how dilated or constricted the coronary arteries are), platelet aggregation (how sticky the platelets are that can form blood clots that may partially or completely occlude the flow of blood to the heart), and collateral blood flow (the heart can grow new blood vessels that provide additional blood flow around partial or even completely blocked arteries if the blockage occurs slowly overtime). (PX0025 (Ornish Expert Report at 0012)).

831. Dr. Sacks testified that another problem with the Ornish MP Study was that the primary endpoint measurement indicated in the published study as the main proof of benefit (SDS) was not identified as the primary endpoint in the protocol. The protocol for the Ornish MP Study provided for measurement of perfusion, but did not identify whether the primary endpoint would be SSS, SRS, SDS or some other imaging measurement. (CX1291 (Sacks Expert Report at 0021); *see also* CX0613 at 0009-10). Dr. Ornish conceded that he did not specify that changes in SDS would be the primary endpoint measure. (PX0025 (Ornish Expert Report at 0014); *see also* Sacks, Tr. 1475).

***101** 832. Dr. Ornish explained in response to Dr. Sacks' criticism (F. 831) that although the Ornish MP Study did not specify that changes in SDS would be the primary endpoint measure, it was not necessary to do so since SDS is a measure of how much of the heart was not receiving enough blood flow. Because SDS is derived by subtracting SRS from SSS, it is a way of factoring out the amount of infarcted or hibernating myocardium, so Dr. Ornish could focus on what he was most interested in: SDS. PX0025 (Ornish Expert Report at 0014)).

833. The 35 percent improvement in myocardial perfusion indicated in the Ornish MP Study pertained only to the SDS scores, and not to the SRS and SSS data. (Sacks, Tr. 1622-24). Dr. Sacks and Dr. Stampfer both stated that the .05 "*p*" value of the reported SDS improvement is not very persuasive where, as here, there were three possible outcome measures (SSS, SRS, and SDS) and only one just met significance. (CX1198 at 0003; Sacks, Tr. 1467 ("when there are ... multiple outcomes ... then a *p*-value of .05 ... doesn't convey the same level of confidence than in a situation where there is one primary outcome"); CX1291 (Sacks Expert Report at 0021-22); Stampfer, Tr. 751 ("[T]he second reason I don't put a lot of weight on this is that the results were only slightly significant just for one of the three endpoints that was not specified as the primary outcome in advance.")).

834. Dr. Ornish testified that while the Ornish MP Study did indicate a statistically significant change in the SDS, Dr. Ornish did not ignore the SSS and SRS measures that were shown in Table 2 of the study. The Ornish MP Study examined all three measurements in an effort to divine the SDS, as the primary hypothesis was that pomegranate juice would result in an improvement in SDS, a measure of the heart not receiving enough blood. (PX0023 at 0003; PX0025 (Ornish Expert Report at 0001); PX0355 (Ornish, Dep. at 128-29; 139)).

835. Complaint Counsel's experts also criticized the Ornish MP Study based on the large discrepancy in the blood flow values between the placebo and active groups at baseline. The baseline SSS for the placebo group was 9.6 ± 6.5, and the baseline SSS of the juice group was 6.4 ± 3.5, meaning that the placebo group was sicker than the juice group when the study started. (CX1198 at 0003 (Table 2); CX1291 (Sacks Expert Report at 0022-23); Sacks, Tr. 1469-72, 77; Stampfer, Tr. 750-52). Study documents from Dr. Ornish's clinic files show that the difference between the baseline SSS values of the placebo and juice groups was so large as to be statistically significant. (CX0701 at 0001 (email from M. Sumner to M. Eller, forwarded to D. Ornish, stating, "[t]here was a baseline difference in SSS between the experimental and the control groups (p <. 04). We don't have to mention this, but we should keep this in mind.")).

836. Complaint Counsel's experts further opined that the imbalance in baseline values in the Ornish MP Study shows that randomization did not produce an active group and a placebo group that were similar on relevant characteristics. (Stampfer, Tr. 751-52; CX1293 (Stampfer Expert Report at 0019); CX1291 (Sacks Expert Report at 0023)). It could be predicted that the control group, having worse coronary perfusion than the POM Juice group at baseline, would have a more accelerated form of the disease and show worsening on follow-up. (CX1291 (Sacks Expert Report at 0022-23); Sacks, Tr.1469-72, 77; *see also* Stampfer, Tr. 751 ("[H]ere, the placebo group was worse off at the start, and it's easy to imagine that if you're worse off at the start, you are going to get worse faster over time. So, the evidence isn't persuasive.")). Dr. Sacks stated that the baseline difference should have been reported in the publication. (Sacks, Tr. 1477; CX1291 (Sacks Expert Report at 0023)).

***102** 837. Dr. Ornish testified that although there was a difference in SSS at baseline, the Ornish MP Study employed an "analysis of variance," which took into account any baseline differences. The Ornish MP Study stated: "To test for the effects of experimental condition and time (and their interaction) on medical characteristics, 2 (experimental vs. placebo) X 2 (baseline vs. 3 months) analyses of variance for repeated measurements were run," which built into the analysis controlling for baseline differences. Further, when researchers recruit randomly and look at a number of different measures, it is not uncommon that one difference may be statistically significant in the group. Even if there had been a difference in SSS at baseline, this would not have undermined the validity of the study, particularly since it was not Dr. Ornish's primary endpoint measure. (Ornish, Tr. 2343-44, 2394; PX0025 (Ornish Expert Report at 0015)).

838. Dr. Sacks criticized the Ornish MP Study on the additional basis that blood pressure, cholesterol, inflammatory biomarkers, and oxidative stress were not improved. (CX1291 (Sacks Expert Report at 0024)).

839. Dr. Ornish himself concluded that "blood pressure ... did not improve" in the Ornish MP Study. (PX0025 (Ornish Expert Report at 17)).

840. Dr. Ornish also explained, the fact that other factors such as blood pressure and cholesterol did not improve in the Ornish MP Study does not in any way provide evidence that pomegranate juice was not beneficial, as its effects may have been mediated via other pathways. (PX0025 (Ornish Expert Report at 0017-18)).

841. Dr. Heber testified that in the Ornish MP Study, even though there was no change in blood pressure, one could not conclude that there was no effect of pomegranate juice on blood pressure, because the primary endpoint was blood flow, not blood pressure. (Heber, Tr. 2101-02).

842. In any clinical study, it is routine to take a blood pressure, pulse, body temperature, among others, to make sure patients are healthy. Although blood pressure is measured in many studies, a specific claim on blood pressure requires a very specific study involving special equipment and personnel. (Heber, Tr. 2101, 2040).

843. Dr. Sacks notes that Dr. Ornish's study originally was designed to last for 12 months, with measurements at baseline, three months, and 12 months, but was halted after three months. Dr. Sacks opined that the study was terminated under unusual circumstances because, according to correspondence, at the time, the *p*-value was considered significant rather than at the time the trial was originally set to end. Dr. Sacks further opined that the shortened study period and failure to report the planned duration is inconsistent with widely-accepted standards for conduct of clinical trials and undermines any confidence in the findings. (CX1291 (Sacks Expert Report at 0023-24); Sacks, Tr. 1474-75).

***103** 844. Dr. Ornish testified that the Ornish MP Study was terminated after three months only because the Resnicks did not provide the funding that they had previously committed to this study, not because the *p*-value was statistically significant at three months. Dr. Ornish further opined that while he did not have 12 months of follow-up data, this does not undermine the confidence in the three-month findings of the Ornish MP Study. (PX0025 (Ornish Expert Report at 0017)).

845. Complaint Counsel's experts concluded: The interpretation of the Ornish MP Study that is most consistent with principles of clinical study design and conduct is that the pomegranate juice treatment had no effect on any measure of cardiac health. (CX1291 (Sacks Expert Report at 0024)). Experts in the field of cardiovascular disease would not consider the Ornish MP Study to support the proposition that pomegranate juice provides a heart disease benefit, either in terms of prevention or treatment. (Sacks, Tr. 1472, 1526-28). In light of the problems in the design and conduct of the study, and the discrepant results of the SSS, SDS, and SRS measures, the study does not even support the conclusion that pomegranate juice had a favorable effect on coronary perfusion (blood flow to the heart). CX1291 (Sacks Expert Report at 0024); CX1293 (Stampfer Expert Report at 0018-19)).

846. Respondents' experts concluded the following about the Ornish MP Study:
• Myocardial perfusion (or blood flow to the heart) is a good predictor or surrogate for cardiac events and a better scientific test than coronary angiography. (PX0025 (Ornish Expert Report at 0012); Ornish, Tr. 2331-34; Heber, Tr. 1973-74).

• SDS is considered a valid surrogate for coronary heart disease and the Ornish MP Study showed SDS, but not SRS or SSS, because SDS measures the primary endpoint, how much blood flow the heart is getting when compared to rest and stress. (Ornish, Tr. 2341-42).

• Differences at baseline for SRS and SSS did not affect the outcome of the Ornish MP Study. (Ornish, Tr. 2343-44, 2394; PX0025 (Ornish Expert Report at 0015).

• Omissions of patient data did not alter the results of the Ornish MP Study. (PX0025 (Ornish Expert Report at 0015); Ornish, Tr. 2347-48; 2394).

• The unblinding of patients or lack of a placebo does not diminish the validity of the Ornish MP Study. (Ornish, Tr. 2345-46; PX0025 (Ornish Expert Report at 0016); CX1339 (Ornish, Dep. at 148-49)).

• The results of the Ornish MP Study are valid even though they were tested over only a three-month period. (PX0025 (Ornish Expert Report at 0017).

847. Dr. Ornish concluded that the Ornish MP Study constitutes credible and reliable science showing that pomegranate juice lessens the risk of cardiovascular problems, that in people who have already had heart disease, it improves the blood flow and reverses the progression of heart disease; and if you can begin to reverse a disease,

it would only make sense that pomegranate juice would work even better to help prevent heart disease in the first place. (Ornish, Tr. 2354-55).

iii. Determination on the Ornish MP Study

***104** 848. The Ornish MP Study does not provide competent and reliable scientific evidence to support claims that the POM Products treat, prevent or reduce the risk of heart disease. (*See* F. 808-846).

e. Ornish CIMT Study

i. About the Ornish CIMT Study

849. The second study Dr. Ornish conducted for Respondents, the Ornish CIMT Study, was completed in 2005 and is unpublished. (JX0003 ¶ B.16).

850. The Ornish CIMT Study was a randomized, double-blind, placebo-controlled 73-person study that measured CIMT, blood pressure, and other related mechanisms for 12 months. The primary endpoint of the Ornish CIMT Study was to investigate the effects of pomegranate juice on CIMT and indices of arterial stiffness for the common carotid arteries (CCA) in patients with at least one cardiovascular risk factor. The treatment group drank one cup (eight ounces) of pomegranate juice concentrate daily, and the control group drank one cup of placebo beverage, daily, for one year. (CX0754 at 0002; CX0613 at 0020).

851. The Ornish CIMT Study was designed to include 200 patients, not 73 patients. Dr. Ornish estimated that he would need at least 200 patients to show a statistically significant difference in CIMT however, because recruitment took longer than anticipated (since most patients with heart disease ended up having angioplasty, stents, and/or bypass surgery at a much higher rate than anticipated), the funding was cut, so Dr. Ornish was only able to recruit 73 patients, from which 56 patients' pre and post data was collected. (Ornish, Tr. 2352; PX0355a007 at 0002).

852. The primary purpose of the Ornish CIMT Study was to determine if pomegranate juice will affect the progression of early/subclinical carotid atherosclerosis. (PX355a0006 at 0004; PX0355a007 at 0010).

853. On or about October 21, 2004, PMRI finished its data collection. (CX0697). Commenting on the study data, Dr. Sumner of PMRI stated, “very few significant interactions ... a mixed, but relatively disappointing bag so far.” (CX0717 at 0001; CX1344 (Sumner, Dep. at 151-52)).

854. On March 24, 2005, Dr. Sumner stated, “I am looking into additional ways to analyze the data” and suggested sending “the IMT results to [another researcher] to check before [sending] them to Harley [Liker]/the Resnicks.” (CX0717 at 0001; *see also* CX0718 at 0001). The next day, another PMRI employee suggested having a biostatistician analyze the data “before concluding the juice had a null effect.” (CX0719 at 0001).

855. Dr. Ornish testified that it would be wrong to classify the Ornish CIMT Study as a “null” study. Instead, Dr. Ornish explained that the study was underpowered because PMRI knew from the beginning that they needed 200 patients. Thus, the study ended with an indeterminate finding, not a clearly nonsignificant finding. (Ornish, Tr. 2456-61).

856. The final analysis for the Ornish CIMT Study results was conducted in approximately June 2005 and the results of the study were provided to Dr. Ornish. (CX1344 (Sumner, Dep. at 168-69); CX0752).

***105** 857. In the Ornish CIMT Study, Dr. Ornish observed an improvement in the carotid artery significant to the 0.13 level as opposed to the 0.15 level. Dr. Ornish testified that if that degree of change had occurred in the larger number of patients he had projected (*i.e.*, 200 instead of 73), it would have been at the 0.05 level or less and, thus, would have reached statistical significance. (Ornish, Tr. 2352-54).

858. According to the Ornish CIMT Study unpublished final report, there were no significant changes in the treatment group relative to the placebo for CIMT thickness or elastic properties. (CX0754 (transmitting "Bev 2 Summary 6-16-05.doc")).

859. In the Ornish CIMT Study unpublished final report, there also were no significant differences in the treatment group relative to the placebo group over time for any of the other heart-related measurements, including systolic and diastolic blood pressure, cholesterol, LDL, HDL, or triglycerides. (CX0754 at 0003, 0005; CX1291 (Sacks Expert Report at 0024-25); Stampfer, Tr. 754-55; CX1293 (Stampfer Expert Report at 0019-20)).

ii. Experts' analysis of the Ornish CIMT Study

860. Complaint Counsel's expert opined that the Ornish CIMT Study appears to have been well-designed and well-conducted. (Sacks, Tr. 1485-88, 1603; CX1291 (Sacks Expert Report at 0026)).

861. Dr. Sacks described the results of this study as "convincingly null, showing that pomegranate juice treatment did not improve CIMT or the other tested parameters" including elasticity of the arteries, blood pressure, or cholesterol. (Sacks, Tr. 1484-86; CX1291 (Sacks Expert Report at 0026); *see also* CX1293 (Stampfer Expert Report at 0019-20); Stampfer, Tr. 755).

862. Dr. Sacks opined that the null results of the Ornish CIMT Study confirm that the purportedly positive results of Dr. Aviram's unrandomized, uncontrolled 19-patient CIMT/BP Study lack credibility. (Sacks, Tr. 1486-88; CX1291 (Sacks Expert Report at 0026)).

863. Dr. Ornish opined that it would be more accurate to see the Ornish CIMT Study as a validation of the studies by Dr. Aviram and Dr. Davidson, since the differences in CIMT would have been statistically significant if the findings measured in 73 patients were found in the 200 patients that Dr. Ornish originally planned to enroll. (PX0025 (Ornish Expert Report at 0019)).

864. Dr. Ornish testified that the Ornish CIMT Study was an indeterminate study that cannot be relied upon: "It neither proves or disproves. It would be, again, as wrong to say that it proves as it would be for Dr. Sacks to assert that it disproves it." (PX0355 (Ornish, Dep. at 192-93)).

865. Dr. Heber did not consider the results of the Ornish CIMT Study in reaching his conclusions on the adequacy of Respondents' substantiation, because it was "incomplete." Dr. Heber observed that the Ornish CIMT Study "had inadequate power at that number of subjects," so no conclusions could be drawn from the study. (PX353 (Heber, Dep. at 180-81); Heber, Tr. 2133-34).

***106** 866. Dr. Heber opined: "The failure of any clinical trial to show a difference cannot be interpreted as a negative finding, however. Only a probability that any difference has been excluded can be calculated, using the

so-called beta type II error calculation, which was not done by Dr. Stampfer." (PX0192 (Heber Expert Report at 0053)).

867. Dr. Sacks admits that the lack of statistical significance for a positive result in the Ornish CIMT Study is not proof of a negative and does not mean pomegranate juice is not beneficial. (Sacks, Tr. 1608-09).

iii. Determination on the Ornish CIMT Study

868. The Ornish CIMT Study does not provide competent and reliable scientific evidence to support claims that the POM Products treat, prevent or reduce the risk of heart disease. (*See* F. 849-867).

f. Davidson CIMT Study

869. In 2003, Dr. Liker approached Dr. Davidson about conducting a CIMT study and a brachial artery reactivity testing study for Respondents. From the beginning, Dr. Liker indicated that the he wanted the study to be randomized, double-blind, and placebo-controlled. (CX1336 (Davidson, Dep. at 92-93); CX0586).

870. In a summary of cardiovascular studies sent to a scientific consultant for POM, Dr. Liker described the Aviram ACE/BP Study, the Aviram CIMT/BP Study, the Ornish MP Study (2005), and the unpublished Ornish CIMT Study, and stated that POM was still exploring its research options "in its efforts to understand whether or not the consumption of pomegranate juice offers cardiovascular benefits." (CX0579 at 0003-04).

871. Dr. Davidson conducted two studies for Respondents: (1) Davidson MH., et al., *Effects of Consumption of Pomegranate Juice on Carotid Intima-Media Thickness in Men and Women at Moderate Risk for Coronary Heart Disease*, 104 Am. J. Cardiology 936 (2009) ("Davidson CIMT Study") (CX1065; *see* JX0003 ¶ B.17); and (2) Davidson MH, *The Effects of Pomegranate Juice on Flow-Mediated Vasodilation* (unpublished, 2004) ("Davidson BART/FMD Study") (CX0684; *see* JX0003 ¶ B.17). The cost for the two studies, sponsored by the Stewart and Lynda Resnick Revocable Trust, was $2,940,494. (CX1134 at 0001).

i. About the Davidson CIMT Study

872. The Davidson CIMT Study was an 18-month, 289-person randomized, double-blinded, placebo-controlled clinical trial conducted at two clinical research sites in accordance with good clinical practice guidelines and under a protocol approved by an institutional review board. (PX0014 at 0001-02).

873. The Davidson CIMT Study was designed to test the effect of pomegranate juice on CIMT progression rates in subjects at moderate coronary heart disease risk. (PX0014 at 0001-02).

874. The Davidson CIMT Study analyzed the results of 289 persons, but actually screened and enrolled 876 and 383 subjects, respectively. (PX0014 at 0002; CX1065 at 0001; CX1291 (Sacks Expert Report at 0027)).

875. Participants in the Davidson CIMT Study were middle-aged men and women with one or more coronary heart disease risk factors (high LDL, low HDL, hypertension or use of hypertension medication, or cigarette smoking) and were required to have a baseline posterior wall common CIMT measurement of > 0.7 and < 2.0 mm on # 1 side (right or left). The study excluded persons with actual coronary heart disease or diabetes. (PX0014 at 0002; CX1065 at 0001-02; CX1291 (Sacks Expert Report at 0027)).

***107** 876. Participants in the Davidson CIMT Study drank eight ounces of pomegranate juice or placebo juice daily. Adherence to study product consumption was assessed at each visit by reviewing daily consumption diaries maintained by the subjects. (CX1065 at 0002).

877. The protocol for the Davidson CIMT Study called for ultrasound testing of the carotid artery at baseline, at 12 months, and at 18 months. (CX0716 at 0018-19). The primary outcome variable identified in the protocol was the difference between placebo and pomegranate juice in posterior wall common CIMT progression rate in mm/year, using non-contrast images, and a secondary outcome measurement was the difference between placebo and pomegranate juice in the anterior wall common CIMT progression rate in mm/year, using contrast images. (CX0716 at 0028). Exploratory endpoints included changes in blood pressure, lipids, and various measures of inflammation and oxidative stress. (CX0716 at 0011; CX1291 (Sacks Expert Report at 0027)).

878. The Davidson CIMT Study indicated the following:
• With the exception of apolipoprotein-B100, which decreased more with pomegranate juice than with control ..., there were no differences between treatment groups for changes from baseline in traditional cardiovascular risk markers, including fasting lipoprotein lipids, blood pressures, or smoking status (data not shown).

• Of the 152 subjects (52%) agreeing to the optional administration of intravenous contrast agent for anterior wall imaging, as expected, baseline values for the anterior wall of the common carotid artery were larger than for the posterior wall.

• Anterior and posterior wall CIMT values and progression rates did not differ significantly between treatment groups at any time point.

• The composite measurement of CIMT showed a significantly smaller value at 12 months in the pomegranate juice group compared to the control group ... However, this difference was no longer significant at the end of the treatment period.

• Exploratory analyses of several subgroups indicated significantly lower values for pomegranate juice versus control after treatment for anterior wall and/or composite CIMT values: subjects in the top tertiles for baseline triglycerides (TG), ... total cholesterol/HDL cholesterol ratio ...; composite ..., TG/HDL cholesterol ratio ... and apolipoprotein-B100 and the lowest tertile for HDL cholesterol. There were no significant differences between treatments in any of these subgroups at baseline for any CIMT measurements or after treatment in posterior wall CIMT values.

• Results of the present study showed no significant influence of 18 months of pomegranate juice consumption on CIMT progression in the overall study sample. However, results from *post hoc* exploratory analyses, which should be interpreted with caution, suggest that the rate of CIMT progression may have been slowed in subgroups characterized by more rapid CIMT progression, including those with increased levels of TG-rich lipoproteins, low levels of HDL cholesterol, and greater oxidative stress.

***108** • Whether possible benefits of pomegranate juice consumption on CIMT progression in some subgroups relate to antioxidant activity is uncertain. A lack of significant improvements in most markers of oxidative stress argues against an important role for antioxidant activity. However, specific reactive oxygen/nitrogen species may be scavenged by pomegranate unique polyphenolic hydrolysable tannins. Indeed, a subgroup for whom there was an apparent benefit was the top tertile for baseline PD — AAPH, suggesting that antioxidant effects may have played a role in the protection against CIMT progression by pomegranate juice consumption.

• Pomegranate juice and/or polyphenol consumption might favorably influence CIMT progression through effects on platelet activity, endothelial function, or shifts in the production of prostacyclin production. However, because none of these variables were measured in the present trial, their potential roles here are unknown.

(PX0014 at 0005-06).

879. The Davidson CIMT Study included a *post hoc* analysis of changes in the CIMT measurements for some of the study subpopulations and stated that there were significantly lower anterior and/or composite CIMT progression rates with higher CVD risk factors. (CX1065 at 0001, 0006; CX1336 (Davidson, Dep. at 57-69)).

880. Dr. Davidson initially submitted a manuscript of the study to the journal, *Arteriosclerosis, Thrombosis, and Vascular Biology*, in late 2008. That journal rejected the manuscript, concluding that it was a negative study. (CX1336 (Davidson, Dep. at 202-03) (discussing CX1016)).

881. In May 2009, Dr. Davidson submitted the manuscript (F. 880) to the *American Journal of Cardiology*. Two expert reviewers provided recommendations and comments. (CX1336 (Davidson, Dep. at 77-78); *see* CX1057 at 0024-27).

882. One reviewer of the manuscript (F. 880) stated that, given the large number of *post hoc* analyses performed, it would be appropriate to conduct a statistical correction for multiple comparisons. (CX1057 at 0025; CX1336 (Davidson, Dep. at 80-81)). Dr. Davidson did not do the statistical correction, but committed to revise the discussion section to emphasize "[t]he possibility of type I errors, the exploratory nature of these findings, and caution regarding interpretation of post-hoc subgroup analyses." (CX1336 (Davidson, Dep. at 73); CX1057 at 0025).

883. Another reviewer of the manuscript (F. 880) advised that "The study needs to be reported as a negative study as it is." (CX1057 at 0027). In response, Dr. Davidson "affirm[ed] that it was a negative study," and committed to revise the manuscript to emphasize that "caution is warranted" with regard to the subgroup findings, and that those findings "should be considered hypotheses that will need to be replicated in future trials designed to assess the efficacy of pomegranate juice consumption" in those subgroups. (CX1336 (Davidson, Dep. at 78-85); CX1057 at 0027).

ii. Experts' analysis of the Davidson CIMT Study

***109** 884. Dr. Sacks testified that the Davidson CIMT Study is the largest of the heart studies conducted on pomegranate juice; was carefully designed, in that the protocol identified the endpoints to be measured, the procedures to be followed, inclusion and exclusion criteria, and the statistical analysis to be conducted; and that there was no evidence of critical problems in the conduct or analysis of the study (except its over-emphasis on the subgroup results). Dr. Sacks concluded that the Davidson CIMT Study is "competent and reliable evidence that consumption of pomegranate juice did not improve CIMT in subjects with one or more cardiovascular risk factors." (CX1291 (Sacks Expert Report at 0029)).

885. Dr. Ornish and Dr. Heber testified that the Davidson CIMT Study constitutes competent and reliable evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, reducing arterial plaque. (PX0025 (Ornish Expert Report at 0019-22); PX0192 (Heber Expert Report at 0039, 0053); Heber Tr. 1979-86; PX0014).

886. In his expert report, Dr. Sacks expressly stated the following regarding the Davidson CIMT Study:
• According to the Davidson [C]IMT report, at the end of the study, there were no significant differences in CIMT progression rates between the subjects in the pomegranate juice and control groups.

• The "composite rate" for all measured carotid artery walls had shown a significantly smaller value at 12 months in the pomegranate juice group, but this difference was no longer significant at the end of the study.

• Further, the anterior wall values and rates, and the posterior wall values and progression rates did not differ significantly at any point in the trial.

• There were also no statistically significant changes in the measured indicators of inflammation and oxidative stress, or in fasting lipoprotein lipids or blood pressure.

(CX1291 (Sacks Expert Report at 0028)).

887. Dr. Ornish agreed with Dr. Sacks' conclusion that the Davidson CIMT Study showed no significant differences in the overall CIMT progression rates between the active and placebo groups at 18 months. (PX0025 (Ornish Expert Report at 0019-20)).

888. In his expert report, Dr. Ornish expressly stated the following regarding the Davidson CIMT Study:
• the fact that these differences in CIMT measurements were not statistically significant at 18 months does not change the fact that these differences were statistically significant after 12 months;

• the bottom line is that pomegranate juice *did* show a statistically significant improvement in CIMT after 12 months in the measure that was most clinically relevant; and

• the Davidson CIMT Study does provide supporting evidence that there was statistically significant lower CIMT progression rates for pomegranate versus control subjects in those with higher cardiovascular disease risk factors.

(PX0025 (Ornish Expert Report at 0020-22)).

***110** 889. Dr. Heber acknowledged that the results at 18 months suggest that in subjects at risk with moderate coronary heart disease, pomegranate juice consumption had no significant effect on overall CIMT progression rate, opining as follows:
• No significant difference in overall CIMT progression rate was observed between pomegranate juice and control treatments.

• In exploratory analyses, in subjects in the most adverse tertiles for baseline serum lipid peroxides, triglycerides (TGs), high-density lipoprotein (HDL) cholesterol, TGs/HDL cholesterol, total cholesterol/HDL cholesterol, and apolipoprotein-B100, those in the pomegranate juice group had significantly less anterior wall and/or composite CIMT progression versus control subjects.

• In conclusion, these results suggest that in subjects at moderate coronary heart disease risk, pomegranate juice consumption had no significant effect on overall CIMT progression rate, but may have slowed CIMT progression in subjects with increased oxidative stress and disturbances in the TG-rich lipoprotein/HDL axis.

(PX0192 (Heber Expert Report at 0039)).

890. Dr. Ornish opined that a potential reason for lack of a change in the CIMT progression rate at 18 months was that participants in the Davidson CIMT Study may have stopped drinking the juice after 12 months. In his 34 years of directing RCTs, Dr. Ornish notes that it is very challenging to motivate patients to continue following any intervention for more than one year. Dr. Ornish further observes that it is not unusual for patients to be less than honest in describing their compliance as patients often describe that it is embarrassing and even humiliating to report that they have not done what they were supposed to do. (PX0025 (Ornish Expert Report at 0020-21); PX0355 (Ornish, Dep. at 202-03)).

891. Dr. Davidson evaluated the compliance with product consumption guidelines during the Davidson CIMT Study. He testified that his review of compliance diaries showed high levels of compliance with product consumption. (CX1336 (Davidson, Dep. at 151-52); CX0788).

892. Dr. Stampfer provided the opinion that that the main result from the Davidson CIMT Study (2009) provides substantial evidence *against* the hypothesis that pomegranate juice can reduce the progression of CIMT. (CX1293 (Stampfer Expert Report at 0020-21); Stampfer, Tr. 758-59 (“So it seems clear that this is a null study, and that's what the authors concluded”)).

893. Dr. Heber expressly disagrees with Dr. Stampfer's conclusion in (F.892) above: Dr. Stampfer contends that the CIMT benefit demonstrated in the subgroup of individuals at increased oxidant stress with increased triglycerides and low HDL does not override his conclusion that “the main result from this large trial provides substantial evidence against the hypothesis that pomegranate juice can reduce progression of CIMT.” I disagree. The subgroup data is particularly important because the CIMT benefit was associated with the specific subgroup that had increased risk factors. (PX0192 (Heber Expert Report at 0053)).

***111** 894. The Davidson CIMT Study included a *post hoc* analysis of changes in the CIMT measurements for some of the study subpopulations. The Davidson CIMT Study described the subgroup analyses as “post hoc exploratory analyses, which should be interpreted with caution[.]” It stated that, “[b]ecause the decrease in CIMT progression in these subgroups was based on analyses that were not preplanned and had no correction for multiple comparisons ..., these findings will need to be confirmed in future investigations.” (CX1065 at 0001, 0006; CX1336 (Davidson, Dep. at 57-69)).

895. A *post hoc* analysis is one that is conceived after the researchers have seen the data and, thus, is generally a less valid approach than one planned for in the protocol, because it is more subject to bias. (Sacks, Tr. 1500-01).

896. Respondents' experts opined that in scientific research, *post hoc* analysis is routine. (Heber, Tr. 1984). Although the exploratory analysis was not called for by the protocol, such analyses, including those on subgroups, are commonly done. (CX1336 (Davidson, Dep. at 57, 221)).

897. With respect to the Davidson CIMT Study, Dr. Ornish opined: “While this is post hoc analysis, and thus not as rigorous as one stated a priori, it does provide supporting evidence that there was statistically significant lower

CIMT progression rates for pomegranate versus control subjects in those with higher cardiovascular disease risk factors." (PX0025 (Ornish Expert Report at 0021)).

898. Dr. Sacks also noted that the subgroup analysis had not been corrected for multiple comparisons, as stated in the Davidson CIMT Study. (CX1291 (Sacks Expert Report at 0030)). When multiple endpoints are being measured, the *p*-value needs to be adjusted downward to correct for multiple comparisons. Without the correction, with each additional subgroup analyzed, the chances increase that one or more will turn out to have a *p*-value of less than .05, by chance alone. (Sacks, Tr. 1505-06; Stampfer, Tr. 760-61). Dr. Davidson never did a correction for multiple comparisons on the subgroup analysis. (CX1336 (Davidson, Dep. at 73)).

899. Dr. Sacks further opined: because the subgroup data is hypothesis generating only, and has not been corrected for multiple comparisons, a qualified scientist could not rely on the *post hoc* analysis of the subgroup populations as reliable scientific evidence to support claims that POM Juice or POMx prevent, reduce the risk of, or treat heart disease in the subpopulations identified in Figure 3 of the Davis CIMT Study. (CX1291 (Sacks Expert Report at 0029-30)).

iii. Determination on the Davidson CIMT Study

900. The Davidson CIMT Study does not provide competent and reliable scientific evidence to support claims that the POM Products treat, prevent or reduce the risk of heart disease. (*See* F. 872-899).

g. Davidson BART/FMD Study

i. About the Davidson BART/FMD Study

901. The brachial artery is a major blood vessel of the arm. Brachial artery reactivity testing ("BART") is a measurement of how much the brachial artery dilates (enlarges) after a blood pressure cuff is inflated, and then released. This is also called flow mediated dilation ("FMD") testing. (JX0003 ¶ A.1-2; CX1336 (Davidson, Dep. at 34-35)).

***112** 902. Flow mediated dilation is the amount by which the brachial artery dilates (gets larger) after the blood pressure cuff is deflated. (JX0003 ¶ A.8).

903. Dr. Davidson conducted the Davidson BART/FMD Study on a subset of 45 Davidson CIMT Study participants. It was a 13-week, randomized, double-blind, placebo-controlled trial to evaluate the effect of consuming POM Juice or placebo on BART, also referred to as FMD testing. (JX0003 ¶ A.1; CX0684; CX0716 at 0010-11, 0074-81; CX1336 (Davidson, Dep. at 37, 102-03); Sacks, Tr. 1508-10; Stampfer, Tr. 764-66).

904. At the conclusion of the Davidson BART/FMD Study, there were no significantant differences between the treatment and placebo groups and no written report was prepared. (PX0019; CX0684 at 0001; CX1336 (Davidson, Dep. at 87-89); Sacks, Tr. 1510-13; CX1291 (Sacks Expert Report at 0030-31); CX1293 (Stampfer Expert Report at 0021); CX0695 at 0001; CX1336 (Davidson, Dep. at 125)).

905. The Davidson BART/FMD Study also took measurements of blood pressure and other vital signs. However, blood pressure, cholesterol, HDL cholesterol, non-HDL cholesterol, triglycerides, ACE, paraoxonase (PON), and thiobarbituric acid reactive substances (TBARS) were not primary or secondary endpoints of the Davidson BART/FMD Study. (CX0684; CX0716 at 0010-11, 0074-81; Sacks, Tr. 1508-10; Stampfer, Tr. 764-66).

906. At the end of the Davidson BART/FMD Study, there were no significant differences between treatment and placebo groups in blood pressure, cholesterol, HDL cholesterol, non-HDL cholesterol, triglycerides, ACE, PON, and two TBARS measurements. (CX1336 (Davidson, Dep. at 86-88; CX0684 at 0005-13, 0019; CX1291 (Sacks Expert Report at 0031)).

ii. Experts' analysis of the Davidson BART/FMD Study

907. Complaint Counsel's expert, Dr. Sacks, opined that the Davidson BART/FMD Study appears to have been properly designed and conducted. The protocol identifies the endpoints to be measured, the procedures to be followed, inclusion and exclusion criteria, and the statistical analysis to be conducted. There is no indication of critical problems in the conduct of the study. (CX1291 (Sacks Expert Report at 0032)).

908. Dr. Sacks opined that although BART/FMD is not a valid or generally recognized surrogate marker of coronary heart disease, it does provide relevant information because FMD is a measure of nitric oxide. Dr. Sacks further opined that if pomegranate juice meaningfully affected nitric oxide metabolism, one would have expected to see a positive result in the FMD testing. (CX1291 (Sacks Expert Report at 0032); Sacks, Tr. 1510-12).

909. Dr. Sacks further opined that the Davidson BART/FMD Study finding of no statistically significant difference in blood pressure or ACE due to POM Juice consumption is inconsistent with Dr. Aviram's ACE/BP Study findings. (F. 774-779; Sacks, Tr. 1512-13; CX1291 (Sacks Expert Report at 0032)).

910. Dr. Heber testified that in the Davidson BART/FMD Study, the primary endpoint was flow-mediated dilation, not blood pressure, and, therefore, any results for blood pressure cannot be relied upon as negative evidence. (Heber, Tr. 2106-07).

***113** 911. Dr. Sacks concedes that just because the Davidson BART/FMD Study does not show statistically significant changes with respect to blood pressure and ACE, among other measurements, the absence of such evidence is not proof there is no effect. (PX0361 (Sacks, Dep. at 230)).

912. Respondents' experts explain that the absence of evidence is not evidence of absence, so the fact that a statistically significant change in ACE or blood pressure was not found does not mean that the result does not exist. (Heber, Tr. 1981; *see also* Sacks, Tr. 1608).

913. Respondents' experts opined that no conclusion can be drawn from the absence of statistically significant changes in the Davidson BART/FMD Study. (Heber, Tr. 1981; Sacks, Tr. 1608-09).

iii. Determination on the Davidson BART/FMD Study

914. The Davidson BART/FMD Study does not constitute competent and reliable scientific evidence supporting a claim that the POM Products treat, prevent or reduce the risk of heart disease. (*See* F. 903-913)

6. Additional biomarker studies sponsored by Respondents

a. The Overweight Studies

915. In 2006, POM sponsored Dr. James Hill, University of Colorado, Denver, to examine the safety and antioxidant activity of POMx on overweight individuals with increased waist size ("Denver Study"). Also in 2006, POM sponsored Dr.Heber and Accelovance to study the safety of POMx and the effect of POMx on biomarkers and inflammation in overweight people ("San Diego Study") (collectively, the "Overweight Studies") (CX0934; CX0819 at 0021-22; CX0859 at 0001).

i. About the Denver Study

916. In 2006, Dr. Hill and his colleagues conducted an unblinded, uncontrolled study of POMx capsules in Denver, Colorado, known as the Denver Study. (CX1291 (Sacks Expert Report at 0032-35); *see* Sacks, Tr. 1513-14).

917. The Denver Study enrolled 24 adults (19 females, 5 males) ages 40 to 70 with abdominal adiposity. Subjects received two POMx capsules per day for 28 days. (CX0877 at 0002-10; CX0934 at 0003-04).

918. The Denver Study measured a "wide range of biomarkers for oxidative stress and inflammation" at baseline and at four weeks, including TBARS (thiobarbituric acid reactive substances) and PON1 activity. TBARS is an important biomarker of oxidative stress in humans and strongly predictive of cardiovascular events in people with stable coronary artery disease, independent of traditional risk factors and inflammatory markers. High-density lipoprotein cholesterol ("HDL" or so called "good cholesterol") contains an antioxidant enzyme, called "paraoxonase" or "PON1" which acts to protect the body against oxygen radicals. Additional measurements included blood pressure, triglycerides, cholesterol, and C-reactive protein. Although the subjects' triglycerides, cholesterol, and C-reactive protein were measured, the study was not designed to assess those factors. (CX0877 at 0002-10; CX1342 (Hill, Dep. at 42-44); Heber, Tr. 1961; CX0934 at 0003-04).

***114** 919. Twenty-two subjects completed the Denver Study. According to the Preliminary Data Analysis, dated February 15, 2007, the participants gained an average of 1.3 pounds during the study, which Dr. Hill attributed to its being conducted during the holiday season. (CX0877 at 0002-03; CX1291 (Sacks Expert Report at 0032-33); CX1342 (Hill, Dep. at 99-103)).

920. TBARS was the primary endpoint chosen to assess the antioxidant activity of the POMx capsules in the Denver Study. (CX1342 (Hill, Dep. at 41-42)). The authors of the study concluded that POMx is safe and that there was evidence of antioxidant activity through a significant reduction in TBARS linked with cardiovascular disease risks. (CX0934 at 0004).

921. After adjusting the statistical analysis for the weight change, during the Denver Study TBARS decreased and free fatty acids increased. The study statistician stated that the change in TBARS was "of borderline significance [and had] not been adjusted for the number of comparisons made." (CX0877 at 0002-03, 0008 (TBARS); CX1291 (Sacks Expert Report at 0032-33)).

922. In the Denver Study, there was no change in PON1 and there were no statistically significant changes in blood pressure. The subjects' blood pressure was taken as a safety measure to protect the subjects, as the study was not designed to assess whether or not POMx capsules had an effect on blood pressure. (CX0877 at 0002-03, 0008, 0010; CX1291 (Sacks Expert Report at 0032-33); CX1342 (Hill, Dep. at 71-72, 97-103, 111-13, 118-19).

923. Although inflammation was not explored as the primary endpoint, the Denver Study concluded, "[w]e did not detect any effect of POMx on inflammation but identification of better biomarker assays for inflammation is needed .... [T]his pilot project suggests that a larger trial is warranted in abdominally obese subjects who may be

at risk for development of metabolic diseases." (CX0877 at 0002-03; CX1291 (Sacks Expert Report at 0032-33); CX1342 (Hill, Dep. at 41-42); CX0934 at 0001).

ii. About the San Diego Study

924. The protocol for the San Diego Study was titled, *A Placebo-Controlled, Randomized, Double-Blind Study to Compare Antioxidant Levels in Normal Subjects with Elevated Waist Circumference When Administered 1 or 2 Pomegranate Dietary Supplement Capsules for 4 Weeks*. (CX0819 at 0014 (Protocol, July 14, 2006); CX1291 (Sacks Expert Report 0033-34)).

925. The San Diego Study was designed as a safety assessment. (CX0934 at 0001).

926. The San Diego Study recruited 64 generally healthy male and female subjects who took either two POMx capsules, two placebo capsules, or one placebo and one POMx capsule, per day, for four weeks. (CX0859 at 0010 (Clinical Study Report); CX1291 (Sacks Expert Report at 0033-34)).

927. Measurements in the San Diego Study included blood pressure, oxidized phospholipids, oxidized LDL/HDL, serum nitric oxide, and PON, but these were not primary endpoints. (CX0934 at 0001; CX0859 at 0003; CX1291 (Sacks Expert Report at 0033-34)).

***115** 928. A portion of the San Diego Study data was presented in a January 11, 2007 Clinical Study Report. (*See* CX0859). This document described the conduct of the study, adverse events, vital signs, and blood pressure data. It stated that "[t]here were no apparent treatment related changes in weight, systolic blood pressure, diastolic blood pressure, pulse rate, respirations, or temperature." The San Diego Study report also stated that the efficacy results of antioxidant and anti-inflammatory levels were shown separately. (CX0859 at 0018, 0020).

929. Dr. Heber prepared a slide presentation about the results of the San Diego Study in which he stated: "there were no changes in ... markers of oxidative stress or inflammation that were studied," including in C-reactive protein, oxidized phospholipids, lipoprotein (a), and nitric oxide and that "[t]he variation among subjects suggests that a more focused study would be more likely to demonstrate significant changes." (CX1254 at 0026; CX1254 at 0001, 0006-26; Heber, Tr. 2119-21).

930. Dr. Heber sent this presentation (F. 929) to POM employees on January 9, 2007 with an accompanying email stating, "we have not proved or disproved efficacy at this point." By efficacy, Dr. Heber meant changes in biomarkers of oxidant stress or inflammation. (CX0858 at 0001). (CX1352 (Heber, Dep. at 107-11) (discussing CX1254)).

931. Dr. Heber's article on the San Diego Study results was published in late 2007 as Heber D. et al., *Safety and Antioxidant Activity of a Pomegranate Ellagitannin-Enriched Polyphenol Dietary Supplement in Overweight Individuals with Increased Waist Size*, J. Agric Food Chem., Vol. 55, No. 24 (2007). (*See* CX0934).

932. Dr. Hebers's article (F. 931) on the Overweight Studies stated that "[p]reliminary evidence of a reduction in TBARS was seen in the subjects who were studied at the Denver site .... TBARS are an important biomarker of oxidative stress .... [T]hese pilot studies demonstrate both the safety and efficacy of POMx ... in humans. However, further studies need to be done to confirm the antioxidant properties of pomegranate ellagitannins administered as a dietary supplement." (CX0934 at 0003-04).

933. Dr. Heber acknowledged that the published article (F. 931) did not provide all of the results of the San Diego Study, including those concerning antioxidant stress or inflammation. Dr. Heber explained that the San Diego Study was primarily studying safety, "with the idea that we would explore the idea of whether any inflammatory markers or oxidant stress markers were elevated in those subjects." Dr. Heber further stated that they found that the studied population had a "great deal of variability" at baseline and four-week measurements. Dr. Heber further explained that there was no interest in publishing the results because the findings concerning anti-inflammatory effects were "indeterminate results, not negative results." (Heber, Tr. 2116-17).

iii. Experts' analysis of the Overweight Studies

***116** 934. Drs. Sacks and Stampfer concluded that the methodological shortfalls in the Denver Study — especially the lack of a control group — render its findings unreliable. (CX1291 (Sacks Expert Report at 0035); *see also* Sacks, Tr. 1519-21; Stampfer, Tr. 768-72).

935. Dr. Ornish agreed that there are limitations to the Denver Study and that it was a pilot study, which only provides preliminary findings to justify doing a larger study. Dr. Ornish further opined that the San Diego Study did not demonstrate efficacy since there were no significant changes in biomarkers. (PX0025 (Ornish Expert Report at 0024-25)).

936. Dr. Heber stated in his expert report that the Denver Study demonstrated the efficacy of POMx as an antioxidant. (CX0934 at 0004). At trial, however, he described the Denver Study as a "pilot study ... not a conclusive demonstration." (Heber, Tr. 2116). Dr. Heber explained, anti-inflammatory effects "were indeterminate results, not negative results." (Heber, Tr. 2117).

937. With respect to the lack of statistically significant changes to blood pressure and other biomarkers, such as triglycerides, HDL, LDL, C-reactive protein, and PON, Dr. Sacks acknowledges that the absence of information does not prove the negative. (PX0361 (Sacks, Dep. at 223-24, 238, 243)).

iv. Determination on the Overweight Studies

938. The Overweight Studies do not constitute competent and reliable scientific evidence to support claims that the POM Products treat, prevent or reduce the risk of heart disease. (*See* F. 915-937).

b. The Diabetes Studies

i. About the Diabetes Studies

939. Respondents have also sponsored studies evaluating the effect of pomegranate juice and/or its derivatives on persons with diabetes, discussed below, (collectively, "the Diabetes Studies"). (PX0038; PX0127; CX0765).

940. The first of the Diabetes Studies, conducted by Dr. Rock, a member of Dr. Aviram's team, published as Rock, W, et al., *Consumption of Wonderful Variety Pomegranate Juice and Extract by Diabetic Patients Increases Paraoxonase I Association with High-Density Lipoprotein and Stimulates Its Catalytic Activities*, 56 J. Agric. Food Chem. (2008), looked at the relationship of PON1 and HDL cholesterol activity in 30 diabetic patients who used pomegranate juice or POMx Liquid for four to six weeks. It indicated a reduction in oxidative stress as

measured by TBARS and improved PON. All measurements were comparisons to baseline. (PX0127; CX1291 (Sacks Expert Report at 0036-37); PX0192 (Heber Expert Report at 0038-39)).

941. The other two Diabetes Studies were conducted by Dr. Heber and Dr. Hill and were randomized, double-blind, placebo-controlled studies to evaluate the antioxidant effect of pomegranate extract capsule and pomegranate juice, respectively, in diabetic patients. (Heber, Tr. 2048-49, 2054; CX1352 (Heber, Dep. at 124-25); CX0949 at 0007-26 (protocol for diabetes extract study); CX1082 at 0007-21 (protocol for diabetes juice study); CX1284).

***117** 942. The POMx protocol called for enrolling 30 diabetics for 12 weeks. (CX949 at 0013). The POM Juice study protocol called for an enrollment of 40 diabetics for 12 weeks. (CX1082 at 0012).

943. The two Diabetes Studies conducted by Dr. Heber and Hill were completed, but the results were not published. (CX1352 (Heber, Dep. at 132-33); CX1342 (Hill, Dep. at 157)).

ii. Experts' analysis of the Diabetes Studies

944. Dr. Sacks testified that the Diabetes Studies do not constitute competent and reliable scientific evidence to support claims that POM Juice or POMx treat, prevent, or reduce the risk of heart disease because they are not RCTs, the study size is too small, and the duration is too limited in scope. (CX1291 (Sacks Expert Report at 0035-37); Sacks, Tr. 1521-24).

945. According to Dr. Heber, the two diabetes studies he conducted did not show a significant change in malondialdehyde, which is a TBARS measure, or in PON, both of which are heart-related biomarkers. (Heber, Tr. 2124 (malondialdehyde), 2137-38 (PON); CX1352 (Heber, Dep. at 161-70)).

946. Dr. Heber did not include the results of his two diabetes studies in his analysis of available human clinical evidence to substantiate heart benefits of POM Products. (PX0192 (Heber Expert Report at 0052-54)).

iii. Determination on the Diabetes Studies

947. The Diabetes Studies do not constitute competent and reliable scientific evidence to support claims that the POM Products treat, prevent or reduce the risk of heart disease. (*See* F. 939-946).

7. Experts' opinions based on the totality of the evidence

a. Summary of Complaint Counsel's experts' opinions

948. Dr. Sacks and Dr. Stampfer both opined that Respondents' research on pomegranate juice provides no evidence that POMx Pills or POMx Liquid will treat, prevent, or reduce the risk of heart disease or that they are clinically proven to do so. (CX1291 (Sacks Expert Report at 0010, 0038); CX1293 (Stampfer Expert Report at 0017)).

949. Dr. Stampfer opined: Respondents' human clinical studies, including a large randomized clinical trial, failed to confirm the results of the animal and *in vitro* studies. Although some promising results appear in several of the smaller studies with important design limitations, the weight of the evidence strongly favors the null hypothesis

of no effect .... The current data does not support the claims for heart disease prevention or treatment. (CX1293 (Stampfer Expert Report at 0022)).

950. Dr. Sacks opined: the evidence is not sufficient to support the conclusion that consumption of POM Juice, POMx Pills, or POMx Liquid treat, prevent, or reduce the risk of heart disease. (CX1291 (Sacks Expert Report at 0038-39)).

951. Dr. Sacks further opined: there is no reliable evidence that POM Juice, POMx Pills, or POMx Liquid reduce or delay the development of arterial plaque; improve blood flow to the heart (or other blood vessels); or reduce blood pressure. (CX1291 (Sacks Expert Report at 0038-39)).

***118** 952. Dr. Sacks opined, in addition, that clinical studies, research and/or trials do not prove that drinking POM Juice or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of or treats heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart. (CX1291 (Sacks Expert Report at 0010)).

b. Summary of Respondents' experts' opinions

953. Dr. Heber opined that based on basic scientific studies focusing on the hydrolysable tannins family, especially punicalagins and ellagitannins, POMx Pills and POMx Liquid are equivalent to POM Juice in providing health benefits to humans. (Heber, Tr. 2002-03; *see also* Heber, Tr. 2186-87 (studies show there is no difference between the antioxidant effect in pomegranate juice and that in POMx and that pomegranate juice and POMx have the same impact on oxidative stress)).

954. Dr. Heber also opined: the body of research on pomegranate juice and extract provides support for potential heart benefits for heart disease. (PX0192 (Heber Expert Report at 0015)).

955. Dr. Heber, in addition, opined that competent and reliable evidence shows that POM and POMx are likely to reduce the risk of cardiovascular disease. (Heber, Tr. 2012, 2087).

956. Dr. Heber further opined: there is credible scientific evidence that pomegranate juice and pomegranate extracts have significant health benefits for human cardiovascular systems, including: (1) decreases in arterial plaque; (2) lowering of blood pressure; and (3) improvement of cardiac blood flow, based on the biological mechanism of prolonging the half-life of nitric oxide in the vasculature. (PX0192 (Heber Expert Report at 0044-45)).

957. Dr. Heber also stated in his expert report that he agreed with Dr. Stampfer that “claims that pomegranate juice and extract have not been proven absolutely effective to treat, prevent, or reduce the risk of heart disease ... based solely on evidence from large double-blind placebo-controlled trials ... But the entire body of scientific evidence should be considered when evaluating nutritional science.” (PX0192 (Heber Expert Report at 0044)).

958. Dr. Ornish opined that in evaluating scientific research related to a whole food, as opposed to a drug, it is not necessary to reach statistical significance to convey information about the product; the convention of a finding that there be a five percent or less likely due to chance finding is an arbitrary convention; and that when you have a *p*-value of 0.05, there is a 95 percent probability of validity as opposed to chance and when you have a *p*-value of 0.058, there is a 94 percent validity as opposed to chance. (Ornish, Tr. 2340).

959. Dr. Ornish opined: taken as a whole, the preponderance of the scientific evidence from basic scientific studies, animal research, and clinical trials in humans reveals that the pomegranate in its various forms (including POM Wonderful 100% Pomegranate Juice, POMx Pills, or POMx Liquid) is likely to be beneficial in maintaining cardiovascular health and is likely to help reduce the risk of cardiovascular disease. (PX0025 (Ornish Expert Report at 0005)).

***119** 960. Dr. Ornish also opined: the universe of existing science provides significant evidence that pomegranate juice is likely to (1) reduce arterial plaque, (2) improve blood flow, and (3) reduce blood pressure. (PX0025 (Ornish Expert Report at 0005); PX0355 (Ornish, Dep. at 42); Ornish, Tr. 2374-75).

8. Conclusions

961. In considering whether a conventional food or dietary supplement is likely to have an effect on the risk or treatment of a disease, it is important to first look at the individual items of evidence, to determine whether they are reliable and probative. Then, it is important to look at the evidence as a whole. (CX1291 (Sacks Expert Report at 0038)).

962. There is insufficient competent and reliable scientific evidence to support the conclusion that the POM Products treat, prevent, or reduce the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart; no clinical studies, research and/or trials prove these effects. (CX1291 (Sacks Expert Report at 0010, 0038-39); CX1293 (Stampfer Expert Report at 0022)).

H. Substantiation for Respondents' Prostate Cancer Claims

1. Substantiation standard for prostate claims

963. Because pomegranate juice is derived from a fruit, is known to be safe, and is not a pharmaceutical drug, physicians who treat patients concerned with prostate health would not hold pomegranate juice to the standards of safety and efficacy traditionally required by the FDA for approval of a pharmaceutical (performance of a large, randomized, double-blind, placebo controlled clinical trial) before recommending pomegranate juice to their patients. (PX0206 (Miller Expert Report)).

964. A claim that a fruit juice that is known to be safe, treats or prevents prostate cancer, if not offered as a substitute or a replacement for a conventional therapy, can be supported if there is reliable and competent scientific data that support the claimed beneficial effect. (PX0206 (Miller Expert Report at 11); Miller, Tr. at 2201).

965. Experts in the field of prostate health would not require RCTs to substantiate health benefit claims for harmless pure fruit products like pomegranate juice. (deKernion, Tr. 3060; *see also* Miller, Tr. 2201).

966. Experts in the field of prostate health would require that a product be scientifically evaluated through rigorous scientific and clinical studies, and believe that animal and *in vitro* studies alone are not sufficient to conclude that the POM Products treats, prevents, or reduces the risk of prostate cancer or that they have been clinically proven to do so. (CX1287 (Eastham Expert Report at 0006, 0012-15); CX1293 (Stampfer Expert Report at 0009-10)).

2. Background facts on prostates and the effects of pomegranates on prostates

a. Prostate function and prostate cancer

967. The prostate is a gland located in the male pelvis that is an organ of sexual function and fertility. (Eastham, Tr. 1236).

***120** 968. Prostate cancer occurs when cells of the prostate, typically the glandular cells, become cancerous, which means they have uncontrolled cell growth. (Eastham, Tr. 1236).

969. Last year about 220,000 men were diagnosed with prostate cancer in the United States. Approximately one in six men over the age of 60 will be diagnosed with prostate cancer each year. The average age of prostate cancer diagnosis is in the sixties. About 30,000 men die from prostate cancer each year. (Eastham, Tr. 1237-39).

970. Prostate cancer does not have a typical course. There are many prostate cancers that, while they are seen under the microscope, they do not represent a threat to the life expectancy or the quality of life of the patient. (Eastham, Tr. 1236).

971. Blood levels of prostate specific antigen (PSA) are measured in healthy men to assess their risk of prostate cancer. (Stampfer, Tr. 774).

972. PSA is a protein that is derived almost exclusively from the prostate and is widely used for screening for the risk of prostate cancer. (Stampfer, Tr. 774).

973. PSA is also used after diagnosis of prostate cancer to monitor the progression of disease. (Stampfer, Tr. 774).

974. The two mainstays of cure for prostate cancer are either radical prostatectomy (surgical removal of the prostate) or radiation therapy to the prostate. (Eastham, Tr. 1237; PX0060 at 0001).

975. Although the mainstays described in F. 974 are adequate for permanent disease control in many patients, a significant number of patients relapse and ultimately develop metastatic disease. (PX0060 at 0001).

976. Approximately one third of prostate cancer patients with clinically confined cancer that are treated with radical prostatectomy will develop a biochemical recurrence. (PX0060 at 0001).

977. There are limited treatment options for patients who have undergone primary therapy with curative intent and who have progressive elevation of their PSA without documented evidence of metastatic disease. (PX0060 at 0002).

978. Androgens are male steroid hormones that regulate prostate cancer cell growth. Hormone-type products increase testosterone levels and, basically, stop the conversion of testosterone to a more potent hormone, androgen. Compounds that contain hormonetype products can impact the PSA if they are used in large quantities. (Stampfer Tr. 773; Eastham Tr. 1242-44).

979. Early initiation of hormonal ablation is associated with significant morbidity and effect on quality of life, including fatigue, hot flashes, loss of libido, decreased muscle mass, and osteoporosis with long-term use. (PX0060 at 0002).

980. Strategies to delay clinical prostate cancer progression and prolong the interval from treatment failure to hormonal ablation would be of paramount importance. (PX0060 at 0002).

981. A combination of epidemiologic and basic science evidence strongly suggests that diet and plant-derived phytochemicals may play an important role in prostate cancer prevention or treatment. (PX0060 at 0002).

***121** 982. Epidemiologic studies suggest that a reduced risk of cancer is associated with the consumption of a phytochemical-rich diet that includes fruits and vegetables. (PX0060 at 0002).

983. Fresh and processed fruits and food products contain high levels of a diverse range of phytochemicals of which polyphenols, including hydrolyzable tannins (ellagitannins and gallotannins) and condensed tannins (proanthocyanidins), and anthocyanins and other flavonoids make up a large proportion. (PX0060 at 0002).

984. Several phytochemicals have been proposed as potential chemoprevention agents based on animal and laboratory evidence of antitumor effects. (PX0060 at 0002).

985. Suggested mechanisms of anticancer effects of polyphenols include the inhibition of cancer cell growth by interfering with growth factor receptor signaling and cell cycle progression, promotion of cellular differentiation, modulation of phosphodiesterase/cyclooxygenase pathways, inhibition of kinases involved in cell signaling, and inhibition of inflammation. (PX0060 at 0002).

b. Mechanism of action of pomegranates in the prostate

986. The pomegranate (*punica granatum* L.) fruit has been used for centuries in ancient cultures for its medicinal purposes. (PX0060 at 0002).

987. Pomegranate fruits are widely consumed fresh and in beverage forms as juice and wines. Commercial pomegranate juice shows potent antioxidant and antiatherosclerotic properties attributed to its high content of polyphenols, including ellagic acid in its free and bound forms (as ellagitannins and ellagic acid glycosides), gallotannins, and anthocyanins (cyanidin, delphinidin, and pelargonidin glycosides) and other flavonoids (quercetin, kaempferol, and luteolin glycoside). (PX0060 at 0002).

988. Atherosclerosis means a build-up of plaque in arteries. (Stampfer, Tr. 700).

989. The most abundant of the polyphenols in pomegranates is punicalagin, an ellagitannin implicated as the bioactive constituent responsible for > 50% of the potent antioxidant activity of the juice. Punicalagin is abundant in the fruit husk and, during processing, is extracted into pomegranate juice in significant quantities reaching levels of > 2g/L juice. (PX0060 at 0002).

990. Ellagic acid and tannins have been shown previously to exhibit *in vitro* and *in vivo* anticarcinogenic properties, such as induction of cell cycle arrest and apoptosis, as well as the inhibition of tumor formation and growth in animals. (PX0060 at 0002).

i. *In vivo* research reporting reduced inflammation in prostate tumors

991. A large body of literature has linked inflammation to prostate carcinogenesis at all stages of the development of prostate cancer from normal tissue to advanced cancer. (PX0192 (Heber Expert Report at 0029); PX0070 at 0001).

992. Inflammation in the human is a key step in prostate cancer progression. (CX1352 (Heber, Dep. at 257-58); PX0070 at 0001).

993. Areas of chronic inflammation are almost universally present in pathologic specimens of the prostate, including biopsy cores in men prior to the diagnosis of prostate cancer, transurethral resection chips, and total prostatectomy specimens. (PX0192 (Heber Expert Report at 0029)).

***122** 994. Ninety-eight percent of prostate tumors removed at surgery for cancer have evidence of inflammation. (CX1352 (Heber, Dep. at 257-58); PX0192 (Heber Expert Report at 0029-30)).

995. *In vivo* research has demonstrated that pomegranate polyphenols reduce inflammation in prostate tumors. (CX1352 (Heber, Dep. at 257-58); Heber, Tr. 1992).

ii. *In vivo* research reporting nuclear factor #B decreased

996. One well-established signaling pathway mediating inflammatory responses relevant to cancer is the nuclear factor-*kappa*B (NF-#B) pathway. (PX0192 (Heber Expert Report at 0030); deKernion, Tr. 3046-47; Heber, Tr. 1992; PX0070 at 0001).

997. The unique protein NF-#B was the subject of Nobel Prize-winning research by Dr. David Baltimore who identified the protein's unique ability to both receive a signal from the outside of a cell and translate that signal into genetic programming of inflammatory proteins that are secreted by cells (“Dr. Baltimore's study”). (PX0192 (Heber Expert Report at 0030); Heber, Tr. 1992).

998. Dr. Baltimore's study involved *in vitro* and animal research. (PX0192 (Heber Expert Report at 0030)).

999. Dr. Baltimore's study showed that the activity of NF-#B is regulated by another protein inhibitor called I#B, which binds to and sequesters NF-#B family members in the fluid part of the cell away from DNA, called the cytoplasm. (PX0192 (Heber Expert Report at 0030); PX0070 at 0001).

1000. Dr. Baltimore's study showed that when the NF-#B pathway is activated, I#B is chemically modified by an enzyme called I#B kinase, which adds a phosphorus atom at specific amino acids on the IkB protein (serine residues 32 and 36). (PX0192 (Heber Expert Report at 0030); PX0070 at 0001).

1001. Dr. Baltimore's study showed that once altered, the inhibitory protein I#B is degraded and NF-#B is free to move to the nucleus, where it functions to activate genetic mechanisms after binding to DNA, resulting in the secretion of proinflammatory signaling proteins. (PX0192 (Heber Expert Report at 0030); PX0070 at 0001).

1002. Dr. Baltimore's study showed that while normal activation of NF-#>B is temporary in response to a stimulus meant to activate immune function, constant or constitutive activation has been observed in breast cancer, liver cancer, melanoma, Hodgkin's disease, and cervical cancer. (PX0192 (Heber Expert Report at 0030); PX0070 at 0001).

1003. Dr. Baltimore's study stated that direct genetic evidence in mouse models of colon and liver cancer have established that NF-#B activation within tumor cells or infiltrating inflammatory cells is required for tumor initiation or promotion. (PX0192 (Heber Expert Report at 0030); PX0070 at 0001).

1004. Dr. Baltimore's study reported that activation of NF-#B is observed in primary prostate cancer specimens as evidenced by its presence in the nucleus of cells where the genes reside and represents an independent risk factor for recurrence of prostate cancer after radical prostatectomy. (PX0192 (Heber Expert Report at 0030); PX0070 at 0001).

***123** 1005. Dr. Baltimore's study reported that pomegranate extract has been shown to inhibit NF-#B in normal human cells, including chondrocytes, epidermal keratinocytes, and vascular endothelial cells. (PX0192 (Heber Expert Report at 0031); PX0070 at 0002).

1006. Dr. Baltimore's study concluded that pomegranate extract inhibits both continuous (constitutive) and stimulated (cytokineinduced) NF-#B activity in prostate cancer cells *in vitro* and that the NF-#B inhibitory effect of pomegranate extract was necessary for the maximal cell killing effects of pomegranate extract. (PX0192 (Heber Expert Report at 0031); Heber, Tr. 1993; PX0070 at 0002).

1007. Respondents' experts testified that in tumors treated with pomegranate extract, the NF-#B decreased, therefore causing decrease of tumor growth. (deKernion, Tr. 3046-47; Heber, Tr. 1993).

1008. Respondents' experts testified that there is an absolute linear connection between the polyphenol mechanisms in pomegranate extract and the decrease in tumor growth. (deKernion, Tr. 3046-47; Heber, Tr. 1993).

1009. The mechanisms of action of the POM Products on inflammation and NF-#>B contributes to the total body of research relied upon by Respondents. (PX0161 (deKernion Expert Report at 0011-12); PX0192 (Heber Expert Report at 0031); PX0206 (Miller Expert Report at 12); PX0070).

3. Basic science studies

a. Summary of the studies

1010. Respondents have conducted four *in vitro* studies and four animal studies relating to prostate cancer, according to their January 13, 2009 summary of their prostate cancer research to date. (CX1029 at 0004).

1011. POM's initial studies involved *in vitro* growing of human tumor cells in petri dishes in laboratories, adding POM and POM products and evaluating the effect on the human tumor cells. These initial studies showed a significant decrease in growth, increase in apoptosis, (programmed tumor death), and decrease in inflammation, factors which are all related to cancer. (deKernion, Tr. 3044).

1012. Subsequent research involved *in vivo* study wherein a human tumor was grown in immune deficient mice, an environment, which behaves as though it were in a human. In these studies which used LAPC4, a particular prostate tumor line, researchers demonstrated that when a prostate tumor is grown in mice and pomegranate extract and pomegranate products are added, the tumors markedly decreased. (deKernion, Tr. 3045). These studies were not of animal glands, but were studies of human prostate tissue put in animals. All of these studies indicated that POM had an antitumor effect on human tumors. (deKernion, Tr. 3049).

1013. In 2001, Agensys, a biotech company, performed early preclinical research for POM investigating the effect of pomegranate juice and prostate cancer. Agensys' unpublished research found that *in vitro* pomegranate juice consumption “substantially inhibits the proliferation of prostate cancer cells” and that pomegranate juice consumption “retards the growth of subcutaneous and orthotopic prostate tumors in mice.” (deKernion, Tr. 3115; Tupper Tr. 1034; PX0065 at 0036-37).

***124** 1014. In a study titled, "*Pomegranate Ellagitannin-Derived Metabolites Inhibit Prostate Cancer Growth and Localize to the Mouse Prostate Gland*," Doctors Navindra Seeram, Arie Belledegrum, David Heber, and colleagues evaluated the effects of pomegranate extract on prostate cancer growth in severe combined immunodeficient mice injected with human prostate cancer cells. The study showed that pomegranate extract significantly inhibited prostate cancer in the mice as compared to the control. Researchers also found that ellagic acid and synthesized urolithins from the pomegranate extract were shown to inhibit the growth of human prostate cancer cells *in vitro*. The researchers concluded that the chemopreventive potential of pomegranate ellagitannins and localization of their bioactive metabolites in mouse prostate tissue suggest that the pomegranate may play a role in prostate cancer treatment and chemoprevention. The researchers also stated "[t]his warrants future human tissue bioavailability studies and further clinical studies in men with CaP [prostate cancer]." (PX0069).

1015. In a study titled, "*Pomegranate polyphenols down-regulate expression of androgensynthesizing genes in human prostate cancer cells overexpressing the androgen receptor*," Doctors Hong, Seeram, and Heber examined the effects of pomegranate polyphenols from POMx Pills and POM Wonderful 100% pomegranate juice on the expression of androgen enzymes and androgen receptors. The study stated: recurrent prostate tumors advance to an androgen-independent state where they progress in the absence of circulating testosterone, leading to advanced cancer. The study also stated: during the development of the androgen-independent state, prostate cells are known to increase intracellular testosterone synthesis, which maintains cancer cell growth in the absence of significant amounts of circulating testosterone and that over-expression of androgen receptor to produce testosterone occurs in androgen-independent prostate cancer. The study found that POM polyphenols from either POMx Pills or POM Wonderful 100% pomegranate juice significantly inhibited gene expression and androgen receptors as a potential mechanism for maintaining healthy prostate cells. The researchers concluded that, "these results suggest that pomegranate polyphenols may be particularly helpful in the subgroup of patients with androgen-independent prostate cancer." (PX0068).

1016. A study by Doctors Rettig, Heber, et al., titled, "*Pomegranate extract inhibits androgen-independent prostate cancer growth through a nuclear factor-kappaB-dependent mechanism*," evaluated POMx Pills and POM Wonderful 100% pomegranate juice and found that their consumption was linked to reduction in cancer growth and decreased plasma PSA levels. The study found that one of the most well-established signaling pathways mediating inflammatory responses relevant to cancer is the NF-kB pathway, which serves as a predictor for recurrence of prostate cancer after radical prostatectomy, and that POMx inhibited NF-kB and cancer cell viability in a dose response fashion *in vitro* and Human LAPC4 prostate cancer xenograft mouse model. Based on the results reported, the researchers concluded "that pomegranate juice could have potential as a dietary agent to prevent the emergence of androgen-independence," thus potentially prolonging life expectancy of prostate cancer patients, and suggested "that this may be a high priority area for future clinical investigation." (PX0070).

***125** 1017. In a study by Dr. Sartippour, et al., titled, "*Ellagitannin-Rich Pomegranate Extract Inhibits Angiogenesis In Prostate Cancer In Vitro And In Vivo*," the *in vivo* results showed that POMx Pills inhibit prostate tumor growth compared to control in immunodeficient mice injected with human prostate cancer cells. The mice were given a dose comparable, using caloric demand scaling, to that found in POMx and taken by humans. The study reported that POMx was shown to significantly decrease the overall blood vessel density in mouse tumors. The study also stated that *in vitro* results showed that POMx Pills significantly inhibited proliferation of human prostate cancer cells at low ug/ml. concentrations. The researchers concluded, "these findings strongly suggest the potential of pomegranate ellagitannins for prevention of the multi-focal development of prostate cancer as well as to prolong survival in the growing population of prostate cancer survivors of primary therapy." (PX0071).

b. Complaint Counsel's experts' opinions of basic research on prostate cancer

1018. Complaint Counsel's experts testified that to substantiate a claim that a food or dietary supplement is an effective treatment for prostate cancer, experts in the field would require an RCT trial with an appropriate sample population of patients with the stage of the disease targeted by the study, and measuring a proper endpoint. (CX1287 (Eastham Expert Report at 0015)).

1019. Complaint Counsel's experts reviewed the available *in vitro* and animal research and concluded that RCTs with proper endpoints are needed to confirm the potential antioxidant effect on prostate cancer observed in a test tube or laboratory setting. (CX1293 (Stampfer Expert Report at 0022); CX1287 (Eastham Expert Report at 0021)).

c. Respondents' experts' opinions of basic research on prostate cancer

1020. Dr. deKernion explained that Respondents' animal studies were on human prostate tissue inserted in the animals and were not merely a study of animal glands. (deKernion, Tr. 3049).

1021. Dr. DeKernion testified that Respondents' *in vitro* and animal studies showed that pomegranate juice inhibited the growth of prostate cancer cells and actually killed cancer cells from humans that had been inserted into mice. (deKernion, Tr. 3044-47, 3120; PX0351 (deKernion, Dep. at 110).

1022. Dr. deKernion testified that while one cannot always extrapolate from *in vitro* and animal results to what the results would be in humans, the pre-clinical studies he reviewed indicated a strong likelihood that, in humans, pomegranate juice would at least inhibit the growth of prostate cancer cells. (deKernion, Tr. 3063-64; PX0161 (deKernion Expert Report at 0011-12)).

1023. Dr. deKernion also testified that that even where the animal and *in vitro* evidence is strong and shows that an agent's mechanism of action works, this evidence does not prove that an agent works in humans. (deKernion, Tr. 3063-64).

d. Determination on Respondents' basic research

***126** 1024. Experts in the field agree that even where the animal and *in vitro* evidence is strong and shows that an agent's mechanism of action works, this evidence alone does not prove that an agent works in humans. (deKernion, Tr. 3063-64; Stampfer, Tr. 722-25 (animal studies do not always correspond with what will occur in humans; one cannot assume that if an *in vitro* assay shows a certain result, the same result will occur in the human body)).

4. Human clinical studies

1025. Respondents have one human clinical study completed and published, the Pantuck Phase II Cancer Study (2006), and one ongoing human clinical study, the Carducci Dose Study, according to their January 13, 2009 summary of their prostate cancer research as of that date. (CX1029 at 0004).

a. Pantuck Phase II Prostate Cancer Study

i. Background to the Pantuck Study

1026. Dr. Allan J. Pantuck is an associate professor of Urology at UCLA Medical School and maintains a clinical practice at UCLA. He attended college at Columbia University, medical school at Robert Woods Johnson Medical School, and has a Masters Degree in Clinical Research from UCLA Medical School. (CX1090 at 0001; CX1341 (Pantuck Dep. at 20-21)).

1027. Dr. Pantuck's clinical appointments include: Attending Urologist at Harbor-UCLA Medical Center, Attending Urologist Wadsworth Veterans Affairs Medical Center, and Attending Urologist, UCLA Medical Center. (CX1090 at 0004).

1028. Dr. Pantuck's professional societies and memberships include the American Society of Clinical Oncology, American Urological Association, Jonsson Comprehensive Cancer Center, and the Society of Urologic Oncology. (CX1090 at 0002).

1029. Dr. Pantuck served as editor of Advances in the Management of Renal Cell Carcinoma and Proceedings of the Irish Society of Surgical Oncology (2003). Dr. Pantuck has been a reviewer for medical journals such as the British Journal of Urology International, The Journal of Urology, Clinical Cancer Research, and Urologic Oncology. (CX1090 at 0003).

1030. In 2001, Dr. Pantuck wrote a letter to Dr. Dornfeld and Dr. Harley Liker (Respondents' scientific advisors) setting forth his protocol concepts for two clinical studies studying the benefits of pomegranate juice in populations of men with prostate cancer. (CX0544 at 0001). According to the letter, “these pilot studies are designed to provide preliminary data to justify further development of pomegranate juice as a chemopreventative agent for prostate cancer.” (CX0544 at 0001). One of the two proposed protocol concepts became the *Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen following Surgery or Radiation for Prostate Cancer* (“Pantuck Study”). (CX1341 (Pantuck, Dep. at 57)).

1031. The Pantuck Study began in 2003. (CX1128 at 0001). According to the protocol, the study was a single-center, three-year study in which approximately 40 patients with prostate cancer treated by radical prostatectomy or radiotherapy with a rising PSA would receive eight ounces of pomegranate juice daily. (CX0666 at 0004-05).

***127** 1032. By 2006, the Pantuck Study was complete and ready for publication. Dr. Pantuck first submitted the manuscript for the study to the *Journal of Clinical Oncology*. (CX1341 (Pantuck, Dep. at 107)). It was initially rejected. (CX1341 (Pantuck, Dep. at 107)). He subsequently submitted it to *Clinical Cancer Research*. (CX1341 (Pantuck, Dep. at 107)). One peer reviewer called the manuscript “excessively advocatory of pomegranate juice as a treatment for prostate cancer.” (CX0790 at 0001). Dr. Pantuck addressed this concern and other comments by making various changes to the manuscript. (CX0790; CX0786).

1033. The Pantuck Study, titled, “*Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Following Surgery or Radiation for Prostate Cancer*,” Pantuck, et al., was published in the journal Clinical Cancer Research in July 2006. (CX0815).

1034. *Clinical Cancer Research* is an extremely well regarded peer-reviewed journal. The process and rigor for being published in *Clinical Cancer Research* is very high. It is considered one of, if not the, finest clinical cancer journals. (CX1352 (Heber Dep. at 268-69).

1035. Dr. Heber testified that the Pantuck Study is considered, “a very highly esteemed paper.” (CX1352 (Heber, Dep. at 268)).

1036. The Pantuck Study was the first clinical trial of pomegranate juice in patients with prostate cancer. (CX0815 at 0001).

1037. According to the published study report, the Pantuck Study was "an open-label, single-arm clinical trial," meaning it was not an RCT and did not have a placebo group. (CX0815 at 0002).

1038. The Pantuck Study cost $479,236.50. (CX1128 at 0001).

ii. About the Pantuck Study

1039. The Pantuck Study included 46 patients who had been diagnosed with prostate cancer. The majority of the patients (68%) had been previously treated for prostate cancer by undergoing radical prostatectomy. The remainder had been treated by radiation (10%), brachytherapy (10%), a combination of surgery and radiation (7%), or cryotherapy (5%). (CX0815 at 0003).

1040. All 46 patients in the Pantuck Study drank eight ounces of pomegranate juice daily until meeting disease progression endpoints. Clinical endpoints were effect on serum prostate specific antigen (PSA), serum-induced proliferation and apoptosis of prostate cancer cells, serum lipid peroxidation, and serum nitric oxide levels. The primary endpoint was the effect on PSA variables, such as change in prostate specific antigen doubling time (PSADT). (CX0815 at 0002).

1041. The presence of detectable PSA after radical prostatectomy or other radical treatment usually indicates cancer is present. (deKernion, Tr. 3051).

1042. PSADT is a mathematical expression of the rapidity with which the prostate specific antigen is rising, and an expression of the rapidity of growth and number of prostate tumor cells. (deKernion, Tr. 3050).

1043. Patients in the Pantuck Study had their blood drawn every three months to have their PSA determined. Disease progression was defined as either a greater than 100% increase in PSA (with a minimum value of 1.0 ng/ml.) compared with the best response observed or any documentation of metastatic or recurrent disease. (CX0815 at 0002).

***128** 1044. Patients in the Pantuck Study who consumed POM Juice experienced a significant statistical increase in PSADT when compared to their own baseline pre-treatment PSADT. (CX0815 at 0001, 0004).

1045. In the Pantuck Study, the average pre-treatment PSADT before intervention was approximately 15 months, and after 33 months, the average post-treatment PSADT was approximately 54 months. Thus, mean PSA doubling time significantly increased from a mean of 15 months at baseline to 54 months post-treatment. (CX1080 at 0004).

1046. The Pantuck Study reported: *in vitro* assays comparing pre-treatment and post-treatment patient serum on the growth of the prostate cancer line LNCaP showed a 12% decrease in cell proliferation and a 17% increase in apoptosis, a 23% increase in serum NO, and significant reductions in oxidative state and sensitivity to oxidation of serum lipids after pomegranate juice consumption versus before pomegranate juice consumption. (CX0815 at 0001).

1047. The Pantuck Study concluded: the statistically significant prolongation of PSA doubling time, coupled with corresponding laboratory effects on prostate cancer *in vitro* cell proliferation and apoptosis, as well as oxidative stress, warrant further testing in a placebo-controlled study. (CX0815 at 0001).

iii. Follow up to the Pantuck Study

1048. In 2008, Dr. Pantuck released the following abstract: Pantuck, AJ, et al., "*Long term follow up of pomegranate juice for men with prostate cancer and rising PSA shows durable improvement in PSA doubling times*," American Society of Clinical Oncology ("Pantuck Phase II Follow-Up Results") which summarized follow-up results for the Pantuck Study. (PX0061).

1049. The Pantuck Phase II Follow-Up Results reported that fifteen (31%) active patients remained on the study. (PX0061). All of the men who had dropped out of the study did so because their PSA had increased. (CX0918 at 0001). As of June 2010, only 12 patients remained active in the study. (CX1128 at 0001).

1050. The Pantuck Phase II Follow-Up Results reported that those who continued on pomegranate juice maintained a lengthening of their PSA doubling time compared to men who did not continue on pomegranate juice. (PX0061; Eastham, Tr. 1305; CX1341 (Pantuck, Dep. at 136)).

1051. The Pantuck Phase II Follow-Up Results reported: mean PSA doubling time for the entire cohort continued to show a significant increase following treatment, from a mean of 15.4 at baseline to 60 months post-treatment, while the median PSA slope decreased 60% from 0.06 to 0.024. Patients remaining on study ("active") were compared to those no longer on study ("non-active"). At baseline, mean PSA doubling times were similar between Active and Non-Active patients. However, post-treatment PSADT prolongation was greater and the decline in median PSA slope was larger in active compared to non-active patients. (PX0061).

1052. The Pantuck Phase II Follow-Up Results concluded that long-term follow up of pomegranate juice consumption in men with prostate cancer and rising PSA following primary therapy demonstrates a durable increase in PSA doubling time and stated that a multi-center, randomized phase III study is ongoing to further evaluate the benefits of pomegranate in a placebo-controlled manner. (PX0061).

iv. Statements by Dr. Pantuck about the Pantuck Study

***129** 1053. Dr. Pantuck explained that the design of the study was for subjects to serve as their own control. Patients had a specific PSA doubling time prior to treatment; patients would then be treated and measured for any change in their doubling time after treatment. (CX1341 (Pantuck, Dep. at 78)).

1054. When the Pantuck Study report was released in 2006, Dr. Pantuck was quoted in an American Association for Cancer Research press release, as stating: "[w]e don't believe we are curing anyone from prostate cancer." He pointed out that "although a third of patients experienced a decrease in PSA during the study, nobody's PSA went to zero." Dr. Pantuck further explained: "The PSA doubling time, however, was longer. For many men, this may extend the years after surgery or radiation that they remain recurrence free and their life expectancy is extended. They may be able to prevent the need to undergo additional therapies, such as radiation, hormonal or chemotherapies." (CX0816 at 0002).

1055. Dr. Pantuck stated that the Pantuck Study did not prove that pomegranate juice prevents or reduces the risk of prostate cancer because all the patients in the study already had prostate cancer, thus his study did not address anything related to causation. (CX1341 (Pantuck, Dep. at 108)).

1056. Dr. Pantuck did not claim that the Pantuck Study proved that pomegranate juice can treat prostate cancer, but explained that the study showed that the doubling time for PSA was prolonged. (CX1341 (Pantuck, Dep. at 108)).

1057. Dr. Pantuck testified that the Pantuck Study showed evidence that the growth of the cancer had been altered by POM Juice. (CX1341 (Pantuck, Dep. at 118-19)).

1058. Dr. Pantuck stated that the feedback from the scientific community with regard to the peer-reviewed published Pantuck Study has primarily been favorable, and that some doctors have discussed the findings with patients. (CX1341 (Pantuck, Dep. at 268-69)).

1059. Dr. Pantuck also stated: "[i]t remains controversial whether modulation of PSA levels represents an equally valid clinical end point." (CX0815 at 0008). According to Dr. Pantuck, "PSA has not been validated prospectively as a surrogate endpoint for a meaningful prostate cancer outcome." (CX1080 at 0001). Dr. Pantuck has also stated that "although PSA changes are thought to be prognostically important, it is based on level 2 evidence, and nobody has ever shown conclusively that changes in PSA kinetics arising from therapeutic intervention is meaningful." (CX1080 at 0001).

1060. Dr. Pantuck testified that the greatest limitation of the Pantuck Study was the lack of a blinded control arm. (CX1341 (Pantuck, Dep. at 110)). In the published study report, Dr. Pantuck specifically pointed to the published study, *Rosiglitizone versus Placebo for Men with Prostate Carcinoma and a Rising Serum Prostate-Specific Antigen Level after Radical Prostatectomy and/or Radiation Therapy*, Cancer 2004: 101:1569-74 ("Rosiglitizone Study"). (CX0815 at 0008).

***130** 1061. The Rosiglitazone Study was a randomized, double-blind placebo-controlled study examining the effect of rosiglitazone in a population of men similar to the patients studied in the Pantuck Study, namely men who had been treated by radical prostatectomy or radiation with a rising PSA. (PX0172 at 0001; CX0815 at 0001; deKernion, Tr. 3069). The Rosiglitazone Study found that 40% of the placebo group and 38% of the treatment group experienced a prolongation in PSADT. (PX0172 at 0001; deKernion, Tr. 3071).

1062. The Rosiglitizone Study authors stated that "[t]he discordance between baseline and post-treatment PSADT in our placebo group suggests caution is required when using changes in PSADT as an outcome in uncontrolled trials and reinforces the value of randomized, placebo-controlled trials in this setting." The Rosiglitazone Study authors concluded that, "the current results do not diminish the potential value of changes in PSADT as an outcome variable for the early evaluation of novel therapeutic agents. In randomized studies of similar design, more active agents may demonstrate the value of PSA kinetics as a screen for biologic activity." (PX0172 at 0006).

1063. Dr. Pantuck stated that the Rosiglitazone Study "highlights the potential limitations of PSA variables in monitoring patients and the need for confirmatory prospective studies using a blinded control arm." (CX0815 at 0008).

b. Carducci Study

i. Background to the Carducci Study

1064. Respondents have also sponsored a human study looking at POMx use in men who have already been treated for prostate cancer. The study is completed and an abstract summarizing the results has been published. *See* M.A. Carducci, et al., *A Phase II Study of Pomegranate Extract for Men with Rising Prostate-Specific Antigen Following Primary Therapy* ("Carducci Study"), J Clin Oncol 29: 2011 (suppl 7; abstr 11). (PX0175; *see also* CX1174). A

final, peer-reviewed study report had not been published at the start of trial in this matter. (*See* Nonparties Johns Hopkins University and Michael A. Carducci, M.D.'s Motion for *In Camera* Treatment, at 5).

1065. The Carducci Study was conducted by Dr. Michael A. Carducci, a professor of oncology and urology at the Johns Hopkins School of Medicine, in Baltimore, Maryland. Within the Cancer Center, he leads two programs, the prostate cancer/genitourinary cancer program and chemical therapeutics. (CX1340 (Carducci, Dep. at 14-15); CX1120).

1066. Dr. Carducci is a graduate of Georgetown University and Wayne State University Medical School. Dr. Carducci did a residency in internal medicine at the University of Colorado in Denver. After completing a year as chief resident at the University of Colorado, he accepted a fellowship in oncology at Johns Hopkins University. (CX1340 (Carducci, Dep. at 13-14)).

1067. Dr. Carducci has conducted 40 to 50 clinical trials relating to prostate cancer and has published approximately 80 articles related to prostate cancer. (CX1340 (Carducci, Dep. at 15-16)).

***131** 1068. In 2006, Dr. Carducci began working with Respondents to design the Carducci Study. (CX0806). Dr. Carducci submitted a proposed protocol for the Carducci Study to Respondents for a larger randomized three-arm study, with two treatment arms and one placebo arm. (CX1340 (Carducci, Dep. at 28-29; CX0064 at 0002, *in camera*).

1069. Respondents conducted a feasibility and cost analysis and decided that the study proposed by Dr. Carducci was too costly. The placebo arm was dropped from the study due to costs, and, in part, due to poor patient acceptance of a placebo. (CX1340 (Carducci, Dep. at 28-29)).

ii. About the Carducci Study

1070. The Carducci Study began in January 2008. (CX1138 at 0002). According to the protocol, the Carducci Study was an 18-month, multi-center, randomized, double-blind, dose-finding study of the effect of two different doses of POMx capsules (one or three capsules) on PSADT in men who had received initial therapy for prostate cancer. (CX1110 at 0007).

1071. An interim analysis of the Carducci Study was conducted in 2009 and shared with Respondents in 2010. (*See* CX1088, *in camera*; CX1102, *in camera*). The final analysis was conducted in August 2010. (CX1146, *in camera*).

1072. In 2011, Dr. Michael Carducci presented the abstract of his clinical research study titled, "*A Phase II Study of Pomegranate Extract for Men with Rising Prostate-specific Antigen Following Primary Therapy*" at the disease specific meeting of the American Society of Clinical Oncology ("Carducci abstract"). (PX0175). Dr. Carducci's abstract was peer-reviewed prior to being selected for presentation. (CX1340 (Carducci, Dep. at 176)).

1073. The Carducci Study was a multi-center, double blind Phase II randomized trial that studied 104 men with rising PSA and without metastases. They were given either a high or low dose (one capsule or three capsules) of POMx, stratified by baseline PSADT and Gleason score, and with no restrictions for PSADT and no upper limit PSA value. (PX0175).

1074. In the Carducci Study, men were treated until progression or for 18 months. PSA levels were obtained every three months. (PX0175).

iii. Results of the Carducci Study

1075. According to the Carducci abstract, 104 men were enrolled and treated for up to six months (92%), 12 months (70%), and 18 months (36%). There was no significant treatment difference ($p = .920$) in PSADT between the one capsule and three capsule dose groups. (CX1174 at 0001).

1076. The Carducci abstract reported: median PSADT lengthened from 11.9 months at baseline to 18.5 months after treatment ($p < .001$), a within group measurement. Thus, it showed that POMx treatment significantly increased the PSA doubling time by over six months in both treatment arms. (CX1174 at 0001).

1077. The Carducci abstract also reported that 13 patients (13%) had declining PSA levels during the study. (CX1174 at 0001).

1078. The Carducci abstract concluded that POMx demonstrates "promising antitumor effects in prostate cancer." (CX1174 at 0001).

iv. Statements by Dr. Carducci about the Carducci Study

***132** 1079. Dr. Carducci testified that the use of PSA doubling time as a primary endpoint to determine if POMx has an effect on the disease state was a scientifically valid way to conduct the study. (CX1340 (Carducci, Dep. at 181-82)).

1080. Dr. Carducci also testified that the endpoint of PSA doubling time is not a standard for regulatory approval of drugs at the FDA level and PSA doubling time as a marker or surrogate has not been proven. (CX1340 (Carducci, Dep. at 89-90)).

1081. Dr. Carducci stated that the Carducci Study was not designed to use endpoints that were "drug-like," but was specifically designed for a natural product and that researchers were looking at safety and whether POMx had an effect on rising PSA. (CX1340 (Carducci, Dep. at 50-51)).

1082. Dr. Carducci testified that the Carducci Study results, as designed and planned, were statistically significant. (CX1340 (Carducci, Dep. at 183)).

1083. Dr. Carducci also testified that without a placebo, he cannot be sure that the effect on PSADT observed in the Carducci Study is attributable to POMx. (CX1340 (Carducci, Dep. at 95)).

1084. According to Dr. Carducci, the Carducci Study was never designed to prove, and did not prove, that POMx prevents or reduces the risk of prostate cancer. (CX1340 (Carducci, Dep. at 87-88)).

1085. According to Dr. Carducci, the Carducci Study was never designed to prove that POMx treats prostate cancer but the study showed that PSA doubling time increased by over six months in both arms of the study. (CX1340 (Carducci, Dep. at 87).

c. Expert opinion on the human clinical studies

i. Complaint Counsel's experts on the Pantuck Study

1086. Complaint Counsel's experts testified that the Pantuck Study fails to provide support for prostate cancer treatment claims for two major reasons: the lack of a placebo control group and the lack of an accepted endpoint marker. (Eastham, Tr. 1295-97; CX1287 (Eastham Expert Report at 0018-19); CX1293 (Stampfer Expert Report at 0024-25); Stampfer, Tr. 782-83).

1087. According to Dr. Stampfer, without a placebo control group in the Pantuck Study, it is not possible to know whether the same change in PSADT would have been observed in this patient group if they had never received POM Juice. (Stampfer, Tr. 869-70; CX1293 (Stampfer Expert Report at 0024)).

1088. According to Dr. Eastham, if the Pantuck Study had included a control group, it is possible that *no* statistical difference between groups would have been observed. Without a placebo, there is no way to eliminate confounding factors that may have impacted PSADT — such as changes in diet, exercise, or the reduction of stress. (Eastham, Tr. 1295-97; CX1287 (Eastham Expert Report at 0018)).

1089. The Pantuck Study used mean PSA doubling time as an endpoint. (PX0060). Complaint Counsel's experts testified that in a prostate cancer treatment trial, PSA doubling time is not a relevant surrogate marker for prostate cancer prevention. Instead, in a prostate cancer treatment trial, overall survival or prostate cancer-specific mortality is the endpoint generally accepted by experts in the field. (CX1293 (Stampfer Expert Report at 0025); Eastham, Tr. 1280; CX1287 (Eastham Expert Report at 0006-09, 0014) (“The primary endpoint in a prostate cancer prevention trial for measuring whether a product has been effective is the prevalence or incidence of prostate cancer between the treatment and placebo groups at the conclusion of the study.”).

***133** 1090. Dr. Eastham criticized the Pantuck Study for the additional reason that the patients studied, with an average pre-treatment PSADT of 15 months, are considered to have a far lower risk of clinical progression, and because of this, it is unclear whether the increase in PSADT observed in the Pantuck Study is clinically significant. (Eastham, Tr. 1297-98).

1091. Complaint Counsel's experts also testified that the Pantuck Study was designed as a treatment study (*i.e.*, study was conducted in men with prostate cancer) and does not provide any evidence that POM Juice is a prostate cancer preventative. (CX1293 (Stampfer Expert Report at 0025); Eastham, Tr. 1294-99).

1092. Dr. Eastham opined that the appropriate sample population for a cancer prevention trial “would involve more than 10,000 healthy men, ages 50 to 65, having no sign of prostate cancer.” (CX1287 (Eastham Expert Report at 0012)).

1093. Dr. Eastham further opined that a “prostate cancer prevention study must be conducted over a long enough period of time to see an effect over time.” CX1287 (Eastham Expert Report at 0014)).

1094. Complaint Counsel's experts also state that the Pantuck Study on POM Juice cannot provide reliable evidence to support claims about POMx Pills' or POMx Liquid's benefit for prostate cancer. (Eastham, Tr. 1306; CX1293 (Stampfer Expert Report at 0025); CX1287 (Eastham Expert Report at 0020)). According to Dr. Eastham, POM Juice is not identical to POMx Pills and POMx Liquid. (CX1287 (Eastham Expert Report at 0020)). POM Juice has more than one active ingredient. Processing may result in eliminating a needed ingredient. (Eastham, Tr. 1306-07). Even if the active ingredient is known and the alternate compound contains the same amount of active ingredient, the alternate compound may contain some other as yet unknown compound that might counter-act the benefit of the active agent. (CX1287 (Eastham Expert Report at 0020)).

1095. Dr. Eastham is not an expert in bioavailability and did not review any of the equivalency studies or articles on POM Juice, POMx Pills or POMx Liquid. (PX0358 (Eastham, Dep. at 94)).

ii. Complaint Counsel's experts on the Carducci Study

1096. Complaint Counsel's experts testified that the Carducci Study cannot provide support for treatment claims because it lacked a placebo-control group and that without a placebo-control group, it is not possible to conclude that POMx caused the change in the patients' PSADT. (Eastham, Tr. 1310; CX1287 (Eastham Expert Report at 0022); Stampfer, Tr. 789-90; CX1293 (Stampfer Expert Report at 0028)).

1097. Complaint Counsel's experts testified also that the Carducci Study cannot provide support for treatment claims because the primary endpoint in the study is PSADT, which has not been accepted by experts in the field as a surrogate for overall survival. (Eastham, Tr. 1310; CX1287 (Eastham Expert Report at 0022); CX1293 (Stampfer Expert Report at 0028)).

1098. As found in F. 1075, the Carducci Study showed no difference between a one pill dose and a three pill dose. Complaint Counsel's expert testified that the lack of a dose response despite a three-fold difference in dosage does not support a causal relationship between POMx and change in PSADT. (Stampfer, Tr. 789-90; CX1293 (Stampfer Expert Report at 0028)).

***134** 1099. Complaint Counsel's experts also testified that the Carducci Study cannot provide support for prevention claims because it evaluated the effect of POMx in men who already had prostate cancer. (Eastham, Tr. 1309-10; *see also* CX1293 (Stampfer Expert Report at 27)).

iii. Complaint Counsel's experts on PSA doubling time

1100. Complaint Counsel's experts testified that in a prostate cancer treatment trial, PSA doubling time is not a relevant surrogate marker for prostate cancer prevention. (Eastham, Tr. 1280; CX1287 (Eastham Expert Report at 0006-09); CX1293 (Stampfer Expert Report at 0025)).

1101. In his testimony, Dr. Eastham stated: modulation of PSA doubling times has not been proven to be of any utility and that no one would propose that changes or modulation of PSA doubling time is a prognostic factor in men with biochemical recurrence after primary therapy for prostate cancer. (Eastham, Tr. 1342, 1345).

1102. Dr. Eastham has also written, in an article titled, "*Prostate-specific antigen doubling time as a prognostic marker in prostate cancer*," Nature Clinical Practice (2005): "PSA doubling time has emerged as an important factor in the evaluation of men with newly diagnosed prostate cancer or prostate cancer that recurs after treatment. PSA doubling time can also be used as a surrogate marker for prostate cancer-specific death." Dr. Eastham's article concluded "PSADT is an important prognostic marker in men with biochemical failure after local therapy for prostate cancer, and it predicts the probable response to salvage radiotherapy, progression to metastatic disease and prostate cancer specific death." (PX0178 at 0001, 0009).

1103. In his expert report, Dr. Stampfer opined "it is unknown if PSADT predicts overall survival in prostate cancer patients throughout its range." (CX1293 (Stampfer Expert Report at 0026)).

1104. Dr. Stampfer also testified that PSA doubling time is a "predictor of disease and mortality" and that, if the extension of PSA doubling time is true, it would substantially prolong lives. (Stampfer, Tr. 869, 873).

iv. Respondents' experts on both clinical studies

(a) PSA doubling time

1105. Dr. deKernion testified that the presence of detectable PSA after radical prostatectomy or other radical treatment usually indicates cancer is present and that PSADT provides an expression of how those tumor cells are going to behave. The longer the PSADT, the less dangerous the growth of the cancer. (deKernion, Tr. 3051-52).

1106. Dr. deKernion testified that the Pantuck Study and the Carducci Study showed that POM Juice and POMx, respectively, slowed down the growth of the tumor cells as expressed by the longer time it took for those tumor cells to double. (deKernion, Tr. 3057).

1107. Dr. deKernion testified that the Pantuck Study and the Carducci Study both showed a dramatic lengthening of PSA doubling time. (deKernion, Tr. 3052-58).

1108. Dr. deKernion opined that PSA doubling time is used to determine success or failure of prostate cancer treatment and that multiple studies support that PSADT is correlated with the risk of clinical tumor and recurrence and, therefore, must have some association with longevity. (PX0161 (deKernion Expert Report-0004; deKernion, Tr. 3050-58).

***135** 1109. Dr. deKernion stated that PSA doubling time is clearly a useful marker in determining risk or outcome in patients following prostate cancer treatment. (deKernion, Tr. 3055).

1110. Dr. deKernion testified that given the understanding of PSA doubling time in predicting risk of clinical recurrence and to some extent survival, it is logical to use changes in PSADT as indicative of an intervention's effectiveness regarding prostate tumor behavior. (PX0161 (deKernion Expert Report at 0007, 0011-12)).

1111. Dr. deKernion also testified that the PSA doubling time is not accepted by experts in the field of prostate cancer as a surrogate endpoint for clinical benefit in chemotherapy trials. (deKernion, Tr. 3096).

1112. Dr. Heber testified that PSA doubling time is a “very important clinically utilized marker of clinical status.” (CX1352 (Heber, Dep. at 314)).

1113. Dr. Heber testified that there is a lot of support from the urological community to get the FDA to accept PSA doubling time as a surrogate endpoint and that there is “a lot of feeling in the urological community and scientific agreement that [the] rate of rise of PSA is an important biomarker.” (CX1352 (Heber, Dep. at 316-17)).

(b) Placebo control arm

1114. Dr. deKernion testified that a control arm is not necessary for an objective Phase II study that is exploratory in nature. Many studies on food and many other categories in science are observational type studies without use of a control—a control is important when there is a high risk that the observed effect could be attributed to something other than the substance being tested. (PX0161 (deKernion Expert Report at 0009); deKernion, Tr. 3059-60, 3066; PX0351 (deKernion, Dep. at 97-99)).

1115. Dr. deKernion testified that in both the Pantuck Study and the Carducci Study, the control was the previous doubling time prior to treatment. The researchers measured the doubling time before patients took POM Juice or POMx and then measured doubling time afterwards, comparing one to the other. This was done in lieu of a separate placebo group. (deKernion, Tr. 3059).

1116. Dr. deKernion testified that a control arm is often used to control for the placebo effect, that one purpose of a placebo control group is to limit confounding factors, and that the use of a placebo group is more important when you have a subjective reporting, as opposed to an objective reporting. (deKernion, Tr. 3059-60, 3066-67; PX0351 (deKernion, Dep. at 97-99)).

1117. Dr. deKernion specifically testified that a placebo control arm is not needed when PSADT is the study endpoint to assess the efficacy of the product or therapy being studied. In the Pantuck Study and the Carducci Study, the researchers were looking and testing objective blood results, and there is no evidence to suggest the placebo effect plays any role in modulating the PSADT of the subject. (deKernion, Tr. 3059-60, 3081; PX0351 (deKernion, Dep. at 97-99).

***136** 1118. Dr. deKernion also testified that without a placebo, one cannot be certain that the effect on PSA doubling time seen in the Carducci Study is attributable to POMx. (deKernion, Tr. 3103).

(c) Respondents' experts' conclusions

1119. Dr. Heber testified that in laboratory studies he conducted, he found no difference in the antioxidant effect between POM Juice and POMx products and that animal studies indicate that the effects of pomegranate juice and POMx Pills on prostate cancer are equivalent. (CX1352 (Heber, Dep. at 336); Heber, Tr. 2002; Heber, Tr. 2186-87).

1120. At trial, Dr. Heber testified that there is competent and reliable science showing that the POM Juice and POMx lengthen the PSA doubling time for men who have had prostate cancer and, thus, it is likely for those men to have a deferred recurrence or death from that disease; and that POM Juice and POMx are likely to lower the risk of prostate problems for men who have not yet been diagnosed with prostate cancer. (Heber, Tr. 2012-13).

1121. In his expert report, Dr. Heber opined: the statistically significant prolongation of PSA doubling time, corresponding laboratory effects on prostate cancer *in vitro* cell proliferation and apoptosis, as well as oxidative stress and inflammation, provide strong scientific rationale for the statement that pomegranate juice promotes prostate health. (PX0192 (Heber Expert Report at 0027)).

1122. Dr. deKernion testified that in order to show an effect of POM Products on prostate cancer, the best way to do that research is on patients whose prostate had been removed because the presence of PSA elevation is almost always an indication of remaining cancer. This is how the Pantuck Study and Carducci Study were conducted. (deKernion, Tr. 3057).

1123. Dr. deKernion opined that all “evidence supports that PSA changes including doubling time after failure of definitive therapy truly reflect a change in the tumor cell growth; no evidence exists to suggest that a biochemical effect on PSA measurement can account for changes; and no evidence exists that PSA doubling time significantly and spontaneously lengthens in a patient with known biochemical or clinical cancer.” (PX0161 (deKernion Expert Report at 0008)). Therefore, in the Pantuck Study, it is only logical to conclude that the agent causing the change in PSA doubling time is POM Juice, especially given the pre-clinical evidence of the effect of the POM Products on

prostate cancer, "and the results of these studies could not be explained otherwise." (PX0161 (deKernion Expert Report at 0011-12)).

1124. Dr. deKernion opined that POM Products are beneficial to prostate health and although there is not 100% proof that POM Products reduce the risk of prostate cancer, the same mechanism shown in the *in vitro* and animal studies and in the Pantuck and Carducci human studies showed, with a "high degree of probability," that POM Juice and POMx would inhibit the clinical development of prostate cancer in men who have not been diagnosed with that disease. (deKernion, Tr. 3119-20, 3126; PX0351 (deKernion, Dep. at 41-42)).

***137** 1125. Dr. deKernion testified that there is a high degree of probability that POM Products inhibit the clinical development of prostate cancer cells even in men not diagnosed with prostate cancer. (deKernion, Tr. 3126; PX0351 (deKernion, Dep. at 76-77) (in healthy men, who have never been diagnosed with prostate cancer, POM Juice and POMx could possibly play a role in preventing them from getting prostate cancer).

1126. Dr. deKernion testified that there is a high probability that the POM Products provide a special benefit to men with PSA after radical prostatectomy. (deKernion, Tr. 3126).

1127. Dr. deKernion also testified that the Carducci Study did not follow patients for a long enough time, especially for those with a long PSA doubling time, to prove that POMx will prolong their lives. (deKernion, Tr. 3103).

5. Determinations on the human clinical studies

a. PSA doubling time

1128. Clinicians use PSADT as a prognostic tool at the time of biochemical recurrence of prostate cancer to predict the odds of clinical progression of the disease in prostate cancer patients who have undergone initial treatment. (Eastham, Tr. 1260; PX0351 (deKernion, Dep. at 93)). *See also* PX0178 at 001 (Complaint Counsel's expert writing: "PSA doubling time has emerged as an important factor in the evaluation of men with newly diagnosed prostate cancer or prostate cancer that recurs after treatment. PSA doubling time can also be used as a surrogate marker for prostate cancer-specific death.").

1129. Clinicians accept PSADT as a useful marker in determining risk or outcome in patients following prostate cancer treatment and measuring the likelihood of recurrence of the tumor after a man has had his prostate removed. (deKernion, Tr. 3051, 3055); *see also* CX1341 (Pantuck Dep. at 254-55) (clinicians find PSADT to be clinically important for prostate cancer treatment and one of the most important variables that a doctor can discuss to characterize a prostate cancer patient).

1130. Some published studies demonstrate acceptance of PSA doubling time as a valid predictor of disease:
• In a study titled, "*Does PSADT After Radical Prostatectomy Correlate With Overall Survival?"* in the January 2011 edition of the Journal of Urology, Dr. Anna Teeter and her colleagues wrote of the "widespread acceptance" that PSADT after radical prostatectomy predicts prostate cancer mortality; that this has been "well established"; that PSADT is a "useful tool for identifying men at increased risk of all-cause mortality early in their disease course"; and that PSADT is "a powerful predictor of overall survival." (PX0167).

• In a study titled, "*Stratification of Patient Risk Based on Prostate-Specific Antigen Doubling Time after Radical Retropublic Prostatectomy*" in the April 2007 issue of Mayo Clinic Proceedings, Dr. Tollefson and colleagues wrote that PSADT was "a highly significant and reliable test" to determine the likelihood of disease recurrence and death, an "excellent indicator of clinical disease recurrence" and the only significant factor that predicts clinical

progression." The researchers concluded that, "prostate-specific antigen doubling time is an independent predictor of clinical disease recurrence and mortality after surgical biochemical failure." (PX0166).

***138** • In a study titled, "*Risk of Prostate Cancer-Specific Mortality Following Biochemical Recurrence After Radical Prostatectomy*," Dr. Freedland and colleagues used PSADT to "define risk factors for prostate cancer death following radical prostatectomy and to develop tables to risk stratify for prostate cancer-specific survival." The researchers found that clinical parameters such as PSADT can help risk stratify patients for prostate cancerspecific mortality following biochemical recurrence after radical prostatectomy. (PX0165).

• In a study titled, "*Recurrence Patterns After Radical Retropubic Prostatectomy: Clinical Usefulness of Prostate Specific Antigen Doubling Times and Log Slope Prostate Specific Antigen*" published in the October 1997 edition of the Journal of Urology, Drs. Patel, deKernion, et al., studied the correlation between prostate specific antigen doubling time and clinical recurrence in patients with detectable PSA after radical retropubic prostatectomy and concluded that, after PSA became detectable, PSA doubling time was a better indicator of the risk and time to clinical recurrence after radical retropubic prostatectomy than other factors including preoperative PSA. (PX0162).

1131. There are no studies proving that modulating PSADT (*i.e.*, changing the rate of the PSA doubling time) changes the natural history of prostate cancer by delaying the development of metastases or death from the disease. (Eastham, Tr. 1261; CX1287 (Eastham Expert Report at 0011, 0019); PX0161 (deKernion Expert Report at 0004); PX0351 (deKernion, Dep. at 52-53)).

1132. The FDA has not accepted PSADT as a surrogate endpoint for clinical benefit in chemotherapy trials. (deKernion, Tr. 3096; CX1352 (Heber, Dep. at 316-17); CX1340 (Carducci, Dep. at 89-90)).

1133. Respondents acknowledged in a report on their expert panel on prostate cancer: "To date, all POM Wonderful clinical evaluations of pomegranate-derived products in prostate cancer have used PSADT as the primary endpoint. While data obtained using this approach has generated a high degree of interest from patients and urologists, it is unclear whether PSADT is acceptable as a registrational endpoint for a drug designed to prolong the time to disease progression after initial therapy for prostate cancer." (CX1104 at 0004).

1134. Experts in the field of prostate cancer agree that PSADT is not an accepted surrogate endpoint for survival or prostate cancer-specific mortality in prostate cancer treatment clinical trials. (Eastham, Tr. 1297; Stampfer, Tr. 782-83; deKernion, Tr. 3096; CX1287 (Eastham Expert Report at 0010); CX1293 (Stampfer Expert Report at 0025); CX1340 (Carducci, Dep. at 88-90); CX1341 (Pantuck, Dep. at 253-54)). Many men with increases in PSA after initial therapy do not die of prostate cancer. On the other hand, some men succumb to prostate cancer without an increase in PSA. (Stampfer, Tr. 783; Eastham, Tr. 1258; deKernion, Tr. 3088).

b. Research results

***139** 1135. There is no clinical study, research or trial that provides 100% proof that the POM Products prevent prostate cancer in humans. (deKernion, Tr. 3062, 3119).

1136. There is no clinical study, research or trial that provides 100% proof that the POM Products reduce the risk of prostate cancer in humans. (deKernion, Tr. 3062-63, 3119).

1137. There is clinical research demonstrating that patients who were given POM Products had their PSA go down, which is significant evidence that something is happening to those tumor cells. (deKernion, Tr. 3065).

1138. Although one cannot make a firm claim that the POM Products are absolutely preventative, given the data presented in the Pantuck Study and the Carducci Study, it is reasonable to state that POM Products have shown an effect on prostate cancer with little or minimal toxicity. (PX0161 (deKernion Expert Report at 0011)).

6. Conclusions

1139. Pomegranate consumption can potentially be used to prevent or delay clinical recurrence of prostate cancer once a patient experiences biochemical recurrences (PSA recurrences) after a radical prostatectomy. (PX0192 (Heber Expert Report at 0027)).

1140. No Phase III randomized trial has been completed to prove that POM Products prolong the life of patients who have recurrence of prostate cancer after supposedly curative therapy. Effective trials are ongoing. As reflected by changes in PSA doubling time, the POM Products are a reasonable adjunct for a patient who wishes to help their general health and possibly avoid a clinical recurrence of prostate cancer. (*See* PX0161 (deKernion Expert Report at 0011)).

1141. The statistically significant prolongation of PSA doubling time, coupled with corresponding laboratory effects on prostate cancer *in vitro* cell proliferation and apoptosis as well as oxidative stress, and inflammation provides strong scientific rationale for the statement that pomegranate juice promotes prostate health and has led to ongoing phase III clinical trials. (PX0192 (Heber Expert Report at 0027)).

1142. Competent and reliable scientific evidence supports the conclusion that the POM Products support prostate health, including by prolonging PSA doubling time in men with rising PSA after primary treatment for prostate cancer. (PX0161 (deKernion Expert Report); (PX0192 (Heber Expert Report at 0027); deKernion, Tr. 3126; PX0351 (deKernion, Dep. at 41-42); Heber, Tr. 2012).

1143. There is insufficient competent and reliable scientific evidence to support the conclusion that the POM Products treat, prevent, or reduce the risk of prostate cancer or that clinical studies, research and/or trials establish these effects. (CX1287 (Eastham Expert Report at 0024-26); Stampfer, Tr. 790-91; CX1293 (Stampfer Expert Report at 0029-30); *see also* Eastham, Tr. 1317-19)); *see also* deKernion, Tr. 3062-63; *see also* PX0161 (deKernion Expert Report at 0011)).

I. Substantiation for Respondents' Erectile Dysfunction Claims

1. Substantiation standard for erectile dysfunction claims

***140** 1144. Clinical evidence supported by basic scientific evidence is sufficient to support claims that pomegranate juice has a potential benefit for vascular blood flow and the vascular health of the penis. (PX0149 (Burnett Expert Report at 0006)).

1145. Experts in the field of erectile dysfunction would not require RCTs to substantiate health benefit claims for harmless pure fruit products like pomegranate juice. (PX0149 (Burnett Expert Report at 0006-07); Burnett, Tr. 2272, 2303; PX0189 (Goldstein Expert Report at 0003); Goldstein, Tr. 2600-02, 2611, 2620).

1146. Experts in the field of erectile dysfunction would not require that pomegranate juice or its derivatives be subjected to RCTs before concluding that pomegranate juice has a beneficial effect on preserving erectile function. (PX0149 (Burnett Expert Report at 0006-07); Burnett, Tr. 2272-74, 2303; PX0189 (Goldstein Expert Report at 0003); Goldstein, Tr. 2600-02, 2611, 2620).

1147. Experts in the field of erectile dysfunction would not require that pomegranate juice or derivatives be subjected to RCTs before concluding that pomegranate juice has a potential beneficial effect on erectile dysfunction. (Burnett, Tr. 2272-74, 2303).

1148. Experts in the field of erectile dysfunction would require that a product be scientifically evaluated through rigorous scientific and clinical studies, and believe that animal and *in vitro* studies alone are not sufficient, before concluding that pomegranate juice treats erectile dysfunction in a clinical sense. (Burnett, Tr. 2261-64; 2285-86; 2303).

2. Background facts on erectile health and dysfunction

a. Erectile health distinguished from erectile dysfunction

1149. Erectile health is having a healthy erectile mechanism. (PX0189 (Goldstein Expert Report at 0008)).

1150. Erectile health is promoted when the male practices strategies that encourage endothelial health, such as exercise, use of the Mediterranean diet, and use of endothelial-healthy medications (such as aspirin, statins, and PDE5-inhibitors). (PX0189 (Goldstein Expert Report at 0008); PX0190; PX0352 (Goldstein, Dep. at 148)).

1151. Erectile health is distinguished from erectile dysfunction. (PX0189 (Goldstein Expert Report at 0008)).

1152. Erectile dysfunction is the consistent or persistent inability to obtain and/or sustain an erection adequate for sexual intercourse. (Burnett, Tr. 2257; PX0189 (Goldstein Expert Report (Goldstein Expert Report at 0008-09)).

1153. Improving ones erectile function may also help improving ones erectile dysfunction. (Burnett, Tr. 2303).

1154. A clinical treatment for erectile dysfunction is different than the concept of something having a potential beneficial effect on erectile tissue function and health. (PX0349 (Burnett, Dep. at 56-57)).

1155. Erectile dysfunction has been estimated to affect up to 30 million men in the United States. (PX0189 (Goldstein Expert Report at 0008-09)).

1156. The most common cause of erectile dysfunction is cardiovascular disease. (PX0189 (Goldstein Expert Report at 0009)).

***141** 1157. “Subjects with ED seem to have a vascular mechanism similar to that seen in atherosclerosis [...] and therefore, a diagnosis of ED may be seen as a sentinel event that should prompt investigation for coronary heart disease (CHD) in asymptomatic men.” (PX0190 at 0002).

1158. Cardiovascular disease is strongly associated with endothelial cell dysfunction. (PX0189 (Goldstein Expert Report at 0009)).

1159. Endothelial cell dysfunction may act to adversely affect the structure and function of the critical arterial inflow mechanism, the critical expandability of the erectile tissue and the critical integrity of the veno-occlusive mechanism. (PX0189 (Goldstein Expert Report at 0009)).

1160. The erectile mechanism is largely dependent on the health, integrity, structure and function of the arterial vascular and corporal erectile tissue systems. (PX0189 (Goldstein Expert Report at 0008)).

b. Physiology of human penile erection

1161. The penis consists of two corpora cavernosa or erectile chambers and a corpus spongiosum or erectile tissue surrounding the urethra. The corpora cavernosa erectile tissue are contained by a thick and strong fibrous lining called the tunica albuginea that stretches to some extent during penile erection but also acts as a container to provide axial rigidity to the erect penis. (PX0189 (Goldstein Expert Report at 0006); Burnett, Tr. 2245).

1162. The erectile tissue includes numerous interconnecting lacunar spaces that fill with blood during erection, and are lined by vascular endothelial cells. The lacunar spaces are surrounded by vascular smooth muscle and connective tissue such as collagen and elastin. (PX0189 (Goldstein Expert Report at 0006)).

1163. Arterial blood enters the corpora cavernosa via the right and left cavernosal arteries. There are numerous small regulatory arteries off the cavernosal artery called helicine arterioles that open into the lacunar spaces. At the peripheral edge of the erectile tissue, underneath the tunica albuginea, there are small veins called sub-tunical venules that drain blood from the peripheral lacunar spaces through the tunica into draining veins at the side of the penis to eventually return blood back to the heart. (PX0189 (Goldstein Expert Report at 0006); Burnett, Tr. 2245-46).

1164. In the flaccid state, smooth muscle in the helicine arterioles and surrounding the lacunar spaces are contracted allowing only small amounts of blood to enter the erectile chambers. Relaxation of the vascular smooth muscle of the corpora cavernosa leads to penile erection. Dilation of the helicine arterioles increases perfusion of high pressure arterial blood into the lacunar spaces. Relaxation of the smooth muscle surrounding the lacunar spaces results in engorgement of the erectile tissue and expansion of the erectile tissue against the tunca albuginea. This erectile tissue expansion results in compression of the sub-tunical venules that restricts blood outflow from the corporal erectile chambers. This venous trapping mechanism is the corporal veno-occlusive mechanism. Due to the hydraulic nature of increasing blood inflow and perfusion pressure and restricting blood outflow, there is an increase in intracavernosal pressure to a value approximating the mean systemic arterial blood pressure. The containment of pressure within the tunica albuginea leads to axial rigidity and penile hardness that enables functional penile penetration. (PX0189 (Goldstein Expert Report at 0006-07); Burnett, Tr. 2246-48).

c. The role of nitric oxide in human penile erection

***142** 1165. Nitric oxide ("NO") has a beneficial effect on blood flow. (Heber, Tr. 1969, 2140; Burnett, Tr. 2250).

1166. Blood vessels and the flow of blood to the penis are important to erectile function. (Melman, Tr. 1169).

1167. While many types of molecules participate in the erection process, NO "is the key molecule that governs penile erection," and is "known to be of paramount importance in the maintenance of good erectile function." (PX0149 (Burnett Expert Report at 0004); Burnett, Tr. 2249-50, 2276; PX0190 at 0006). Complaint Counsel's erectile dysfunction expert, Dr. Melman, agreed that NO employs a critical role in the erectile process

and that there are men whose erectile dysfunction is caused by the inadequate production of NO. (Melman, Tr. 1169; PX0360 (Melman, Dep. at 32)).

1168. The physiologic mechanism of penile erection involves release of NO in the corpus cavernsosum during sexual stimulation. (PX0149 (Burnett Expert Report at 0004-05); PX0189 (Goldstein Expert Report at 0007)).

1169. The NO is released from shear stress off the endothelial cells in the lacunar spaces within the corpora cavernosa and from autonomic nerves that innervate the erectile tissue and are activated during sexual stimulation. (PX0189 (Goldstein Expert Report at 0007); Burnett, Tr. 2248-49; PX0349 (Burnett, Dep. at 88-90)).

1170. Upon its synthesis and release from their cellular sources, NO diffuses to neighboring vascular and trabecular smooth muscle cells lining the lacunar spaces. (PX0149 (Burnett Expert Report at 0004-05); PX0189 (Goldstein Expert Report at 0007); PX0349 (Burnett, Dep. at 87-90)).

1171. The NO activates the enzyme guanylate cyclase within the vascular smooth muscle cells that results in increased levels of cyclic guanosine monophosphate (cGMP), an effector of smooth muscle relaxation via protein kinase G (PKG) actions. (PX0149 (Burnett Expert Report at 0004-05); PX0189 (Goldstein Expert Report at 0007); PX0349 (Burnett, Dep. at 87-90)).

1172. NO, cGMP and PKG mediate the relaxation of the cavernous smooth muscle and vasodilation of blood vessels. (PX0149 (Burnett Expert Report at 0004); PX0189 (Goldstein Expert Report at 0007)).

1173. Persistent smooth muscle relaxation leads to tissue engorgement within the corpora cavernosa and penile erection. (PX0189 (Goldstein Expert Report at 0007)).

1174. Cyclic guanosine monophosphate is hydrolyzed by the phosphodiesterases, predominantly type 5 (“PDE5”), to inactive 5'-GMP, terminating penile erection. (PX0149 (Burnett Expert Report at 0004-05); PX0349 (Burnett, Dep. at 92-93)).

1175. PDE5 inhibitors such as sildenafil (Viagra), vardenafil (Levitra) and tadalafil (Cialis) inhibit PDE5, thereby augmenting cGMP levels. (PX0149 (Burnett Expert Report at 0004-05); PX0349 (Burnett, Dep. at 93)).

1176. Endothelial NO function is fundamental to the vascular process of penile erection. (Burnett, Tr. 2290).

1177. The vascular function of vessels in various parts of the body behave similarly. (Burnett, Tr. 2290).

d. Antioxidant activity of pomegranate juice

***143** 1178. Oxidative stress molecules in the body, which are produced by various kinds of conditions of inflammatory change, disease states, etc., have deleterious effects throughout the body in the vasculature and in the penis that actually counter-effect the body's NO regulatory mechanism, not just for transient effects to bring about erection, but also to maintain the wellness of the erectile tissue. (PX0349 (Burnett, Dep. at 89-90); Burnett, Tr. 2250-51; Goldstein, Tr. 2604-05; PX0190 at 0006).

1179. Antioxidants are well known to enhance the biological actions of NO by virtue of their capacity to stabilize NO by protecting against the oxidative destruction of NO by oxidative stress molecules. (PX0056 at 0002; PX0059 at 0001, 0004; PX0190 at 0006; PX0149 (Burnett Expert Report at 0005-06); PX0189 (Goldstein Expert Report at 0004-05); Goldstein, Tr. 2604-05).

1180. The antioxidant effect described in F. 1179 results in much higher and more prolonged cellular concentrations of NO, leading to markedly increased biological actions of NO. (PX0056 at 0002; PX0059 at 0001, 0004; PX0149 (Burnett Expert Report at 0005-06)).

1181. Antioxidants play a potential role in preserving erectile tissue health and function. (Burnett, Tr. 2285-86; Goldstein, Tr. 2604-05).

1182. Pomegranate juice possesses potent flavonoid antioxidants. (PX0149 (Burnett Expert Report at 0005-06); Burnett, Tr. 2250-51; PX0189 (Goldstein Expert Report at 0011); PX0056; PX0058; PX0051; PX0004).

1183. Pomegranate juice enhances the production of endothelial NO formation by suppressing the oxidative stress molecules that oppose the endothelial NO synthase function. (PX0149 (Burnett Expert Report at 0005-06); PX0349 (Burnett, Dep. at 103, 119); Burnett, Tr. 2251-54).

1184. Pomegranate juice possesses anti-oxidative molecular effects and these effects activate endothelial NO mechanisms in vasculature which serve potential beneficial effects on vascular blood flow and promote vascular biologic health of the penis. (PX0149 (Burnett Expert Report at 0005-06)).

3. Erectile dysfunction studies

1185. Respondents have sponsored two human studies addressing erectile dysfunction-related endpoints and at least six *in vitro* and animal studies looking at NO metabolism in an effort to identify a potential erectile dysfunction benefit from pomegranate juice. (CX1193 at 0001; CX0716 at 0029; PX0051 at 0001; PX0056 at 0001; PX0057 at 0001; PX0059 at 0001; PX0004 at 0001; PX0058 at 0001).

a. Tools for human clinical studies evaluating erectile function

1186. Both Complaint Counsel's and Respondents' erectile dysfunction experts agree it is important to use a validated tool when conducting a human clinical trial investigating whether a product treats, prevents, or reduces the risk of erectile dysfunction. (Melman, Tr. 1099; CX1289 (Melman Expert Report at 0010); Burnett, Tr. 2266 (agreeing that experts would rely on a validated tool when conducting a human clinical trial investigating whether a product treats erectile dysfunction)).

***144** 1187. A validated tool is “established as measuring erectile dysfunction through rigorous assessments involving reliability testing, validity testing, construct validity, and other criteria.” (Burnett, Tr. 2266; *see also* Melman, Tr. 1100 (stating that validation means that a measure has been shown to have statistical reliability)).

1188. Validation is important because “[r]igorous assessment of patient-reported outcomes is necessary to ensure reliability, responsiveness, and discriminant and predictive validity. These attributes ensure that the instrument measures what it states it measures, and that the results are reproducible and sensitive to change.” (PX0352a02 at 0002; PX0352 (Goldstein, Dep. at 55-56)).

1189. Dr. Melman testified that a study to support a treatment for erectile dysfunction must show that a man can complete intercourse with sexual satisfaction and achieve orgasm. (Melman, Tr. 1141-43). *See also* Melman, Tr. 1146-47 (In the hypothetical case of “a man [that] hasn't been able to have an erection for five years, then he tries [a] product and he now has an erection and he can penetrate his wife and bring her to sexual satisfaction,

but he doesn't have an orgasm himself," the maker of the product "can't tell the public about what [the product has] done.").

i. The IIEF

1190. The International Index of Erectile Function ("IIEF") is a validated measure for evaluating change in erectile function. (JX0003 ¶ A.9; Melman, Tr. 1099; CX1289 (Melman Expert Report at 0010); Burnett, Tr. 2293; PX0352 (Goldstein, Dep. at 65); CX1193 at 0002; *see also* CX1240 at 0003, *in camera* (stating in a pre-investigational new drug application for POMx that the FDA considered the "erectile function domain of the IIEF ... as the most appropriate measure of the efficacy of the product for treating erectile dysfunction")).

1191. The IIEF is a 15 question psychometrically validated instrument designed to assess a man's overall erectile and sexual function via the individual domains of erectile function, orgasmic function, sexual desire, intercourse satisfaction and overall satisfaction. (PX0189 (Goldstein Expert Report at 0009); Melman, Tr. 1099-1101; CX0686 at 0026-29; CX1193 at 0002 (stating that the "IIEF is a validated questionnaire whose erectile function domain score has been demonstrated to correlate with ED [erectile dysfunction] intensity")).

1192. The erectile function domain relates only to erectile performance and does not evaluate orgasm or ejaculation. (Goldstein, Tr. 2604).

1193. The IIEF was designed for evaluating pharmaceuticals, not natural botanical products. (Goldstein, Tr. 2603-04).

1194. Dr. Goldstein, who was at the Pfizer Drug Company meeting where the IIEF was developed for its pharmaceutical product Viagra, testified that the IIEF was originally intended for pharmaceutical products in patients with IIEF scores consistent with erectile dysfunction. (PX0352 (Goldstein, Dep. at 67-69)).

***145** 1195. The IIEF has some ambiguous questions. For example, one question asks how often do you get an erection, but does not qualify as to what type of erection, *i.e.*, mild erection; moderate erection, etc. (Goldstein, Tr. 2603). Also, IIEF has deficiencies as it requires patient recall and involves patients' subjective interpretation of their erection physiology. (Burnett, Tr. 2293-94).

ii. The GAQ

1196. The Global Assessment Questionnaire ("GAQ") is not a validated measure for assessing erectile function. (Melman, Tr. 1118; Burnett, Tr. 2294; PX0352 (Goldstein, Dep. at 73)).

1197. By itself, experts would not consider the GAQ to be a sufficient endpoint in a clinical study evaluating a treatment for erectile dysfunction. (Burnett, Tr. 2294-95) (agreeing that the GAQ was more vague and nonspecific than a validated tool in measuring whether a therapy had an effect on the ability to achieve and maintain erections).

1198. The GAQ is commonly accepted as a standardized instrument among those conducting erectile dysfunction research. The GAQ's "clinical meaningfulness based on its simplicity makes it extremely widely used and very important in assessing erectile function." (Goldstein, Tr. 2602-03, 2634; Burnett, Tr. 2304; PX0349 (Burnett, Dep. at 127); CX1337 (Forest, Dep. at 79)).

1199. In the development of pharmaceutical products for sexual medicine, the FDA widely approves of non-validated, patient-reported outcomes, such as the GAQ. (PX0352 (Goldstein, Dep. at 57)).

1200. The GAQ does not measure the degree of improvement, indicate how often a study participant experienced improved erections, or show whether he was able to complete sexual intercourse. (Melman, Tr. 1120, 1122; CX1289 (Melman Expert Report at 0014)).

1201. The GAQ is a single yes/no question designed to assess the individual self-evaluation of the study treatment (*e.g.*, pomegranate juice consumption versus placebo consumption) effect on the patient's sexual health concern. (PX0189 (Goldstein Expert Report at 0009); Goldstein, Tr. 2603).

1202. The GAQ is a very easy evaluation and written for a high school educated person to understand. (Goldstein, Tr. 2603; CX1337 (Forest, Dep. at 151-52)).

1203. The GAQ is used in all sexual medicine trials. (Goldstein, Tr. 2603; PX0352 (Goldstein, Dep. at 57)).

1204. The GAQ was used by Pfizer in testing sildenafil (Viagra) and in every vardenafil (Levitra) and tadalafil (Cialis) trial. (Burnett, Tr. 2304; Goldstein, Tr. 2602; PX0352 (Goldstein, Dep. at 57)).

1205. The GAQ is a very “acceptable,” informative,” and “valuable” tool to use for testing pomegranate juice. (Burnett, Tr. 2294, 2304).

b. The Forest/Padma-Nathan Study

i. About the Forest/Padma-Nathan Study

1206. POM sponsored a study by Mr. Christopher Forest, Dr. Harin Padma-Nathan, and Dr. Harley Liker, titled, *Efficacy and Safety of Pomegranate Juice on Improvement of Erectile Dysfunction in Male Patients with Mild to Moderate Erectile Dysfunction: A Randomized, Placebo-Controlled, Double-Blind, Crossover Study* (“Forest/Padma-Nathan Study”). (CX1147 at 0004; CX1193 at 0001, 0004). The clinical trial was conducted in 2004 to 2005, and the results were later published in the *International Journal of Impotence Research* in 2007. (CX1193 at 0001; CX1147 at 0004).

***146** 1207. Dr. Padma-Nathan, the principal investigator of the Forest/Padma-Nathan Study, received the first fellowship from the American Foundation for Urologic Disease that was awarded in the area of erectile dysfunction. The prestigious fellowship is awarded to two urologists annually. His work involved two years of basic lab and *in vitro* scientific research in smooth muscle pharmacology cosponsored by the Department of Urology and the Department of Cardiology at Boston University. (CX1338 (Padma-Nathan, Dep. at 23, 32-33)). Dr. Padma-Nathan is a man of repute in the field of urology. (Heber, Tr. 2000).

1208. Mr. Forest, at the time of the Forest/Padma-Nathan Study, was Physician Assistant and Director of Clinical Trials, working for Dr. Padma-Nathan. (CX1337 (Forest Dep. at 20)).

1209. Dr. Liker, POM's medical director, was involved with the design and conduct of the Forest/Padma-Nathan Study. (*See* CX 1350 (Liker, Dep. at 191); CX0637 at 0001; CX0622 at 0001; CX0704 at 0001; CX0644 at 0001-02; CX0834 at 0001-02). Dr. Liker also reviewed and approved changes to the article prior to publication. (CX0881 at 0001-02; *see also* CX0856 at 0001) (sending revised draft of manuscript to Dr. Liker)).

1210. The Forest/Padma-Nathan Study was a randomized, double-blinded, placebo-controlled pilot study that examined the efficacy of POM Juice versus placebo in improving erections in 53 men with mild to moderate erectile dysfunction. (CX1193 at 0001; CX1289 (Melman Expert Report at 0012-13)).

1211. The Forest/Padma-Nathan Study used a crossover design, and the 53 participants who completed the study received a different beverage during the two 28-day treatment periods. (CX1289 (Melman Expert Report at 0012-13); CX1193 at 0002-03). Participants in cohort one consumed POM Juice in period one and then switched to the placebo beverage in period two. (CX1193 at 0002-03). Participants in cohort two consumed the placebo beverage in period one and POM Juice in period two. (CX1193 at 0002-03).

1212. The Forest/Padma-Nathan Study used the GAQ as the primary outcome measure and the IIEF as the secondary outcome measure. (CX1337 (Forest, Dep. at 84); CX1193 at 0002; Melman, Tr. 1120; CX0686 at 0008).

1213. The Forest/Padma-Nathan Study hypothesized that treatment of the participants with POM Juice would produce: 1) statistically significant positive GAQ scores when compared to placebo-controlled patients, and 2) changes in the erectile function domain of the IIEF when the values are compared with the baseline and between the two groups. (CX0686 at 0008).

1214. The Forest/Padma-Nathan Study's GAQ asked participants the following yes or no question: “While using the study beverage, did you feel that your erections improved?” (CX0686 at 0025).

1215. Dr. Padma-Nathan, the lead researcher, testified that while the GAQ is not a validated measure for measuring erectile function, “it's not unreasonable to have it as a single question, to try to capture a signal for any evidence of [erectile] treatment effect.” (CX1338 (Padma-Nathan Dep. at 90-91, 94)).

***147** 1216. The erectile function domain questions of the IIEF have graded response scales and ask specific questions relating to erectile function, such as “Over the last month, when you attempted sexual intercourse, how often were you able to penetrate (enter) your partner?” and “Over the last month, during sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?” (CX0686 at 0026-27; *see also* Melman, Tr. 1123).

1217. Dr. Padma-Nathan testified that the IIEF was a validated measure and the “gold standard.” (CX1338 (Padma-Nathan, Dep. at 90)).

1218. Dr. Padma-Nathan considered the Forest/Padma-Nathan RCT Study “a scientifically rigorous study.” (CX1338 (Padma-Nathan Dep. at 196-97)).

1219. A study as scientifically rigorous as the Forest/Padma-Nathan RCT Study is almost unheard of in the food industry. (Goldstein, Tr. 2601-02, 2613-14).

1220. Dr. Goldstein, indicated that as editor in chief of the *International Journal of Impotence Research*, the Forest/Padma-Nathan Study “is the first and only nutraceutical clinical trial that is randomized and double-blind that [he has] ever come across in [the] field.” (Goldstein, Tr. 2598).

ii. Results of the Forest/Padma-Nathan Study

1221. Of the 53 participants who completed the Forest/Padma-Nathan Study, a total of 42 subjects demonstrated improved GAQ scores, 25 after drinking pomegranate juice. (PX0189 (Goldstein Expert Report at 0012-13); CX0908).

1222. In the pomegranate juice-placebo sequence, 56% demonstrated improvement of GAQ score versus 33% in the placebo-pomegranate juice sequence. (PX0189 (Goldstein Expert Report at 0012-13); CX0908).

1223. In the placebo-pomegranate juice sequence, 38% versus 29% reported improvement in GAQ score. (PX0189 (Goldstein Expert Report at 0012-13); CX0908).

1224. Overall, the GAQ scores demonstrated that pomegranate juice drinkers enjoyed a nearly 50% better improvement in erections over the placebo drinkers. (CX0908 at 0003; PX0352 (Goldstein, Dep. at 109, 144); CX1338 (Padma-Nathan, Dep. at 191-92)).

1225. The Forest/Padma-Nathan Study's GAQ results achieved a probability value ("*p*-value") of 0.058, which is not statistically significant, as it is slightly above the statistical significance measure of 0.050. (PX0189 (Goldstein Expert Report at 0012-13); CX0908; Heber, Tr. 1978; Goldstein, Tr. 2598). This means the study had a 94%, rather than 95%, probability of being valid and not the result of chance. (Heber, Tr. 1978; Goldstein, Tr. 2599; Burnett, Tr. 2305).

1226. The Forest/Padma-Nathan RCT Study's IIEF erectile function domain results achieved a *p*-value of 0.72, which is not statistically significant. (Melman, Tr. 1120-21; Burnett, Tr. 2297 (agreeing that a *p*-value of 0.72 is "nowhere near approaching statistical significance"); PX0352 (Goldstein, Dep. at 65); CX1193 at 0003; CX1213 at 0001 (comparing the change from baseline for the treatment group versus the control group)).

***148** 1227. The Forest/Padma-Nathan Study report noted the treatment period was a limitation because it might not have been long enough to allow for a clinical response. (CX1193 at 0004). *See also* Melman, Tr. 1125, 1127; CX1289 (Melman Expert Report at 0014) (the study not conducted over a sufficient duration to show a sustained clinically significant effect on erectile function).

1228. Dr. Padma-Nathan also testified that the Forest/Padma-Nathan RCT Study was "[u]nder-powered to achieve statistical significance ... [but] that shouldn't be misconstrued to mean that the study was a deficient one." (CX1338 (Padma-Nathan, Dep. at 106, 108)). Dr. Padma-Nathan further testified that he did not think they were "trying to achieve [statistical significance] and didn't believe [they would] get statistical significance." (CX1338 (Padma-Nathan, Dep. at 106)).

1229. Dr. Padma-Nathan testified that the study concluded that there was a potential for pomegranate juice to have beneficial effects on erectile dysfunction, with the caveat of the need for further studies to confirm. (CX1338 (Padma-Nathan, Dep. at 184)).

1230. Dr. Padma-Nathan and Mr. Forest testified that the study did not conclude that POM Juice treats, prevents, or reduces the risk of erectile dysfunction. (CX1338 (Padma-Nathan, Dep. at 157-58); CX1337 (Forest, Dep. at 165-66)).

1231. After the Forest/Padma-Nathan Study was submitted for publication, a peer reviewer for the *International Journal of Impotence Research* stated that it was "a negative study, not a positive study, and should be presented that way." (CX0856 at 0001).

1232. A published review by Dr. Jacob Rajfer, Professor of Urology at UCLA, *Pomegranate Juice: Is It the New, All-Natural Phosphodiesterase Type 5 Inhibitor?*, 10 Rev. Urol. 168-69 (2008), also stated that the Forest/Padma-Nathan Study had negative results. (CX1290 at Ex. C; Melman, Tr. 1128-29; CX1289 (Melman Expert Report at 0016)).

iii. Expert opinion on the Forest/Padma-Nathan Study

1233. Dr. Melman testified that the GAQ is not a validated measure for assessing erectile function; has not been tested for statistical reliability; and does not measure the degree of improvement, indicate how often a study participant experienced improved erections, or show whether he was able to complete sexual intercourse. (Melman, Tr. 1118-22; CX1289 (Melman Expert Report at 0014)). Dr. Melman further testified that without the ability to show meaningful change of erectile function, the GAQ does not provide clinically significant information. (Melman, Tr. 1118-22; CX1289 (Melman Expert Report at 0014)).

1234. Dr. Melman had not heard of the term GAQ until being involved as an expert in this case and he formed his opinions about the GAQ after being involved in this case. (Melman, Tr. 1180-81).

1235. Dr. Melman testified that the Forest/Padma-Nathan Study was not conducted over a sufficient duration to show a sustained clinically significant effect on erectile function. (Melman, Tr. 1125, 1127; CX1289 (Melman Expert Report at 0014)). Dr. Melman further opined that experts in the erectile dysfunction field would require that a study be conducted over an appropriate duration because, even if there is improvement in the quality of erection, a treatment is not efficacious when the participant is still unable to complete intercourse. (CX1289 (Melman Expert Report at 0011-12)).

***149** 1236. Dr. Melman testified that the Forest/Padma-Nathan Study's IIEF erectile function domain results achieved a *p*-value of 0.72 and GAQ results achieved a *p*-value of 0.058, which are not statistically significant. (Melman, Tr. 1120-21). Dr. Melman further testified that nearly achieving statistical significance is insufficient to prove a product's efficacy in treating, preventing, or reducing the risk of erectile dysfunction in humans. (Melman, Tr. 1103, 1121).

1237. Dr. Melman also testified that based on the results of an animal study and one study on 11 men, Dr. Melman has made public statements that a gene-transfer therapy for erectile dysfunction called hMaxi-K would help erectile dysfunction. (Melman, Tr. 1148, 1150, 1155).

1238. Respondents' experts testified that even though the statistical significance was not reached, the Forest/Padma-Nathan Study “provides very valuable information” regarding erectile health and function and is absolutely “clinically significant” because “it supports the conclusion that the positive results in the basic science are borne out in human function.” (Goldstein, Tr. 2598-99, 2605, 2608; PX0352 (Goldstein, Dep. at 34-47, 105-09)).

1239. Dr. Goldstein testified that the results of the Forest/Padma-Nathan Study showed that “there were 50 percent more people than the placebo who thought that there was erectile benefit from using this drug. And I will call that clinically significant in conjunction with the fact that there are no deaths, no priapisms, no heart attacks, no strokes, no flushing, no nasal congestion, none of the traditional side effects seen by PDE5 inhibitors. No need for stents, drug-eluting stints, no need for surgery. No need for penile prosthetic procedures.” (PX0352 (Goldstein, Dep. at 109)).

1240. Dr. Goldstein also testified that the Forest/Padma-Nathan Study “is of extreme relevance to the clinician and consumer” and is “suggestive evidence that use of pomegranate juice would benefit [a] patient with erectile

dysfunction." (PX0189 (Goldstein Expert Report at 0014); Goldstein, Tr. 2605; PX0352 (Goldstein, Dep. at 34, 105-06)).

1241. Dr. Goldstein opined that the short treatment period in the Forest/Padma-Nathan Study "actually resulted in less favorable findings such that one would anticipate that a more robustly designed study would certainly have obtained statistically significant results." (PX0189 (Goldstein Expert Report at 0013); PX0352 (Goldstein, Dep. at 80)).

1242. Dr. Burnett testified that the results of the Forest/Padma-Nathan Study provide support that pomegranate juice "may be an intervention that would complement conventional ED treatment, and [he] would support its use by patients." (Burnett, Tr. 2298).

1243. Dr. Burnett opined that the Forest/Padma-Nathan Study supports the conclusion that pomegranate juice has a beneficial effect on erectile tissue physiology, health, and function, and is "a potential treatment for ED." (PX0149 (Burnett Expert Report at 0006); Burnett, Tr. 2255-56, 2270; PX0349 (Burnett, Dep. at 103, 112, 116-18, 138-39, 142)).

***150** 1244. Dr. Heber opined that the Forest/Padma-Nathan Study showed that consumption of POM juice created a marked improvement in erectile function among men who had experienced erectile dysfunction, and it had major clinical significance in showing a benefit from pomegranate juice despite barely missing statistical significance. (Heber, Tr. 1830-31, 1979).

1245. Dr. Heber testified that the Forest/Padma-Nathan Study "could [not] be disregarded" and that "it is a positive in providing important scientific information consistent with the basic science that pomegranate juice may be helpful for men with erectile dysfunction." (Heber, Tr. 2001).

iv. Determinations on the Forest/Padma-Nathan Study

1246. The GAQ is an adequate tool for testing a product like pomegranate juice. (Burnett, Tr. 2303-04).

1247. The Forest/Padma-Nathan Study's IIEF erectile function results of a *p*-value of 0.72 is not statistically significant. (Melman, Tr. 1120-21; Burnett, Tr. 2297).

1248. The Forest/Padma-Nathan Study's GAQ results of a *p*-value of 0.058 was a few thousandths of a percentage point short of the 95% threshold, and thus not "statistically significant." (PX0189 (Goldstein Expert Report at 0012-13); CX0908; Heber, Tr. 1978; Goldstein, Tr. 2598-99; Burnett, Tr. 2305).

1249. As noted in the Forest/Padma-Nathan Study itself, the treatment period was a limitation because it might not have been long enough to allow for a clinical response. (CX1193 at 0004).

1250. Despite the limitations stated in F. 1247-1249, the Forest/Padma-Nathan Study has clinical significance in showing a benefit from pomegranate juice on erectile tissue physiology and health. (PX0189 (Goldstein Expert Report at 0013); PX0149 (Burnett Expert Report at 0006); CX0908; Heber, Tr. 1979, 2001; Goldstein, Tr. 2598-99; PX0352 (Goldstein, Dep. at 108-09); Burnett, Tr. 2256; PX0349 (Burnett, Dep. at 138-39)).

1251. The Forest/Padma-Nathan Study supports the conclusion that pomegranate juice has a beneficial effect on erectile tissue physiology, health, and function. (PX0149 (Burnett Expert Report at 0006); Burnett, Tr. 2255-56; PX0349 (Burnett, Dep. at 103, 112, 116-18, 138-39, 142)).

1252. The Forest/Padma-Nathan Study supports the conclusion that pomegranate juice is a potential treatment for erectile dysfunction. (PX0349 (Burnett, Dep. at 142); CX1338 (Padma-Nathan, Dep. at 184)).

1253. The Forest/Padma-Nathan Study does not support the conclusion that POM Juice treats, prevents, or reduces the risk of erectile dysfunction. (CX1338 (Padma-Nathan, Dep. at 157-58); CX1337 (Forest, Dep. at 165-66); PX0349 (Burnett, Dep. at 142)).

c. Davidson BART/FMD Study

1254. A subset of 27 participants from the Davidson BART/FMD Study, a randomized, double blind, and placebo-controlled cardiovascular study funded by Roll (discussed in F. 903), also completed the IIEF questionnaire. (CX1065 at 0001; CX0716 at 0029; CX0684 at 0001, 0014). This analysis was planned for in the protocol for the Davidson BART/FMD Study. (CX0716 at 0029).

***151** 1255. The Davidson BART/FMD Study was primarily a cardiovascular study and therefore its protocols did not include any of the type of inclusion or exclusion criteria one would expect to see in a basic erectile dysfunction clinical trial. (CX0716; PX0019; Melman, Tr. 1092).

1256. The unpublished IIEF results from the Davidson BART/FMD Study were not statistically significant for the intent to treat population. (Melman, Tr. 1130-31; CX1289 (Melman Expert Report at 0017); CX1336 (Davidson, Dep. at 88-89)). The *p*-value was 0.7887 when comparing the intent to treat population's change in IIEF erectile function domain scores for the treatment group versus the control group. (CX0684 at 0014).

1257. The erectile dysfunction findings in the Davidson BART/FMD Study were flawed since one of the two study sites was unable to collect any data for the baseline IIEF measurement. (CX0654 at 0001 ("IIEF data not collected on most subjects at site 2; Mary Sue was aware of this and site staff reported that subjects are uncomfortable completing this questionnaire in the office (close quarters) so they tried to send it to them prior to their visit for them to bring in completed, yet it still was incomplete. Unfortunately, this baseline data will be missing.")).

1258. Neither Dr. Burnett nor Dr. Goldstein reviewed the IIEF data from the Davidson BART/FMD Study. (PX0352 (Goldstein, Dep. at 142); PX0349 (Burnett, Dep. at 170)).

1259. The IIEF results from Davidson BART/FMD study do not support the conclusion that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of erectile dysfunction. (Melman, Tr. 1130-31; CX1289 (Melman Expert Report at 0017)).

d. Nitric oxide studies

i. Studies sponsored by Respondents

1260. Respondents have sponsored at least six *in vitro* and/or *in vivo* studies investigating the effects of pomegranate juice on NO levels, including:
• *Pomegranate Juice Consumption Reduces Oxidative Stress, Atherogenic Modifications to LDL, and Platelet Aggregation: Studies in Humans and in Atherosclerotic Apolipoprotein E-Deficient Mice*, by Dr. Aviram;

• *Oxidative Stress in Arteriogenic Erectile Dysfunction: Prophylactic Role of Antioxidants*, by Dr. Azadzoi;

• *Effects of a Pomegranate Fruit Extract Rich in Punicalagin on Oxidation-Sensitive Genes and eNOS Activity at sites of Perturbed Shear Stress and Atherogenesis*, by Dr. de Nigris;

• *The Influence of Pomegranate Fruit Extract in Comparison to Regular Pomegranate Juice and Seed Oil on Nitric Oxide and Arterial Function in Obese Zucker Rats*, by Dr. de Nigris;

• *Beneficial Effects of Pomegranate Juice on Oxidation-Sensitive Genes and Endothelial Nitric Oxide Synthase Activity at Sites of Perturbed Shear Stress*, by Dr. de Nigris; and

• *Pomegranate Juice Protects Nitric Oxide Against Oxidative Destruction and Enhances the Biological Actions of Nitric Oxide*, by Dr. Ignarro.

***152** (PX0051 at 0001; PX0056 at 0001; PX0057 at 0001; PX0059 at 0001; PX0004 at 0001; PX0058 at 0001).

1261. Respondents' *in vitro* and *in vivo* studies are "basic science" or "pre-clinical." (PX0149 (Burnett Expert Report at 0005-06); PX0189 (Goldstein Expert Report at 0010-13) (describing the de Nigris, Aviram, Ignarro, and Azadzoi studies as *in vitro* or *in vivo*); CX0982 at 0011-14 (describing the de Nigris, Aviram, Ignarro, and Azadzoi studies as "pre-clinical" studies)).

(a) Dr. Aviram's Study

1262. Dr. Aviram is a distinguished professor of biochemistry and researcher at the Technion Faculty of Medicine and the Rambam Medical Center in Haifa, Israel, and head of the Lipid Research Laboratory. (PX0004; CX1358 (Aviram, Dep. at 7-8)).

1263. Dr. Melman, described Technion Institute in Haifa, Israel as a "terrific" institution. (Melman, Tr. 1168).

1264. For over 30 years, Dr. Aviram's major research focused on antioxidants in general, and on its dietary role in cardiovascular disease. (CX1358 (Aviram, Dep. at 5)).

1265. Dr. Aviram has concluded, based on his medical research, that pomegranate juice had greater antioxidant potencies than red wine, which he believed at the time possessed the most potent antioxidant. (CX1358 (Aviram, Dep. at 5-6)).

1266. Dr. Aviram's Study, titled, *Pomegranate juice consumption reduces oxidative stress, atherogenic modifications to LDL, and platelet aggregation: studies in humans and in atherosclerotic apolipoprotein E-deficient mice*, reported that dietary supplementation with nutrients rich in antioxidants was associated with inhibition of atherosclerosis. (PX0189 (Goldstein Expert Report at 0012); PX0004).

1267. Dr. Aviram and his colleagues studied, in healthy male volunteers and in atherosclerotic apolipoprotein E-deficient mice, the effect of consumption of pomegranate juice on such outcomes as lipoprotein oxidation, aggregation and retention, macrophage atherogenicity, platelet aggregation and atherosclerosis. (PX0189 (Goldstein Expert Report at 0012); PX0004).

1268. Dr. Aviram and colleagues found that in humans, pomegranate juice consumption decreased low-density lipoprotein ("LDL") susceptibility to aggregation and retention and increased an high-density lipoprotein ("HDL") associated esterase that can protect against lipid peroxidation. (PX0189 (Goldstein Expert Report at 0012); PX0004).

1269. Similar positive anti-atherosclerosis effects were seen in the E-deficient mice. (PX0189 (Goldstein Expert Report at 0012); PX0004).

1270. Dr. Aviram and colleagues concluded that pomegranate juice had potent antiatherogenic effects in humans (and atherosclerotic mice) that may be attributable to its antioxidative properties. (PX0189 (Goldstein Expert Report at 0012); PX0004).

1271. Dr. Goldstein noted that Dr. Aviram's Study is "a very fascinating and very important piece of information." (PX0352 (Goldstein, Dep. at 127)).

(b) Dr. Azadzoi's Study

***153** 1272. Dr. Azadzoi is a distinguished research professor of urology and pathology at the Boston University School of Medicine and Director of Urology Research at the Veterans Affairs Boston Healthcare System. (PX0051).

1273. Dr. Azadzoi, along with Dr. Goldstein, developed an atherosclerotic animal model for erectile dysfunction. (Goldstein, Tr. 2595).

1274. Dr. Azadzoi has published extensively on studies using atherosclerotic animal models with erectile dysfunction. (Goldstein, Tr. 2595).

1275. Dr. Azadzoi's Study, titled, *Oxidative Stress in Arteriogenic Erectile Dysfunction: ProphylacticRrole of Antioxidants*, studied the antioxidant properties of various fruit juices, such as orange juice, blueberry juice, and cranberry juice, and other known antioxidant beverages such as green tea and red wine, and reported that pomegranate juice possessed the highest free radical scavenging capacity. (PX0189 (Goldstein Expert Report at 0011-12); PX0051; PX0352 (Goldstein, Dep. at 123-24); Goldstein, Tr. 2595).

1276. Dr. Azadzoi and colleagues examined that effect of various antioxidant beverages on arteriogenic erectile dysfunction in rabbits that demonstrated decreased intracavernous blood flow, erectile dysfunction, loss of smooth muscle relaxation, decreased endothelial NO synthase, and neuronal NO synthase, diffuse cavernosal fibrosis and increased cavernous levels of the oxidative product isoprostane 8 — epi — prostaglandin F 2 alpha. (PX0189 (Goldstein Expert Report at 0011-12); PX0051).

1277. Dr. Azadzoi and colleagues found that long term pomegranate juice intake increased intracavernosal blood flow, improved erectile responses, improved smooth muscle relaxation, and decreased erectile tissue fibrosis. (PX0189 (Goldstein Expert Report at 0011-12); PX0051; PX0352 (Goldstein, Dep. at 123); Goldstein, Tr. 2595-97).

1278. Dr. Azadzoi and colleagues concluded that arteriogenic erectile dysfunction accumulates oxidative products in erectile tissues and that oxidative stress may be of great importance in the pathophysiology of erectile dysfunction. (PX0189 (Goldstein Expert Report at 0011-12); PX0051).

1279. Dr. Azadzoi and colleagues found that antioxidant therapy may be useful as a prophylactic for preventing smooth muscle dysfunction and fibrosis in erectile dysfunction. (PX0189 (Goldstein Expert Report at 0011-12); PX0051).

(c) Dr. de Nigris Study One

1280. Dr. de Nigris, of the Department of General Pathology and Excellence Research Center on Cardiovascular Diseases of the 1st School of Medicine at the II University of Naples, Italy, and colleagues, including Dr. Louis Ignarro, evaluated the effects of intervention with pomegranate juice on oxidation-sensitive genes and endothelial NO synthase expression induced by high shear stress *in vitro* and *in vivo.* (PX0059). The study was titled, *Beneficial effects of pomegranate juice on oxidation-sensitive genes and endothelial nitric oxide synthase activity at sites of perturbed shear stress*, and is referred to herein as "de Nigris Study One." (PX0059).

***154** 1281. Cultured human coronary artery endothelial cells exposed to high shear stress *in vitro* and hypercholesterolemic mice were used in the de Nigris Study One. (PX0059).

1282. Dr. de Nigris and colleagues found that pomegranate juice concentrate reduced the activation of redox-sensitive genes and increased endothelial NO synthase expression in cultured human coronary artery endothelial cells and hypercholesterolemic mice. (PX0059; Burnett, Tr. 2290).

1283. Dr. de Nigris and colleagues also found that oral administration of pomegranate juice to hypercholesterolemic mice at various stages of disease reduced significantly the progression of atherosclerosis. (PX0059).

1284. The de Nigris Study One indicates that polyphenolic antioxidants contained in pomegranate juice can contribute to the reduction of oxidative stress and atherogenesis. (PX0059; Burnett, Tr. 2290).

(d) Dr. de Nigris Study Two

1285. In a study titled, *Effects of a Pomegranate Fruit Extract rich in punicalagin on oxidation-sensitive genes and eNOS activity at sites of perturbed shear stress and atherogenesis*, (referred to herein as de Negris Study Two), Dr. de Nigris and colleagues showed that atherosclerosis is enhanced in arterial segments exposed to perturbed shear stress as a result of increased expression of oxidation-sensitive responsive genes. (PX0189 (Goldstein Expert Report at 0010-11); PX0056).

1286. The authors of the de Nigris Study Two studied the effect of pomegranate fruit extract and pomegranate juice antioxidant activity on reduction of oxidative stress and atherogenesis during disturbed shear stress flow using cultured human coronary artery endothelial cells. (PX0189 (Goldstein Expert Report at 0010-11); PX0056).

1287. The de Nigris Study Two showed that pomegranate fruit extract and pomegranate juice reduced the activation of oxidation-sensitive genes and increased endothelial NO synthase expression. (PX0189 (Goldstein Expert Report at 0010-11); PX0056).

1288. The de Nigris Study Two also showed that pomegranate fruit extract and pomegranate juice increased cyclic GMP levels. (PX0189 (Goldstein Expert Report at 0010-11); PX0056).

1289. The de Nigris Study Two further showed that administration of pomegranate juice reduced the progression of atherosclerosis in hypercholesterolemic mice. (PX0189 (Goldstein Expert Report at 0010-11); PX0056).

1290. The authors of the de Nigris Study Two concluded that the proatherogenic effects of perturbed shear stress can be reversed with chronic administration of pomegranate fruit extract. (PX0189 (Goldstein Expert Report at 0010-11); PX0056).

1291. The authors of the de Nigris Study Two also stated that some large clinical trials for different antioxidants have failed to show any beneficial effect in terms of preventing major cardiovascular events. (PX0056 at 0008).

(e) Dr. Ignarro's Study

1292. Dr. Louis Ignarro has won a Nobel prize for his discoveries concerning NO. Dr. Ignarro conducted an *in vitro* study, titled, *Pomegranate juice protects nitric oxide against oxidative destruction and enhances the biological actions of nitric oxide, to evaluate pomegranate juice's capacity to protect nitric oxide against oxidative destruction*. (PX0189 (Goldstein Expert Report at 0011); PX0058; Goldstein, Tr. 2593-95; Heber, Tr. 1995-96; Burnett, Tr. 2252-53).

***155** 1293. Dr. Ignarro has tested pomegranate juice for its capacity to protect NO against oxidative destruction and found that pomegranate juice was around 5,000 times more potent than the other antioxidants he has tested and possesses more antioxidant activity than grape juice, blueberry juice, red wine and ascorbic acid. (PX0189 (Goldstein Expert Report at 0011); Goldstein, Tr. 2594-95; Heber, Tr. 1967; Burnett, Tr. 2253; PX0058).

1294. Based on a series of studies that were performed on vascular endothelial cells, Dr. Ignarro concluded that pomegranate juice possesses potent antioxidant activity that results in marked protection of NO against oxidative destruction, thereby augmenting the biologic actions of NO. (PX0189 (Goldstein Expert Report at 0011); PX0058).

1295. Dr. Goldstein testified that the “Ignarro study is another part of the sequence of evidence that supports that a nutraceutical, specifically pomegranate juice, has incredible vascular-sparing properties that ultimately, when you follow this path leads to the improvement of erectile function in men with erectile health issues.” (PX0352 (Goldstein, Dep. at 133)).

1296. Dr. Goldstein testified also that “you have to study humans to make statements about humans.” (PX0352 (Goldstein, Dep. at 124)).

1297. Complaint Counsel's expert, Dr. Melman, recognizes that Dr. Ignarro is highly respected and that UCLA School of Medicine, where Dr. Ignarro is a professor in molecular and medical pharmacology, has a good reputation. (Melman, Tr. 1167-68).

ii. Expert opinions on the basic science relied upon by Respondents

1298. Dr. Burnett, offered the following expert opinions regarding the basic science relied upon by Respondents:
• “basic scientific evidence exists that establishes that pomegranate juice possesses potent antioxidative molecular effects and these effects operate by activating endothelial NO mechanisms in vasculature [structures involved in human penile erection].” (PX0149 (Burnett Expert Report at 0005-06));

• basic science alone "support[s] the potential benefit at the human level to improve the physiology of erectile tissue preserving erect tissue health." (PX0149 (Burnett Expert Report at 0004-05); PX0349 (Burnett, Dep. at 103, 112, 116-18)); and

• on the basis of animal studies or *in vitro* studies, pomegranate juice has a "potential benefit ... to likely improve one's erection physiology." (Burnett, Tr. 2262-63).

1299. Dr. Goldstein provided the following expert opinions regarding the basic science relied upon by Respondents:
• "pomegranate juice has excellent basic science both in animal tissue and human tissue and excellent animal model data." (PX0352 (Goldstein, Dep. at 51-52)); and

• POM's "strong *in vitro* and *in vivo* studies ... suggest a probable benefit of pomegranate juice on erectile health," and that "in and of itself it has shown huge pieces of information that will be helpful in understanding how it would work in humans ...." (PX0189 (Goldstein Expert Report at 0013); Goldstein, Tr. 2644).

***156** 1300. Dr. Goldstein also provided the following expert opinions:
• competent and reliable scientific evidences shows that pomegranate juice provides a benefit to erectile function. (Goldstein, Tr. 2605); and

• competent and reliable scientific evidence exists upon which clinicians who treat men with erectile health concerns would rely in concluding that pomegranate juice promotes erectile health. (PX0189 (Goldstein Expert Report at 0014)).

1301. Dr. Melman provided the following expert opinions regarding the basic science relied upon by Respondents:
• basic research studies about antioxidants' effects on NO levels may relate to the biochemical process for erectile function. (CX1289 (Melman Expert Report at 0017-18)); and

• basic research studies do not directly involve erectile function in humans and cannot alone prove that POM Juice treats, prevents, or reduces the risk of erectile dysfunction in humans. (CX1289 (Melman Expert Report at 0017-18)).

1302. Notwithstanding Dr. Melman's opinion in F. 1301, Dr. Melman also testified that based on the results in an animal model testing gene therapy erectile dysfunction product (*see* F. 653), he was "personally satisfied" that it would also work in humans. (PX0360 (Melman, Dep. at 56-57)).

4. Determinations

1303. There is no true preventative intervention for erectile dysfunction. There are a wide variety of interventions believed to have some potential benefit, anything from dietary changes to weight loss and perhaps things that

are still being evaluated, although the role played is not sure. Because these interventions seem to be potentially beneficial and do not necessarily have harms, physicians feel comfortable in promoting them. (PX0349 (Burnett Dep. at 79); Burnett, Tr. 2301, 2272-73).

1304. "[T]reatment can have different meanings .... [T]reatment in the context of a pharmaceutical drug that is approved by the FDA as an intervention for a disease may have a different meaning ... than the broad term of treatment, which is to intervene for a condition." (Burnett, Tr. 2312).

1305. Pomegranate juice "could be a treatment [to erectile dysfunction] in the sense that it offers some potential health benefits." (Burnett, Tr. 2312).

1306. Urologists would recommend pomegranate juice as a management tool to promote erectile health in men who are aware that their erectile function is declining but who do not yet meet the clinical definition of erectile dysfunction under the IIEF and therefore do not qualify for pharmacologic treatment. (PX0189 (Goldstein Expert Report at 0014-0015); PX0352 (Goldstein, Dep. at 42-45); Goldstein, Tr. 2609).

1307. Urologists would recommend pomegranate juice as a complement to conventional erectile dysfunction treatment. (Burnett, Tr. 2298, 2313; PX0349 (Burnett, Dep. at 78-79)) ("To the extent that any intervention out there has some potential benefit of a better benefit than harm that meets some level of safety, I would support that intervention, at least as a complimentary intervention and not a mainstay of ED treatment.") (PX0352 (Goldstein, Dep. at 80) (there are patients in whom there are erectile dysfunction and/or erectile health problems related to inflammatory endothelial dysfunctions, and ... pomegranate juice has a logical context in the treatment of those patients.").

***157** 1308. Dr. Goldstein "would strongly suggest and encourage" use of pomegranate juice to treat erectile dysfunction in a subpopulation of men who have had an insufficient response to PDE5 inhibitors (like Viagra, Levitra and Cialis) and who wish to reestablish erectile function without invasive or mechanical technology or therapies. (PX0352 (Goldstein, Dep. at 37-42, 46)). Dr. Goldstein opined that the consumption of pomegranate juice is a logical option for men who are not responsive to conventional drugs designed to treat erectile dysfunction and who are unwilling to consider invasive or mechanical therapies for treatment of their erectile dysfunction. (PX0189 (Goldstein Expert Report at 0005); PX0352 (Goldstein, Dep. at 37-42); Goldstein, Tr. 2605, 2641).

1309. Pomegranate juice costs far less than Viagra and there are no side effects to drinking pomegranate juice. (PX0352 (Goldstein, Dep. at 44).

5. Conclusions

1310. The available body of scientific literature — including *in vitro*, *in vivo*, and preliminary clinical trials — suggests that consuming pomegranate juice promotes erectile health. (PX0189 (Goldstein Expert Report at 0003)).

1311. The use of pomegranate juice to promote erectile *health* is a separate and distinct concept from the use of this neutraceutical as a safe and effective treatment for the medical condition of erectile *dysfunction* such as with a PDE5 inhibitor. (PX0189 (Goldstein Expert Report at 0004) (emphasis in original)).

1312. Competent and reliable scientific evidence shows that pomegranate juice provides a benefit to promoting erectile health and erectile function. (Goldstein, Tr. 2605, 2608; PX0189 (Goldstein Expert Report at 0014); PX0149 (Burnett Expert Report at 0006); Burnett, Tr. 2255-56).

1313. There is insufficient competent and reliable scientific evidence to show that pomegranate juice prevents or reduces the risk of erectile dysfunction or has been clinically proven to do so. (Burnett, Tr. 2274, 2300-01; CX1289 (Melman Expert Report at 0018)).

1314. There is insufficient competent and reliable scientific evidence to show that pomegranate juice treats erectile dysfunction in a clinical sense or has been clinically proven to do so. (Burnett Tr. 2285, 2300; Goldstein, Tr. 2611; CX1289 (Melman Expert Report at 0018). *See also* Burnett, Tr. 2261-64).

J. Materiality

1. Overview

1315. Mrs. Resnick believes that part of the intrinsic value of pomegranate juice is that it has been shown to reduce arterial plaque and factors leading to atherosclerosis and was shown to have a "powerful effect against prostate cancer." (L. Resnick, Tr. 75-76).

1316. Mr. Resnick testified that POM communicates to consumers the "[company's] belief that pomegranate juice is beneficial in treating some causes of impotence, for the purpose of promoting sales of its product." (CX1372 (S. Resnick, Tropicana Dep. at 45)).

1317. Mr. Resnick acknowledged that the kinds of benefits revealed by POM's research results are the primary reason people buy pomegranate juice. (CX1372 (S. Resnick, Tropicana Dep. at 31)). Mr. Resnick also acknowledged that consumers buy pomegranate juice "because they believe and in fact it does postpone the onset of prostate cancer, which postpones the onset of death." (CX1376 (S. Resnick, Ocean Spray Dep. at 217)).

***158** 1318. Mr. Resnick expressed his belief that a great deal of consumers are buying POM Juice because they believe "that we've proven that ... [POM Juice] really does prolong people's lives if they are getting the onset of prostate cancer." (CX1376 (S. Resnick, Ocean Spray Dep. at 218-19)).

1319. According to a draft creative brief for POMx dated October 12, 2006, the concept behind communicating the amount of money the company spent on research is: "We don't just say our product is great, we have clinical studies that prove its efficacy." (CX0409 at 0057).

1320. POM was aware that among those purchasing the POM products were "people that have heart disease or prostate cancer in their family, or have a fear of having it themselves." (CX1368 at 17 (L. Resnick, Welch Dep. at 67)).

1321. According to a September 2006 press article, Ms. Posell, POM's then vice president of corporate communications, said "every time new research is released touting" a health benefit of pomegranate juice, "there is a spike in sales. The study ... linking the consumption of pomegranate juice to a reduction in prostate cancer was especially helpful, she said ... Pom Wonderful can see the results in increased sales every time a new study surfaces." (CX0433 at 0004).

1322. According to a July 2004 e-mail from John Regal, POM's head of marketing at the time, with the subject line "POM Medical research timing and advertising", POM's goal for its 2-page *Prevention* "advertorial" (CX0029, F. 297-305, *supra*) was to convey "how POM is particularly good for clean & healthy arteries. We also wanted to highlight the new Aviram study regarding plaque reduction in humans." (Leow, Tr. 437; CX0667 at 0001).

1323. In evaluating how copy dense or medically oriented to make a planned POMx Pill advertisement, Ms. Kuyoomjian, Senior Vice President of Marketing for POM from 2008 to 2009, reminded Mrs. Resnick in a January 2009 e-mail: "you'll recall that a previous ad test with less copy did not generate as many orders. That would suggest we keep the research info in the new ad, which would make it information dense as well." (CX1357 (Kuyoomjian Dep. at 22); CX0266 at 0002).

1324. Mr. Perdigao, the head of Fire Station, Roll's in-house advertising agency used by POM (F. 134, 138), noted in an e-mail dated June 11, 2009, that the "consumer benefit" of proposed advertisements that did not reference prostate health or heart health was less compelling than more general references to POM being good for you because it offers antioxidants that reduce free radicals. As Mr. Perdigao explained, less specific advertising is generally less provocative. (CX0320 at 0002; L. Resnick, Tr. 90; *see also* Perdigao, Tr. 670-73).

1325. A creative brief (*see* F. 145-151) for the POM Wonderful website, from June 2008, stated the objective for the assignment was to "tell the story (health benefits, research & how POM fits)." For the "Health Benefits" section of the POM Wonderful website, the creative brief further stated that, to engage viewers, the page should identify "What are the health benefits?", including "heart health," "prostate health," and "E.D."; "How does it work?", including antioxidant and anti-inflammatory properties, the "commitment" to research; "What the experts say," on such matters as heart and prostate, and a "comprehensive research database," searchable by subject matter, including heart and prostate, and by results. The directed tone and manner included "authoritative." (CX0200 at 0001-02).

***159** 1326. Ms. Leow, a creative director for Roll, stated that scientific information in advertising and marketing material helps sell the products, because the scientific information provided the consumer with a "reason to believe." (Leow, Tr. 512-13; CX0095).

1327. A creative brief for POMx Pills, dated September 1, 2006, included the sentence in an opening narrative paragraph, as a bullet point: "main creative focus is prostate cancer." (CX0409 at 0023).

1328. A creative brief for POMx Pills, dated September 5, 2006, stated under "benefit," in bold type, "Main creative focus for 1st round is prostate cancer. (The benefits are from the studies — which showed a decrease in the doubling time of PSA levels)." The "benefit" section continued: "The other versions of the creative [brief] should definitely focus on the other benefits of POM — antioxidant, anti-aging, heart health, etc." (CX0409 at 028).

1329. Respondents' marketing expert, Dr. David Reibstein, stated that it was indeed possible, and he would expect that, consumers in POM's target audience who were concerned about heart disease would find a claim that drinking a bottle of POM Juice a day prevents or treats heart disease to be important, that those concerned about prostate cancer would find a prostate cancer prevention or treatment claim important, and that those concerned about erectile dysfunction would find an erectile dysfunction prevention or treatment claim important. (PX0356 (Reibstein, Dep. at 117-19)).

2. OTX A&U Study and Zoomerang survey

1330. In the ordinary course of business, POM conducted consumer research to understand the characteristics, attitudes and usage habits of their customers and to identify barriers and opportunities for increasing consumption, particularly *vis-à-vis* other brands of pomegranate juice. (CX0370 at 0002; CX0292; CX0136; CX0453 at 0004).

1331. In June 2009, OTX, a consumer research firm, conducted an Attitudes and Usage consumer survey ("OTX A&U Study") on POM's behalf. (CX0370 at 0002, 0004; PX0227). The A&U Study's sample included current and

former POM Juice drinkers, other pomegranate juice drinkers and users of other antioxidant fruit juices. (CX0370 at 0003).

1332. In the OTX A&U Study, among other things, current pomegranate juice users, including users of POM Juice, were asked why they drink pomegranate juice, and were given a list of options, including: "It's healthy/good for my health," "I like the taste," "I like pomegranates," "it's all natural," or "Other (specify"), and were directed to select all that applied. (PX0227 at 0006). Among the POM Juice drinkers, 85% said they drank pomegranate juice because "it's healthy good for my health," 75% said "I like the taste," 59% said "I like pomegranates," 50% said "it's all natural," 29% said "it's new/interesting food trend," and 4% said "other." (CX0370 at 0011).

1333. Those in the OTX A&U Study that responded, "It's healthy/good for my health," were asked a follow-up question, "Which specific health reasons below describe why you personally drink pomegranate juice?" and were presented with a list of reasons, depending on whether they were male or female. (CX0370 at 0012; PX0227 at 0006; Reibstein, Tr. 2558-59; Mazis, Tr. 2682-84).

***160** 1334. The choices given to the survey respondents identified in F. 1333 were: helps promote heart health; helps protect against prostate cancer [for males only]; helps protect against other cancers (besides prostate); contains naturally occurring antioxidants; will help me live longer; helps improve thinking and memory; good for bone and joint health; helps protect against urinary tract infections; provides immunity from colds and flu; promotes healthy pregnancy [for females only]; promotes menstrual health [for females only] and "[o]ther (specify)." (PX0227 at 0006).

1335. Among the POM Juice drinkers responding to the question in F. 1334, 91% said "contains naturally occurring antioxidants," 57% said "helps promote heart health," 47% of men said "helps protect against prostate cancer," 45% said "provides immunity from colds and flu," 43% said "helps protect against other cancers (besides prostate); 38% said "helps protect against urinary tract infections," 28% said "will help me live longer," 28% said "good for bone and joint health," 25% said "helps improve thinking and memory," 14% said "promotes menopausal/post-menopausal health," 6% said "promotes healthy pregnancy," and 2% said "other." The percentages attributed for the different responses attributable to non-POM Juice and other antioxidant beverage drinkers were slightly less. (CX0370 at 0012).

1336. POM's Senior Vice President of Marketing, Ms. Kuyoomjian, was not surprised by the OTX A&U Study result that, for 47% of male POM users, part of the reason they drink POM Juice is because they believe it helps protect against prostate cancer. (CX1357 (Kuyoomjian, Dep. at 259-60)).

1337. Dr. Reibstein reviewed the OTX A&U Study and concluded that although it presented some information contradictory to the conclusions he drew from his own survey (*see* F. 1344-1372), the OTX A&U Study had methodological flaws, cannot be relied upon, and does not invalidate the results of Dr. Reibstein's survey. (PX0223 (Reibstein Expert Report at 0021)).

1338. In rebuttal to the opinion of Respondents' expert Dr. Reibstein, that the OTX A&U Study was not reliable or relevant (F. 1337), Complaint Counsel's expert, Dr. Mazis, reviewed the OTX A&U Study and expressed his opinion that the OTX A&U Study was highly relevant and demonstrated that the heart disease and prostate cancer claims are important to consumers, and are reasons that POM Juice users choose to purchase POM Juice. (Mazis, Tr. 2688-89, 2760; CX1297 (Mazis Expert Report at 0012-13)).

1339. Dr. Mazis testified that, with respect to the likely importance that the challenged claims would have on consumers' purchase or use decisions, he finds the OTX A&U Study more reliable than the Reibstein Survey (*see* F. 1344-1372; Mazis, Tr. 2689).

1340. In Dr. Reibstein's opinion, the OTX A&U Study used closed-ended questions, in that it provided respondents with a list of five choices as to why they drink pomegranate juice, and that this method "cues" the survey respondent to certain answers, excludes other potential answers that were not included on the list of choices, and inflates results. (PX0227 at 0006; Reibstein, Tr. at 2518-20).

***161** 1341. Dr. Mazis opined that, when studying purchase motivations, the use of closed-ended questions have an advantage because it allows the researcher to get some specificity, and, therefore, closed-ended questions tend to be used in most of these types of studies. Although close-ended questions have a disadvantage in that they may lead to some upward bias, in a study like the OTX A&U Study, one accounts for this by giving a long list of choices, as was done in the OTX A&U Study, and examining the relative ranking of responses. (Mazis Tr. 2662-63).

1342. In August 2007, Respondents commissioned a Zoomerang online survey of the general public, "to better understand pomegranate and non-pomegranate juice consumers," with respect to, among other things, "importance of certain health benefits." The survey included 287 heavy pomegranate juice drinkers. Six health benefits were listed and these respondents were asked to rank which health benefit was the most important to them personally. For heavy pomegranate juice drinkers, the number one response, for both males and females was "cardiovascular," and the number two choice for men was "prostate." (*See* CX0292 at 0025; CX0136 at 0001, 0003, 0006).

1343. For members of the general public responding to the Zoomerang survey question regarding ranking of health benefits (F. 1342), 60% ranked cardiovascular health as the first or second most important benefit, 40% of males ranked prostate health as the first or second most important benefit, and approximately 18% of males did so for erectile dysfunction. (CX0136 at 0002, 07-08; CX0453 at 0004).

3. Reibstein Survey

1344. The Reibstein Survey was conducted on behalf of POM Wonderful in connection with this litigation, by an independent market research company, Horizon Consumer Science ("HCS") under the direction of Dr. David J. Reibstein. (PX0223 (Reibstein Expert Report at 0001, 0003); F. 266-275).

1345. HCS maintains an online panel of over one million subjects. From this population, a stratified sample of 2,164 was drawn from the United States population. (PX0223 (Reibstein Expert Report at 0004)).

1346. The Reibstein Survey sought to reveal (i) a buyer's motivation for purchasing pomegranate juice; (ii) whether having previously seen POM Juice advertisements in the normal sequence of viewing advertisements and not in an artificial setting, the advertisements affected the buyer's motivations for buying pomegranate juice; and (iii) whether the buyer's awareness of the legal issues around the case might have affected their motivation for buying pomegranate juice. (PX0223 (Reibstein Expert Report at 0005); Reibstein, Tr. 2487; PX0356 (Reibstein Dep. at 11, 38-39, 51)).

1347. The Reibstein Survey was conducted in October 2010. (Reibstein, Tr. 2541).

1348. Dr. Reibstein's Survey did not address POMx or the purchase motivations of POMx purchasers, and Dr. Reibstein did not undertake to extrapolate the results of his survey to POMx purchasers. (Reibstein, Tr. 2565-66).

***162** 1349. To qualify for the Reibstein Survey, respondents had to meet the following criteria: (i) purchased pomegranate juice in the six months prior to the survey; (ii) had not completed any online survey within the 3 months prior to the survey for any beverage products; (iii) did not work in any of the following industries:

advertising, public relations, beverages, marketing or market research; and (iv) was over 18 years old. This was accomplished through a series of screening questions. (PX0223 (Reibstein Expert Report at 0004); PX0237 at 0001-02; PX0356 (Reibstein, Dep. at 50-51, 57-58)).

1350. Of the 2,164 panelists that completed the online Reibstein Survey, 750 of them met the qualification criteria, and actually completed the survey. (PX0223 (Reibstein Expert Report at 0004)).

1351. The Reibstein Survey surveyed two groups, 406 respondents who purchased POM Juice in the past six months ("POM Juice consumers") and 344 respondents who purchased brands of pomegranate juice other than POM in the past six months. (PX0223 (Reibstein Expert Report at 0004); Reibstein, Tr. 2493-94).

1352. The Reibstein Survey employed two types of controls. The first control was to draw a sample of non-POM Juice buyers and ask them the same questions as the POM Juice buyers to see if these buyers had different motivations for purchasing pomegranate juice. The second control was to compare the responses of people who had seen POM advertisements against those who had not seen any POM advertisements. (PX0223 (Reibstein Expert Report at 0004-05); Reibstein, Tr. 2488-89, 2493; PX0356 (Reibstein, Dep. at 73-74)).

1353. For the sample of 406 POM Juice consumers, the Reibstein Survey asked three primary open-ended questions in Questions E through G, set forth below in F. 1354-1356. (PX0223 (Reibstein Expert Report at 0005)).

1354. Question E asked "Why did you purchase POM Wonderful 100% Pomegranate Juice? *Please include as many specific details*." (PX0237 at 0002 (italics in original); PX0223 (Reibstein Expert Report at 0006)).

1355. Question F asked "Would you consider purchasing POM Wonderful 100% Pomegranate Juice again?

(SELECT ONE ONLY)

1. Yes a. Why? *Please include as many specific details as to why you would?*

2. No a. Why not? *Please include as many specific details as to why you would not?*

3. Don't know."

(PX0237 at 0002 (emphases in original); PX0223 (Reibstein Expert Report at 0007)).
1356. Question G asked "Would you recommend POM Wonderful 100% Pomegranate Juice to a friend?

(SELECT ONE ONLY)

1. Yes a. Why? *Please include as many specific details as to why you would?*

2. No a. Why not? *Please include as many specific details as to why you would not?*

3. Don't know."

(PX0237 at 0002 (emphases in original); PX0223 (Reibstein Expert Report at 0008)).

1357. For the 344 non-POM Juice pomegranate juice consumers, the Reibstein Survey asked three primary open-ended questions in Questions H through J, set forth below in F. 1358-1360. (PX0223 (Reibstein Expert Report at 0005)).

***163** 1358. Question H asked "You indicated that you have purchased pomegranate juice. *Please include as many specific details* as to why you purchased it. *Please* be *as detailed as possible*." (PX0237 at 0002 (emphases in original); PX0223 (Reibstein Expert Report at 0006)).

1359. Question I asked "Would you consider purchasing pomegranate juice again?

(SELECT ONE ONLY)

1. Yes a. Why? *Please include as many specific details as to why you would again*?

2. No. a. Why not? *Please include as many specific details as to why you* would *not again*?

3. Don't know."

(PX0237 at 0003 (emphases in original)).
1360. Question J asked "Would you recommend pomegranate juice to a friend?

(SELECT ONE ONLY)

1. Yes a. Why? *Please include as many specific details as to why* you *would?*

2. No. a. Why not? *Please include as many specific details as to why you would not?*

3. Don't know."

(PX0237 at 0003 (emphases in original)).
1361. A summary of the results of the responses to Questions E-J was set forth by Dr. Reibstein in Figure 5 in his expert report. Figure 5 is set forth below:

Question	**Percentage of POM Wonderful Juice Buyers whose response mentions a specific disease reference n=406**	**Percentage of Pomegranate Juice Buyers whose response mentions a specific disease reference n=344**
E/H (Why did you purchase?)	1.0% (4/406)	.9% (3/344)
F/I (Why would you purchase/not purchase again?)	.5% (2/406)	0% (0/344)

G/J		
(Why would/would not recommend?)	.3% (1/406)	.9% (3/344)
NET	**1.48% (6/406)**	**1.74% (6/344)**

***164** (PX0223 (Reibstien Expert Report at 0020)).

1362. The "specific disease" references, as reported by respondents to the Reibstein Survey (F. 1361) included: heart disease, getting rid of plaque, cancer, urinary tract infections, bowel movements, diabetes, kidney stones, and arthritis pain. (PX0223 (Reibstein Expert Report at 0011-12)).

1363. The above findings (F. 1361-1362) reflect 12 unique survey respondents, because one participant responded to both Question E and Question F with a disease reference. This respondent is counted only once in the "net" results. (PX0223 (Reibstein Expert Report at 0011, 0020 n.1-6)).

1364. Questions E through J of the Reibstein Survey were in open-ended format, to reduce any biasing of the survey respondents. (PX0223 (Reibstein Expert Report at 0005); PX0356 (Reibstein Dep. at 84-85)).

1365. In response to questions E and H of the Reibstein Survey, respectively, 35.2% of POM Juice purchasers stated that they purchased or would repurchase POM Juice because it was "healthy" and 46.8% stated that they would recommend it to a friend because it was "healthy." In addition, 43.6% of POM Juice purchasers stated they purchased because of the taste, and 74% stated they would repurchase because of the taste. (PX0223 (Reibstein Expert Report at 0006-07)).

1366. Question K asked respondents: "Have you ever seen a POM Wonderful 100% Pomegranate Juice advertisement?

(SELECT ONE ONLY)

1. Yes a. Please include as many specific details as to what you remember about the ad. *Please be as detailed as possible*.

2. No

3. Don't know."

(PX0237 at 0003 (emphases in original); PX0223 (Reibstein Expert Report at 0016); Reibstein, Tr. 2507, 2567).

1367. In response to Question K of the Reibstein Survey, 39.6% of people (297 out of 750) who consumed pomegranate juice in the prior six months had seen a POM advertisement. (PX0223 (Reibstein Expert Report at 0009, 0016); PX0233 at 0028; Reibstein, Tr. 2536).

1368. In response to Question K of the Reibstein Survey, while 20% of the respondents reported "healthy," none of the respondents who saw a POM advertisement responded that they remember the advertisement making a specific disease claim. Other common details reported by POM Juice purchasers were bottle appearance (22.4%); people or objects in the advertisement (20.6%); and "don't know/no response" '2820%). (PX0223 (Reibstein Expert Report at 0009); PX0233 at 0029).

1369. In the Reibstein Survey, among the 12 unique respondents out of 750 total respondents, including non-POM Juice buyers, who mentioned a specific disease as a reason for purchasing or recommending pomegranate juice, 4 reported having seen a POM advertisement at some point and 8 reported not ever having seen an advertisement. (PX0223 (Reibstein Expert Report 0009, 0016-19)).

1370. Based on the Reibstein Survey findings, Dr. Reibstein, expressed the opinion that POM advertisements had no impact on buyers' purchase motivations. (PX0223 (Reibstein Expert Report at 0020)).

***165** 1371. Dr. Reibstein did not expose consumers to the Challenged Advertisements. (Reibstein, Tr. 2494).

1372. Based on the Reibstein Survey results, Dr. Reibstein, expressed the opinion that there is a very small percentage of people that bought, would buy again, or would recommend POM Juice to a friend because they believe that it cures or prevents a specific disease. (PX0223 (Reibstein Expert Report at 0020)).

1373. In rebutting the opinions of Dr. Reibstein, Dr. Mazis opined that the Reibstein Survey did not employ a valid measure of materiality of the challenged claims in this case because the survey was a general assessment of consumer motivations but did not assess whether any one of the challenged claims in the complaint would be important in the decision to purchase or to use POM Juice. According to Dr. Mazis, what a consumer might identify as a motivation for purchasing a product is not the same thing as assessing whether, if a consumer knew of a claim, that claim would be important in his or her decision to purchase the product. (CX1297 (Mazis Expert Report at 0008); Mazis, Tr. 2673).

1374. According to Dr. Mazis, in order to do a survey on materiality, “you don't have to show them the ad, but you have to give them a statement about what the claim was and you have to ask them how important they think that claim would be in their potential purchase decision.” (Mazis, Tr. 2728).

1375. Dr. Mazis further opined that Dr. Reibstein's methodology was flawed because he asked only open-ended questions but did not follow-up with questions probing further what the respondents meant when referring to POM Juice being “healthy” or having “health benefits” as their motivation for purchasing. According to Dr. Mazis, the Reibstein Survey should have explored what survey respondents meant by their “healthy” response and whether there were specific reasons or benefits that underlay “healthy” responses. (Mazis, Tr. 2756-57, 2707-09; PX0296 (Mazis Expert Report at 0009-10)).

1376. Dr. Mazis agreed that open-ended questions make it “significantly less likely that the respondents will be led into giving a particular answer.” (Mazis, Tr. 2732).

1377. Dr. Mazis expressed the opinion that “the impact of advertising on beliefs about a product is not an appropriate measure of materiality or ad claim communication.” (CX1297 (Mazis Expert Report at 0009)).

K. Remedy

1. Roll Global and POM entities

1378. Roll Global (“Roll”) is an approximately $2 billion corporation that includes under its umbrella the companies Teleflora, Fiji Water, Paramount Farms (which sells Wonderful Pistachios and Wonderful Almonds), Paramount Citrus (which sells Cuties), Justin Vineyards and Winery, and Suterra. (JX0003 ¶ B.3; S. Resnick, Tr. 1629-30; Perdigao, Tr. 593-94).

1379. POM manufactures, advertises, and sells other products containing pomegranate, including various POM Juice blends, Lite POM Juice, POMx bars, POMx iced tea and iced coffee, and a POMx sports recovery beverage. (JX0003 ¶ B.8).

***166** 1380. POM is headquartered in the same building as Roll, in many cases with employees of both companies occupying the same floor. For example, Mr. Perdigao, the president of Roll's in-house advertising agency, Fire Station and Roll's Corporate Communications department (F. 134, 138), and Ms. Leow, Fire Station's Creative Director, are located on the same floor as the offices of Mrs. Resnick, Mr. Resnick, and Mr. Tupper, among other POM employees. (Tupper, Tr. 888; Leow, Tr. 418; PX0277 at 0002-03).

1381. Mrs. Resnick describes Roll as "the umbrella company for all of our businesses" and others that work for Respondents describe Roll similarly and consider POM to be part of Roll. (CX0001 at 00011; Posell, Tr. 298, 305; Tupper, Tr. 894; Perdigao, Tr. 593).

1382. Mr. and Mrs. Resnick each maintain a business address at 11444 West Olympic Blvd., 10th Floor, Los Angeles, CA 90064, which is also the business address for POM and Roll. (PX0277 at 0002-03; *see also* PX0276 at 0002).

1383. Mrs. Resnick does not have a specific corporate title at POM. (L. Resnick, Tr. 287-88; CX1359 (L. Resnick, Dep. at 37)).

1384. Although Roll's affiliated companies' pay Roll for certain provided services, including advertising (F. 13-14), not all expenses, such as advertising and marketing services, provided to POM were reimbursed. Roll has provided various services over the years to POM relating to POM Juice, POMx Pills, and POMx Liquid "with some portion charged back to POM ...." (CX1383 at 0014; CX1357 (Kuyoomjian, Dep. at 235)). For example, the former Vice President of Corporate Communications at Roll testified she was not required to keep track of her time based on whether she was working on a POM project or a project for another Roll company. (Posell, Tr. 325). In addition, Roll provides risk management, human resources, consulting, and travel services to POM without any reimbursement. (CX1354 (Bryant, Dep. at 41-42, 48-50, 55-64)).

1385. When Fire Station acts as Roll's in-house advertising agency, Fire Station bills POM and other Roll entities separately, and each client pays for advertising and marketing expenses incurred. (CX1376 (S. Resnick, Ocean Spray Dep. at 24-25); L. Resnick, Tr. 88-89; CX1359 (L. Resnick, Dep. at 26); Perdigao Tr. 616-17).

1386. The Resnicks have had ultimate say over all business functions of Roll and POM. They have set policy and supervised the senior executives of both companies, disregarding corporate formalities. For example, Mrs. Resnick has had complete oversight over POM's business, despite lacking any formal position with the company. (CX1368 at 0002-03 (L. Resnick, Welch Dep. at 8-9); CX1362 at 0012 (L. Resnick, Coke Dep. at 45-46); CX1374 (Tupper, Ocean Spray Dep. at 18-19); S. Resnick, Tr. 1631 (stating that Mrs. Resnick is very involved in setting POM's marketing and advertising budget); L. Resnick, Tr. 184 (stating that she has interviewed candidates for the chief marketing officer or other senior vice president positions at POM); JX0001 ¶ 18 (showing overlapping officers between POM and Roll); Posell, Tr. 321, 325 (stating that while Vice President of Corporate Communications, Ms. Posell reported to Mr. Tupper and Mrs. Resnick)).

***167** 1387. For accounting purposes, Roll and its affiliated companies, including POM, were represented as being under common control or ownership and have been included together on consolidated financial and tax statements. (CX1354 (Bryant, Dep. at 23, 27, 52-53), *in camera*; *see also* CX1355 (Hemmati, Dep. at 52-54) (stating that Roll provided information about the Resnick Trust's payments for medical research to POM); CX1276 at 0003).

1388. POM's Consumer Affairs representative would typically respond to consumer complaints; however, "if necessary, [they] might get escalated" to others at POM or Roll, such as Roll's Corporate Communications, which may respond directly to the consumer. (CX1357 (Kuyoomjian, Dep. at 204-10)

1389. Roll also interacts with POM for the purposes of joint cash management, as noted by Roll's Chief Financial Officer, Robert Bryant, who stated that Roll "pool[s] together the cash from each one of [its] operating companies and will invest that cash ... overnight for purposes of investments ... [o]r if [Roll has] debt outstanding on [its] working capital lines, then [Roll] will use that cash to pay down those working capital ... lines." (CX1354 (Bryant, Dep. at 67)).

1390. POM's medical research program was sponsored and funded by various Resnick entities (*e.g.*, Roll, POM, and the Resnick Trust). (CX1118 at 0001; CX0604 at 0022 (stating that "Roll Int'l will reimburse Technion [Institute] directly," even though POM was listed as the research sponsor); CX0628 at 0001 (describing a study on pomegranate juice as the "Roll Beverage Study"); *see also* F. 1391).

2. The Resnicks

1391. The Stewart and Lynda Resnick Revocable Trust entered into contracts to fund research; however, regardless of which Resnick-controlled organization has paid for pomegranate research, the money ultimately comes from the Resnicks. (CX0610; S. Resnick, Tr. 1657, 1675-76, 1722-23; CX1363 at 0016 (S. Resnick, Coke Dep. at 61) (whether a study is sponsored by Roll or POM, "[t]he money comes out of the same pockets"); *see also* CX1376 (S. Resnick, Ocean Spray Dep. at 229-30 (the $34 million referenced in a POM advertisement is ultimately "our money, however it comes")); L. Resnick, Tr. 198-99).

1392. Mr. Resnick has been directly involved in the development of POM's scientific research program by engaging and communicating with scientific consultants, participating in scientific advisory board meetings, and convening company-sponsored research summits. (CX1360 (S. Resnick, Dep. at 85, 110-12); Tupper, Tr. 1027-28; Liker, Tr. 1880, 1889, 1891; CX0589).

1393. With regard to the medical research budget, Mr. Resnick reviews and approves the POM research budget annually, and when necessary if any changes occur during the year. (CX1376 (S. Resnick, Ocean Spray Dep. at 227)).

1394. Mr. Resnick reviews the results of the scientific research he sponsors, and has seen the results of all the important tests and also some of the draft manuscripts before they were published. (S. Resnick, Tr. 1656-57).

***168** 1395. Mr. Resnick meets with POM and its scientific advisors about POM-sponsored research ten to twelve times a year "officially" and three to four additional times to review what has been learned and where the company's research may go. (CX1376 (S. Resnick, Ocean Spray Dep. at 223-24).

1396. Mrs. Resnick participated in POM's business on almost a daily basis in the company's early years, and on a weekly or biweekly basis thereafter and through 2010. (L. Resnick, Tr. 93, 157-58; *see also* CX1375 (L. Resnick, Tropicana Dep. at 19-22, 78); CX1359 (L. Resnick, Dep. at 108)).

1397. If there were disputes or issues to resolve regarding advertising decisions, the final authority was either Mr. or Mrs. Resnick. As the overseer of all branding and marketing, Mrs. Resnick had the "final word" on advertising content and concepts. (CX1365 (Perdigao, Coke Dep. at 36-37)); CX1368 at 0003 (L. Resnick, Welch's Dep. at 9); L. Resnick, Tr. 93; CX1347 (Glovsky, Dep. at 36); CX1357 (Kuyoomjian, Dep. at 84)).

1398. Mrs. Resnick has participated in the hiring and firing of heads of marketing at POM. (L. Resnick, Tr. 183-84, 227-28).

1399. Mrs. Resnick has had a principal role in approving advertising content since POM's inception. For example, Mrs. Resnick requested that copies of all advertising campaigns be submitted to her for final approval including the headlines used in POM's advertisements. (CX1368 at 0003 (L. Resnick, Welch Dep. at 9); *see also* CX1357 (Kuyoomjian, Dep. at 56-57, 77, 127); CX1346 (Rushton, Dep. at 42 (approval of website designs)); CX0147).

1400. At LRR Meetings (F. 141) and during other interactions with POM Marketing and Fire Station, Mrs. Resnick would approve a general direction for POM's advertising and also approved the lion's share of POM's advertising concepts. (*see* F. 143).

1401. Mrs. Resnick was "very involved" in developing the POMx brochure, identified as CX1426, Exhibit I "Antioxidant Superpill" package insert, when it was first produced. (L. Resnick, Tr. 246; *see* F. 328-342).

1402. Mrs. Resnick was involved in the approval of the print advertisement identified as CX0029 ("10 OUT OF 10 PEOPLE DON'T WANT TO DIE") (CX0471 at 0007-08; L. Resnick, Tr. 158; CX0029; *see* F. 299-305).

1403. Mrs. Resnick approved the headline for the POMx print advertisement headlined "The Only Antioxidant Supplement Rated X." (L. Resnick, Tr. 266; *see* CX0351 and CX0355; *see* F. 321-327)).

1404. Mrs. Resnick approved the print advertisement identified as CX0031 ("Floss your arteries" print advertisement); CX0471 at 0010; L. Resnick, Tr. 158-59; CX0031; *see* F. 440-448).

3. Matthew Tupper

1405. Mr. Tupper has never had any ownership interest in POM Wonderful and has no expectation of ever having such an interest. (CX1353 (Tupper, Dep. at 14-15); Tupper, Tr. 2973).

1406. Mr. Tupper had no more authority at POM than was delegated to him by Mr. Resnick. Mr. Resnick delegated to Mr. Tupper the authority to decide which advertisements should run. (S. Resnick, Tr. 1870).

***169** 1407. When Mrs. Resnick reduced her day-to-day involvement in POM's business beginning in 2007, Mrs. Resnick felt confident that Mr. Tupper would be able to take care of the marketing aspects of the business, as she had previously done. (L. Resnick, Tr. 229).

1408. Mr. Tupper reviewed work on each of POM's large advertising campaigns at the concept stage, before they were shown to Mrs. Resnick. (Leow, Tr. 459-60).

1409. With respect to health benefit advertising, Mr. Tupper was the "connecting piece" or "liaison" between the marketing vision and the communication of the science. (Tupper, Tr. 2975-76).

1410. Mr. Tupper led meetings to review advertising copy from a scientific perspective prior to its dissemination. (Dreher, Tr. 530).

1411. Mr. Tupper was engaged in the medical research aspect of POM's business from the time he first joined POM full-time in 2003. Beginning in late 2006 or early in 2007, he became more engaged as the "connecting piece" between research and marketing. (Tupper, Tr. 2975-77; *see* F. 1409).

1412. As POM's president, Mr. Tupper attended most of the marketing review meetings with Mrs. Resnick, which included discussions of POM's scientific research. (Tupper, Tr. 929-30; CX1351 (McLaws, Dep. at 33-34); CX1347 (Glovsky, Dep. at 149-50)).

1413. Mr. Tupper was significantly involved in the research aspects of POM's business, the internal decision-making as to what research to fund, and overseeing for POM the clinical trials on POM's products that were conducted by research institutions. (Tupper, Tr. 895-96, 906; *see also* CX0770; CX0779; CX0800; CX0919; CX0920).

1414. POM's former Senior Vice President of Marketing, Ms. Diane Kuyoomjian, relied on her conversations with Mr. Tupper to understand the content in POM's advertising regarding the relationship between POM advertisements and the scientific support for these advertisements. She relied on Mr. Tupper to be the "arbiter" of whether people felt POM's advertising was accurate. (CX1378 (Kuyoomjian, Ocean Spray Dep. at 71-72)).

1415. Ms. Kuyoomjian, "would never do something [Mr. Tupper] wasn't involved in. He was [her] boss." (CX1357 (Kuyoomjian, Dep. at 51)).

1416. As one of the senior leaders at POM, Mr. Tupper organized meetings to review advertising copy from a scientific perspective. (Dreher, Tr. 530).

1417. Mr. Tupper reviewed and gave direction to POM's marketing staff on parts or elements of creative briefs. (Tupper, Tr. 924).

1418. According to POM's former Senior Vice President of Marketing, Ms. Kuyoomjian, Mr. Tupper was the primary person from whom she received information on POM's medical research, including information that would appear in consumer advertising copy, and Mr. Tupper in general would provide input as to how to describe the medical research used in advertisement copy. (CX1357 (Kuyoomjian, Dep. at 164-66); *see also* CX0906 at 0001-02 (providing guidance on what types of studies should be used in newsletters and websites)).

***170** 1419. Mr. Tupper participated in meetings in which Fire Station and POM personnel presented and reviewed advertising concepts and advertising. (L. Resnick, Tr. 91-92; Tupper, Tr. 929).

1420. Mr. Tupper reviewed advertising copy (including headlines), made changes to copy, and, depending on the project, had final say over POM advertising content and which advertisements should or should not run. (L. Resnick, Tr. 87; Leow, Tr. 423-24, 464-66; Tupper, Tr. 925-27; S. Resnick, Tr. 1870; CX1357 (Kuyoomjian, Dep. at 141-42)).

1421. Sometimes, Mr. Tupper would provide the specific words to use when presenting medical research facts, and in other instances, POM Marketing or Fire Station employees would "take a stab at writing [this information] and send it to [Mr. Tupper] to approve." (CX1357 (Kuyoomjian, Dep. at 169-70)).

1422. On average, Mr. Tupper has interacted with Mr. Perdigao, head of Fire Station creative agency, once a week. (Perdigao, Tr. 613).

1423. During periods when the position of head of marketing at POM was vacant, Mr. Tupper would step in to some extent, and if the subject matter required a high level person, Mr. Tupper would take the lead in communicating with Fire Station. (L. Resnick, Tr. 185; Perdigao, Tr. 611-12).

1424. Mr. Tupper had direct contact with research scientists who were working on POM's products, including substantive discussions of the underlying science. (Tupper, Tr. 899, 914).

1425. Mr. Tupper worked with Dr. Dreher in preparing summaries of POM's research portfolio. Mr. Tupper offered the business perspective by drafting the "where do we go from here" sections of POM's medical research summaries. He also edited the research summaries. (Dreher, Tr. 555-56, 558; CX1015 at 0001; CX1029).

1426. Mr. Tupper, along with Mr. Resnick, would meet on occasion with Dr. Liker, POM's Medical Director, to communicate the scientific research areas that POM was interested in exploring. (Liker, Tr. 1880).

1427. Mr. Tupper's responsibilities included keeping up to date on the status of medical research on POM's products, as well as reviewing the unpublished and published data that resulted from studies on POM's products. (Tupper, Tr. 913-14, 941; S. Resnick, Tr. 1720-21).

1428. Mr. Tupper, along with Mr. Resnick, participated in meetings with POM's scientific advisors to review research summaries, discuss research results, and come up with future plans for additional research. (Liker, Tr. 1889, 1915, 1925; Dreher, Tr. 555-56). Some of these scientific research meetings also included POM's scientific director at the time (either Risa Schulman, Dr. Dreher, or Dr. Gillespie), Dr. Liker, Dr. Heber, or Dr. David Kessler ("Dr. Kessler"), an advisor to POM. (Liker, Tr. 1889; Heber, Tr. 2068, 2072; Heber, Tr. 2072; S. Resnick, Tr. 1859).

1429. Mr. Tupper participated in regular research summits, which were meetings with scientists that helped POM interpret the results of scientific research and facilitated discussions about future research. (Liker, Tr. 1890-92).

***171** 1430. Mr. Tupper reviewed press releases prior to issuance. (Posell, Tr. 368; CX0062; CX0127).

1431. Mr. Tupper participated in drafting the *Time* magazine cover wraps found herein to have made the claims alleged in the Complaint (*see* F. 308-320, 581; CX1378 (Kuyoomjian, Ocean Spray Dep. at 88-90)).

III. ANALYSIS

A. Burden of Proof

The parties' burdens of proof are governed by Rule 3.43(a) of the Federal Trade Commission's Rules of Practice, Section 556(d) of the Administrative Procedure Act ("APA"), and case law. Pursuant to Commission Rule 3.43(a), "[c]ounsel representing the Commission ... shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto." 16 C.F.R. § 3.43(a). Under the APA, "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. § 556(d).

It is well established that the preponderance of the evidence standard governs Federal Trade Commission ("FTC") enforcement actions. *In re Telebrands Corp.*, No. 9313, 140 F.T.C. 278, 426, 2004 FTC LEXIS 154, at *76 (Sept. 15, 2004) (Initial Decision), *aff'd*, 140 F.T.C. 278, 2005 FTC LEXIS 178 (Sept. 19, 2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *In re Automotive Breakthrough Sciences, Inc.*, No. 9275, 1998 FTC LEXIS 112, at *38 n.45 (Sept.

9, 1998) (holding that each finding must be "supported by a preponderance of the evidence in the record"); *In re Adventist Health System/West*, No. 9234, 117 F.T.C. 224, 1994 FTC LEXIS 54, at *28 (Apr. 1, 1994) ("[e]ach element of the case must be established by a preponderance of the evidence"); *In re Bristol-Meyers Co.*, No. 8917, 102 F.T.C. 21, 1983 FTC LEXIS 64, at *143 (Sept. 28, 1979) (Initial Decision) (stating that complaint counsel has "the burden of proving by a preponderance of credible evidence that the challenged advertising claims have not been established or did not have a reasonable basis"), *aff'd*, 1983 FTC LEXIS 21, at *242 (July 5, 1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984). *See also Steadman v. SEC*, 450 U.S. 91, 102 (1981) (holding that the APA establishes preponderance of the evidence standard of proof for formal administrative adjudicatory proceedings).

The Complaint in this case alleges that Respondents disseminated advertising and promotional materials representing that the consumption of eight ounces of POM Juice, one POMx Pill, or one teaspoon of POMx Liquid (the "POM Products") daily "prevents or reduces the risk of" or "treats" heart disease, prostate cancer or erectile dysfunction. Complaint ¶¶ 9, 10, 19. The Complaint further alleges that Respondents represented that they possessed and relied upon, but in fact did not possess or rely upon, a reasonable basis substantiating such claims, and thus, Respondents' representations were false or misleading. Complaint ¶¶ 19-21. In addition, the Complaint alleges that Respondents have disseminated advertising and promotional materials representing that "clinical studies, research, and/or trials prove" that consuming the POM Products "prevents or reduces the risk of" or "treats" heart disease, prostate cancer or erectile dysfunction, Complaint ¶¶ 9, 10, 12, 14, 16, but that these representations were false or misleading because clinical studies, research, and/or trials do not in fact prove that consuming the POM Products, "prevents or reduces the risk of" or "treats" heart disease, prostate cancer or erectile dysfunction. Complaint ¶¶ 13, 15, 17, 18. Complaint Counsel has the burden of proving each of the foregoing factual issues by a preponderance of credible evidence. *In re Bristol-Myers Co.*, 1983 FTC LEXIS 64, at *143-44. *See also FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 959 (N.D. Ill. 2006), *aff'd*, 512 F.3d 858 (7th Cir. 2008).

B. Jurisdiction

***172** Section 5 of the Federal Trade Commission Act ("FTC Act") grants the Federal Trade Commission the authority to "prevent unfair or deceptive acts or practices in or affecting commerce" by "persons, partnerships, or corporations." 15 U.S.C. § 45(a)(1)-(2) (2012). Section 4 of the FTC Act defines "corporation," in part, as "any company, trust, so-called Massachusetts trust, or association, incorporated or unincorporated, which is organized to carry on business for its own profit or that of its members, and has shares of capital or capital stock or certificates of interest ...." 15 U.S.C. § 44.

POM Wonderful ("POM Wonderful" or "POM") is a limited liability company. F. 1. Roll International Corporation, which was reorganized at the end of 2010 and is currently known as Roll Global ("Roll"), is a separate corporation. F. 7-8. POM Wonderful is one of several separate operating businesses under Roll's ownership umbrella. F. 11. Mr. Stewart Resnick ("Mr. Resnick") and Mrs. Lynda Resnick ("Mrs. Resnick") are the sole owners of Roll and its affiliated companies, including POM Wonderful. F. 12. Mr. Resnick is the Chairman and President of Roll and the Chairman and Chief Executive Officer of POM Wonderful. F. 19-21. Mrs. Resnick is Vice Chairman of Roll. F. 27-28. She is the chief marketing person at POM, with responsibilities for marketing, branding, public relations, and product development. F. 29-31. Mr. Matthew Tupper was the President of POM and managed the day-to-day operations of POM Wonderful, including the POM marketing team, prior to his retirement in 2011. F. 37-38, 40, 44. Thus, POM Wonderful and Roll Global are partnerships or corporations and Mr. and Mrs. Resnick and Mr. Tupper are individuals over which the FTC has jurisdiction.

POM Wonderful is currently in the business of selling fresh pomegranates and pomegranate-related products, including 100% pomegranate juice ("POM Juice") and pomegranate extract products known as POMx Pills and POMx Liquid ("POMx"). F. 6. Respondents began selling POM Juice in 2002. F. 5, 95. POM Juice is sold in supermarkets nationally and is a major seller in the premium juice category. F. 95. POM's U.S. Sales of 100%

POM Juice, from September 2002 to November 2010, totaled approximately $247,739,776. F. 96. Respondents admit that "[t]he acts and practices of respondents alleged in this complaint have been in or affecting commerce, as 'commerce' is defined in Section 4 of the Federal Trade Commission Act." Answer ¶ 8. In addition, Respondents promoted the POM Products through various methods, including print advertisements in magazines, freestanding inserts in newspapers, out of home media such as billboards and bus shelters, posters in health clubs and doctors' offices, Internet websites, online banner advertisements, press releases, and television advertisements. F. 171. The acts and practices charged in the Complaint in this matter are in or affecting commerce within the meaning of the FTC Act, as amended. 15 U.S.C. § 41 *et seq.* Accordingly, the Commission has jurisdiction over the conduct challenged in the Complaint, pursuant to Sections 4 and 5 of the FTC Act. 15 U.S.C. §§ 44, 45.

C. Scope of Challenged Advertisements in this Case

1. "Advertisements"

***173** The Complaint charges Respondents with violating Sections 5 and 12 of the FTC Act. Complaint ¶ 22. Section 5(a) of the FTC Act provides that "unfair or deceptive acts or practices in or affecting commerce are hereby declared unlawful." 15 U.S.C. § 45(a)(1). Section 12 of the FTC Act prohibits the dissemination of "any false advertisement" in order to induce the purchase of "food, drugs, devices, services, or cosmetics." 15 U.S.C. § 52(a)(2). For the purposes of Section 12, "false advertisement" is defined as "an advertisement, other than labeling, which is misleading in a material respect[.]" 15 U.S.C. § 55(a).

The interrelation between Section 5(a) and Section 12 of the FTC Act was recently described by the Court of Appeals for the First Circuit as follows:
[T]he FTC statute ... provides that both "unfair or deceptive acts or practices in or affecting commerce" (15 U.S.C. § 45(a)(1)) and "disseminat [ing], or caus[ing] to be disseminated, any false advertisement ... in or having an effect upon commerce" (15 U.S.C. § 52(a)) are "unlawful." 15 U.S.C. § 55 defines the term "false advertisement" as "an advertisement, other than labeling, which is misleading in a material respect ...." Given the strong similarity between the terms "deceptive" and "misleading," it is no surprise that sections 45 and 52 are sometimes applied in tandem as the basis for an FTC action against an alleged false advertiser; indeed, such a tandem reading is expressly allowed by 15 U.S.C. § 52(b).

FTC v. Direct Marketing Concepts, Inc., 624 F.3d 1, 7-8 (1st Cir. 2010).

Complaint Counsel in this case has challenged 43 items, which Complaint Counsel describes as "Respondents' ads and promotional pieces," as violating Sections 5 and 12 of the FTC Act. CCB at 19; CCB Appendix A, Tables 1 and 2 (hereafter, "CCB Appendix A"). Specifically, Complaint Counsel challenges print advertisements, newsletters, website advertising, and "public relations" promotional pieces, including press releases and press interviews. CCB Appendix A; *see also* CCB at 13. Complaint Counsel asserts that all of the challenged promotional pieces constitute "advertisements" within the scope of Section 12 of the FTC Act, 15 U.S.C. § 52, and deceptive acts or practices within the scope of Section 5 of the FTC Act, 15 U.S.C. § 45. CCB at 14.

***174** Respondents contend that the following four challenged items do not constitute "advertisements" in violation of Sections 5 and 12 of the FTC Act: [5]
1. Mrs. Resnick's November 2008 television appearance on *The Martha Stewart Show*, during which she shared personal recipes for a POMtini cocktail and Thanksgiving stuffing, (CX1426 (Compl. Ex. E-6));

2. Mrs. Resnick's February 2009 television appearance on *The Early Show*, during which she shared some marketing ideas for POM and FIJI Water, (CX0472 at 0003);

3. an interview of Mrs. Resnick in *Newsweek* magazine, dated March 20, 2009, discussing the economy, her business acumen, and promoting the sale of her book, *Rubies in the Orchard*, (CX1426 (Compl. Ex. F)); and

4. a June 2008 television interview of Mr. Tupper on FOX Business discussing the newest "hot" wave in foods — the pomegranate — and the pomegranate juice industry, (CX1426 (Compl. Ex. E-7)).

Respondents assert that these four interviews are not actionable under the FTC Act because they do not constitute "advertising." RB at 92. Complaint Counsel charges that these media appearances constitute "advertisements" within the scope of Section 12, CCB at 14, and contends that neither Section 5 nor Section 12 limits the FTC's reach to paid for advertising. CCRB at 44. Complaint Counsel further argues that the Commission's authority to regulate advertising is circumscribed only by its statutory authority and the limits of the commercial speech doctrine. CCRB at 44 (citing *In re R.J. Reynolds Tobacco Co.*, No. 9206, 111 F.T.C. 539, 542 (Mar. 4, 1988)).

The term "advertisement" is not defined in the FTC Act. However, in *R.J. Reynolds Tobacco*, the Commission made clear that it "understands[] [the term advertisement] to mean a notice or announcement that is publicly published or broadcast and is paid-for." *R.J. Reynolds Tobacco Co.*, 1988 FTC LEXIS 9, at *20. Complaint Counsel does not contend and has not pointed to any evidence to support a conclusion that Respondents paid anyone for their participation in the interviews or to allow them to speak about their products. *See* CCFF 570-577. Moreover, these media interviews were conducted by individuals working with *The Martha Stewart Show*, *The Early Show*, *Newsweek*, and FOX Business — entities other than the Respondents — and were not sponsored by Respondents. *See* F. 575-578. By contrast, the radio program that was found to constitute an "advertisement" in *Daniel Chapter One* ran on a radio network founded and funded by respondents, was titled "Daniel Chapter One HealthWatch," and was co-hosted by the individual respondents who were responsible for its content. *In re Daniel Chapter One*, No. 9329, 2009 FTC LEXIS 157, *21-22, 48, 163, 169-70 (Aug. 5, 2009) (Initial Decision), *aff'd*, 2009 FTC LEXIS 259 (Dec. 24, 2009). [6] *See also In re Witkower Press, Inc.*, 57 F.T.C. 145, 1960 FTC LEXIS 186, *157 (July 19, 1960) (finding "respondents' newspaper advertisements, book jackets and the television shows *sponsored by them* unquestionably constitute commercial advertising") (emphasis added).

***175** Complaint Counsel has cited no cases where the Commission charged a respondent with violating Section 12 of the FTC Act based on public statements that were not paid for or sponsored by the respondent. *E.g.*, *In re R. J. Reynolds Tobacco Co.*, 1988 FTC LEXIS 9, *1 ("This case involves an advertisement, entitled 'Of Cigarettes and Science,' allegedly disseminated by Reynolds in the course of its business of manufacturing, advertising and selling cigarettes."); *FTC v. Nat'l Comm'n on Egg Nutrition*, 517 F.2d 485, 487-88 (7th Cir. 1975) ("[P]ublished and broadcast statements, in the form of paid advertisements, representing in substance that there is no scientific evidence that eating eggs increases the risk of heart disease or a heart attack ... were advertisements within the meaning of that term as used in the [FTC] Act, because they were representations concerning the qualities of a product and promoting its purchase and use."); *Nat'l Comm'n on Egg Nutrition v. FTC*, 570 F.2d 157, 159 (7th Cir. 1977) (enforcing, in part, order imposed on industry association which "mounted an advertising and public relations campaign to convey the message that eggs are harmless and are needed in human nutrition").

The only case found involving statements made in a public speaking engagement, cited by Respondents and addressed by Complaint Counsel, is *FTC v. Koch*, 206 F.2d 311 (6th Cir. 1953). The court there, without addressing whether promotional materials must be paid for to constitute advertising, found that a challenged book, which "set forth primarily matter of opinion," did "not fall within the provisions of the statutes involved here." *Id.* at 317. The court explained:

We also think that if these provisions of the statutes were construed so as to prohibit dissemination of such a book they would violate the First Amendment to the Constitution of the United States. It was not error for the Commission to consider this book and to quote extracts from it as throwing light upon the existence or non-existence of facts supporting the charge in the complaint, for the book was introduced by the respondents. However, we hold that it is not an advertisement covered by Sections 5, 12, or 15(a). We make a similar conclusion with reference to Dr. Koch's address before the College of Physicians and Surgeons of Quebec in 1939. If the record contained only these two exhibits, the Commission would not have jurisdiction in this proceeding.

Id.

Complaint Counsel has offered no authority to support a conclusion that publicly disseminated information that is not paid for or sponsored by Respondents constitutes "advertisements" within the scope of Section 12 of the FTC Act. Under the Commission's precedent regarding the statutory term "advertisement," the media appearances and interviews by Respondents in this case do not constitute "advertisements" within the scope of Section 12 of the FTC Act because they were not paid for or sponsored by Respondents. Therefore, the issue of whether the media interviews constitute constitutionally protected speech need not be, and is not, decided. Because the following exhibits — CX1426 (Compl. Ex. E-6) (Mrs. Resnick's November 2008 television appearance on *The Martha Stewart Show*); CX0472 at 0003 (Mrs. Resnick's February 2009 television appearance on *The Early Show*); CX1426 (Compl. Ex. F) (interview of Mrs. Resnick in *Newsweek* magazine); and CX1426 (Compl. Ex. E-7) (television interview of Mr. Tupper on FOX Business) — do not constitute "advertisements," this Initial Decision does not evaluate whether Respondents made any of the alleged claims in those exhibits. Moreover, the term, "Challenged Advertisements," as used herein, does not include these four media appearances and interviews.

2. "Food" or "drug"

***176** The FTC Act defines the words "food" and "drug" broadly for purposes of Section 12. 15 U.S.C. § 55(b), (c) (defining "food" as, among other things, "articles used for food or drink for man," and defining "drug" as, among other things, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man"). Courts have repeatedly held that these definitions of "food" or "drug" cover dietary supplements. *In re Daniel Chapter One*, 2009 FTC LEXIS 157, at *171-73 (Initial Decision) (citing *FTC v. Natural Solution, Inc.*, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. 2007); *FTC v. Nat'l Urological Group*, 645 F. Supp. 2d 1167, 1190 (N.D. Ga. 2008); *Direct Marketing*, 569 F. Supp. 2d at 300-03). POM Juice is a juice derived from pomegranate fruits. F. 57-58. POMx Pills and Liquid are extracts derived from the pomegranate. F. 67, 70-71, 89-90. Accordingly, each of the POM Products are a "food" or "drug" (F. 60, 61, 67, 70-71, 89-90) as defined in Section 12 of the FTC Act.

D. Overview of Applicable Law

An "advertisement is deceptive under the [FTC] Act if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect." *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992) (citing *In re Thompson Medical Co.*, No. 9149, 104 F.T.C. 648, 788, 1984 FTC LEXIS 6, at *311 (Nov. 23, 1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986)); *In re Cliffdale Assocs.*, No. 9156, 103 F.T.C. 110, 164-66, 1984 FTC LEXIS 71, at *104 (Mar. 23, 1984)). The determination of whether Respondents disseminated false advertisements in violation of the FTC Act requires a three-part inquiry: (1) whether Respondents disseminated advertisements conveying the claims alleged in the Complaint; (2) whether those claims were false or misleading; and (3) whether those claims are material to prospective consumers. *Kraft*, 970 F.2d at 314;*FTC v. Pantron I Corp.*, 33 F.3d 1088, 1095 (9th Cir. 1994); *Direct Marketing*, 569 F. Supp. 2d at 297. Each of these elements is addressed below.

E. Whether Respondents Disseminated Advertisements Conveying the Alleged Claims

1. General principles

"The Commission will deem an advertisement to convey a claim if consumers, acting reasonably under the circumstances, would interpret the advertisement to contain that message." *Thompson Medical*, 104 F.T.C. at 788; *Cliffdale Associates, Inc.*, 103 F.T.C. at 164-66; *Federal Trade Commission Policy Statement on Deception*, appended to *Cliffdale Associates, Inc.*, 103 F.T.C. 110, 1984 FTC LEXIS 71, at *176-77 (1984) (the "*Deception Statement*"); *In re Kraft, Inc.*, 114 F.T.C. 40, 1991 FTC LEXIS 38, at *10 (1991).

***177** Advertising claims may be conveyed either expressly or impliedly. Express claims directly state the representation at issue. *Kraft*, 970 F.2d at 319 n.4;*Thompson Medical*, 104 F.T.C. at 788, 1984 FTC LEXIS 6, at *311; *Cliffdale*, 1984 FTC LEXIS 71, at *108 (1984). Because the claim is stated unequivocally, the statement itself establishes its meaning, and it is, therefore, reasonable to interpret such advertisement as making the alleged claim. *Thompson Medical*, 104 F.T.C. at 788, 1984 FTC LEXIS 6, at *311-12. Implied claims are made in an oblique or indirect way. *Kraft*, 970 F.2d at 319 n.4.

An interpretation of an advertisement may be reasonable even though it is not shared by a majority of consumers. *Kraft*, 1991 FTC LEXIS 38, at *14; *Deception Statement*, 1984 FTC LEXIS 71, at *177 n.20. A reasonable interpretation is one that would be shared by a "significant minority" of reasonable consumers. *Id.*; *In re Novartis Corporation*, No. 9279, 127 F.T.C. 580, 1999 FTC LEXIS 63, at *22-23 (May 13, 1999); *Kraft*, 1991 FTC LEXIS 38, at *14; *see also Telebrands Corp.*, 140 F.T.C. at 291 ("An ad is misleading if at least a significant minority of reasonable consumers are likely to take away the misleading claim.").

"[F]indings with respect to what representations are made in advertisements are factual. *See, e.g.*, *Thompson Medical v. FTC*, 791 F.2d 189, 197 (D.C. Cir. 1986) (quoting from the FTC's brief); *AHP [American Home Products]*, 695 F.2d [681,] 686 [(3rd Cir. 1982)]; *Beneficial Corp. v. FTC*, 542 F.2d 611, 617 (3d Cir. 1976)." *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1496 (1st Cir. 1989). In the instant case, it has been found as a fact that none of the Challenged Advertisements expressly (*i.e.*, unequivocally and directly) states that "drinking eight ounces of POM Juice daily" or "taking one POMx Pill daily," or "taking one teaspoon of POMx Liquid daily" (1) "treats," "prevents," or "reduces the risk" of "heart disease," including by reducing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart, or that these effects are "clinically proven"; (2) "treats," "prevents," or "reduces the risk" of "prostate cancer," including by prolonging prostate-specific antigen doubling time, or that these effects are "clinically proven"; or (3) "treats," "prevents," or "reduces the risk" of erectile dysfunction, or that these effects are "clinically proven." F. 586. Thus, the issue is whether any of the Challenged Advertisements made the alleged claims implicitly; that is, whether a significant minority of consumers, acting reasonably in the circumstances, would interpret any of the Challenged Advertisements to convey the claims alleged in the Complaint. The methodology used in making this factual determination is further explained in below.

a. Facial analysis

***178** To determine whether an advertisement conveys an alleged claim, the first step is to examine the advertisement itself (a "facial analysis"). *Thompson Medical*, 1984 FTC LEXIS 6, at *313; *Cliffdale*, 1984 FTC LEXIS 71, at *108. A proper facial analysis requires "an evaluation of such factors as the entire document, the juxtaposition of various phrases in the document, the nature of the claim, and the nature of the transaction." *Deception Statement*, 103 F.T.C. 110, 1984 FTC LEXIS 71, at *172. The advertisement must be viewed as a whole "without emphasizing isolated words or phrases apart from their context." *Removatron*, 884 F.2d at 1496 (quoting *AHP*), 695 F.2d at 687;*see also FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963) ("The entire mosaic should be viewed rather than each tile separately."). "But the Commission may not inject novel meanings into ads and then strike them down as unsupported; ads must be judged by the impression they make on reasonable

members of the public." *In re Bristol-Meyers Co.*, No. 8917, 102 F.T.C. 21, 1983 FTC LEXIS 64, *249 (July 5, 1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984).

"If, after examining the interaction of all the different elements in the ad, the Commission can conclude with confidence that an advertisement can reasonably be read to contain a particular claim, a facial analysis is sufficient basis to conclude that the advertisement conveys the claim. *See Kraft*, 114 F.T.C. at 121; *Thompson Medical*, 104 F.T.C. at 789." *In re Stouffer Foods Corp*, No. 9250, 118 F.T.C. 746, 1994 FTC LEXIS 196, at *9 (Sept. 26, 1994). However, the alleged claim must be reasonably clear or conspicuous from the face of the advertisement. *Kraft*, 970 F.2d at 319 (holding that the Commission can rely on its own reasoned analysis to determine what claims, including implied ones, are conveyed in a challenged advertisement "so long as those claims are reasonably clear from the face of the advertisement"); *accord Nat'l Urological Group*, 645 F. Supp. 2d at 1189 (holding that facial analysis is sufficient basis to find alleged claim was made if claims are "clear and conspicuous" or "apparent" on the face of the advertisement); *QT, Inc.*, 448 F. Supp. 2d at 958 ("Where implied claims are conspicuous and reasonably clear from the face of the advertisements, extrinsic evidence is not required.").

***179** If, after a facial analysis, it cannot be concluded with confidence that a particular advertisement can reasonably be read to contain a particular implied message, "the Commission will not find the ad to have made the claim unless extrinsic evidence allows the conclusion that such a reading of the ad is reasonable. *Kraft*, 114 F.T.C. at 121; *Thompson Medical*, 104 F.T.C. at 789." *Stouffer*, 1994 FTC LEXIS 196, at *10. In all cases, however, if extrinsic evidence has been introduced, that evidence "must be considered by the Commission in reaching its conclusion on the meaning of the advertisement." *Bristol-Meyers*, 1983 FTC LEXIS 64, at *247-48; *see Deception Statement*, 1984 FTC LEXIS 71, at *172-73; *Thompson Medical*, 1984 FTC LEXIS 6, at *324-25 (holding that because Thompson offered extrinsic evidence, the Commission was "obliged to consider it"). The Commission will carefully consider any extrinsic evidence that is introduced, taking into account the quality and reliability of the evidence. *See Kraft*, 114 F.T.C. at 122, 1991 FTC LEXIS 38, at *14; *Stouffer*, 1994 FTC LEXIS 196, at *10.

b. Extrinsic evidence

Extrinsic evidence includes, but is not limited to, "reliable results from methodologically sound consumer surveys." *Kraft*, 114 F.T.C. at 121, 1991 FTC LEXIS 38, at *13; *Cliffdale*, 103 F.T.C. at 164-66, 1984 FTC LEXIS 71, at *108-09. In determining whether a consumer survey is methodologically sound, the Commission will look to whether it "draws[s] valid samples from the appropriate population, ask[s] appropriate questions in ways that minimize bias, and analyze[s] results correctly." *Thompson Medical*, 104 F.T.C. at 790, 1984 FTC LEXIS 6, at *315. "The Commission does not require methodological perfection before it will rely on a copy test or other type of consumer survey, but looks to whether such evidence is reasonably reliable and probative. *See Bristol-Myers Co.*, 85 F.T.C. 688, 743-44 (1975). Flaws in the methodology may affect the weight that is given to the results of the copy test or other consumer survey." *Stouffer*, 1994 FTC LEXIS 196, at *10-11.

In addition to consumer surveys, another type of extrinsic evidence the Commission will look at is:
evidence not specifically showing how consumers understood the advertisements at issue before us, but showing how consumers might ordinarily be expected to perceive or understand representations like those contained in the ads we are reviewing. For example, we might look at the dictionary definition of a word to identify the word's common usages. Or we might look at principles derived from market research, as expressed by marketing experts, which show that consumers generally respond in a certain manner to ads that are presented in a particular way, and presume that consumer reactions to a particular ad before us would be consistent with the general response pattern. Where we apply such marketing principles, we will derive them from research presented in references generally accepted as reliable in the field of marketing. Such references may be cited by marketing experts called to testify in the proceeding.

***180** *Thompson Medical*, 1984 FTC LEXIS 6, at *315-16.

A third type of evidence the Commission "will consider if offered is the opinion of expert witnesses in the proceeding as to how an advertisement might reasonably be interpreted. For example, we might consider the opinion of a marketing expert who stated his or her view that consumers would interpret an advertisement in a particular manner. However, where the opinions voiced by experts are not adequately supported we ordinarily give them little weight." *Thompson Medical*, 1984 FTC LEXIS 6, at *316-17.

Whether examining the advertisement itself, extrinsic evidence, or both, the Commission considers the overall, common-sense, net impression made by the advertisement in determining whether the alleged claim may reasonably be ascribed to it. *FTC v. Tashman*, 318 F.3d 1273, 1283 (11th Cir. 2003); *Kraft*, 114 F.T.C. at 122; *Thompson Medical*, 104 F.T.C. at 790; *Stouffer* 118 F.T.C. 746, 1994 FTC LEXIS 196, at *11. Ultimately, "[t]he meaning of an advertisement, the claims or net impressions communicated to reasonable consumers, is fundamentally a question of fact .... This question of fact may be resolved by the terms of the advertisement itself or by evidence of what consumers interpreted the advertisement to convey." *Nat'l Urological Group*, 645 F. Supp. 2d at 1189;*QT*, 448 F. Supp. 2d at 957-58;*see also Removatron*, 884 F.2d at 1497 (holding that findings with respect to what representations are made in advertisements are factual).

c. Intent of the advertiser

Complaint Counsel urges that the evidence shows that Respondents intended to make the claims alleged in the Complaint. Citing *Telebrands Corp.*, 140 F.T.C. at 304 and *Novartis Corp.*, 127 F.T.C. at 683, Complaint Counsel argues that such intent constitutes extrinsic evidence that the Challenged Advertisements in fact conveyed the claims alleged. Respondents deny any intent to make the disease claims alleged in the Complaint. This Initial Decision need not, and does not, determine whether or not Respondents intended to make the disease claims alleged in the Complaint because the evidence is sufficient to conclude that Respondents disseminated advertisements containing the alleged claims, without regard to Respondents' alleged intent. *See* Section III.E.2, *infra*. Moreover, to the extent Complaint Counsel is arguing that advertiser intent alone can support interpreting an advertisement to contain an alleged claim, absent a facial analysis and/or other extrinsic evidence demonstrating that such claim was made, that argument is rejected, as more fully explained below.

***181** It is well established that liability under Section 5 of the FTC Act does not require proof of intent to deceive. *FTC v. World Travel Vacation Brokers, Inc.*, 861 F.2d 1020, 1029 (7th Cir. Ill. 1988); *Chrysler Corp. v. FTC*, 561 F.2d 357, 363 & n.5 (D.C. Cir. 1977); *Kraft*, 114 F.T.C. at 121. Similarly, it is no defense to an action for deceptive advertising that the advertiser did not intend to make the claim alleged. *World Travel Vacation Brokers*, 861 F.2d at 1029;*FTC v. Sabal*, 32 F. Supp. 2d 1004, 1007 (N.D. Ill. 1998). It would be incongruous, at best, if intent could be used as a sword but not a shield.

Moreover, the law is clear that the goal of advertising interpretation is to determine whether reasonable consumers would interpret an advertisement to convey an alleged claim. *See, e.g.*, *Thompson Medical*, 104 F.T.C. at 788, 1984 FTC LEXIS 6, at *311 (holding that an advertisement conveys a claim if consumers, acting reasonably under the circumstances, would interpret the advertisement to contain that message); *Nat'l Urological Group*, 645 F. Supp. 2d at 1189 (question of advertisement's meaning "may be resolved by the terms of the advertisement itself or by evidence of what consumers interpreted the advertisement to convey"). Complaint Counsel's suggested approach is contrary to law because it would have the analysis of the Challenged Advertisements focus on the perspective of the advertiser, based on the intent of a respondent, rather than focus on the perspective of the audience, *i.e.*, the consumer who sees or hears the advertisement. It is also noteworthy that, while extrinsic evidence of consumer interpretation is appropriate to consider, advertiser "intent" is not mentioned among the types of extrinsic evidence that is considered in determining how consumers would interpret an advertisement. As

the Commission explained in the *Deception Statement*, extrinsic evidence "can consist of expert opinion, consumer testimony (particularly in cases involving oral representations), copy tests, surveys, *or any other reliable evidence of consumer interpretation*." 1984 FTC LEXIS 71, at *173 n.8 (emphasis added); *see also Thompson Medical*, 1984 FTC LEXIS 6, at *315-16.

In *Telebrands*, upon which Complaint Counsel relies, the Commission held: "Based on our own review of the challenged advertising, we conclude that consumers would reasonably interpret respondents' Ab Force ads to mean that the device (1) causes loss of weight, inches, or fat; (2) creates well-defined abdominal muscles; and (3) is an effective alternative to regular exercise ...." 140 F.T.C. at 301. The Commission further held that "other considerations," including "ample evidence that respondents intended to convey the challenged claims," provided further support for the conclusions of the facial analysis. *Telebrands Corp.*, 140 F.T.C. at 304. Similarly, in *Novartis*, 127 F.T.C. at 683, also cited by Complaint Counsel, the Commission stated that "evidence of intent to make a claim may support a finding that the claims were indeed made." The Commission held, however, similar to *Telebrands*, that the challenged claim was "plain from a facial analysis of the challenged ads alone" and that the "extrinsic evidence" indicating respondent intended to make the challenged claim "provide[d] additional support for [the] finding that the superiority claims" were made. *Novartis*, 127 F.T.C. at 683-84. Indeed, in *Novartis*, "the issue of whether the claim was made [was] not a close one." *Id.* at 683.

***182** Thus, while *Telebrands* and *Novartis* indicate that evidence of an advertiser's intent to make a claim can bolster or confirm a finding that a claim was in fact made, the law does not indicate that advertiser intent alone is a valid basis for finding that a claim was made, absent a facial analysis and/or other extrinsic evidence demonstrating that such claim was made. In the instant case, the evidence is sufficient to conclude that Respondents disseminated advertisements containing the alleged claims, and it is, therefore, not necessary to determine, or rely upon, Respondents' alleged intent.

d. Target audience

Complaint Counsel argues that the Challenged Advertisements must be interpreted from the perspective of the target audience for POM Product advertising which, according to Complaint Counsel, consists of "consumers concerned about preventing or reducing their risk of illness." CCB at 18. *See Telebrands*, 140 F.T.C. at 291 (stating that "[i]f an ad is targeted at a particular audience, the Commission analyzes ads from the perspective of that audience" (citing *Deception Statement*, 1984 FTC LEXIS 71, at *178-79)); *Thompson Medical*, 1984 FTC LEXIS 6, *321 n.15 (recognizing precedent that persons with health-related problems can be a target audience). In support of the argument that consumers concerned about preventing or reducing their risk of illness constitute a "target audience" for purposes of interpreting the Challenged Advertisements, Complaint Counsel relies principally on certain "creative briefs" prepared by POM Marketing and provided to the in-house advertising agency, Fire Station, which served to guide Fire Station's work in developing advertising for POM Juice, POMx Pills and Pomwonderful.com. CCFF 299-308; CX0409; F. 145-152. These creative briefs include a section titled, "target audience," which, for the purpose of these documents, meant the audience to whom the advertisement would appeal. F. 148, 175. Complaint Counsel also notes that Respondents placed advertising in health-oriented magazines, such as *Prevention* and *Men's Fitness*, in health clubs, on prescription drug bags, and on medical-oriented websites (*e.g.*, WebMD). CCB at 19.

Respondents dispute that the creative briefs or POM's alleged focus on healthconscious consumers are probative in this matter, and further note that the POM Products were advertised in a wide variety of local and national publications that are not devoted to health. RRB at 49-50. Respondents do not appear to dispute, however, that health-conscious consumers are among POM's target consumers.

The creative briefs, as well as the fact that Respondents sought to reach healthconscious consumers by placing advertising in such magazines as *Health Magazine*, *Men's Health*, and *Men's Fitness*, and in health clubs, on prescription drug bags, and on medical219 oriented websites (*e.g.*, WebMD), show that Respondents endeavored to reach educated, affluent, and health-conscious individuals. F. 171, 179, 181.[7] Although at least one creative brief for POM Pills specifically included within the "target audience," among others, middleaged men or seniors who are concerned or "scared" about prostate cancer, *e.g.*, F. 178, Complaint Counsel's extrapolation from such evidence that POM's target group was "consumers concerned about preventing or reducing their risk of illness" in general is unpersuasive and is, therefore, rejected. Moreover, the evidence shows that Respondents' advertising was also directed to a more general audience. F. 169-171. In particular, the evidence shows that the Challenged Advertisements were disseminated in a wide variety of locally and nationally distributed publications, well beyond health-oriented publications, including the *Chicago Tribune, Details, Rolling Stone*, I*nStyle, Town and Country, Fortune*, the *New York Times, Discover, Popular Science*, and *Time*. F. 169-170.

***183** In any event, even if Respondents' advertising sought to appeal to educated, affluent, and health-conscious individuals, this conclusion has no practical utility in the instant case. As the Commission stated in *Thompson Medical*, with respect to "target audiences": "[A]lmost all advertising is targeted at some demographic group, such as farmers, housewives, or residents of a particular area. This alone does not mean that we apply a standard different from our customary one." *Thompson Medical*, 1984 FTC LEXIS 6, *321 n.15. The term, "target audiences," for purposes of interpreting advertising, refers to "special audiences who as a group have a greater or lesser capability to recognize deceptive advertising than ordinary members of the adult population or a distinctive reaction to particular advertising claims [.]" *Id.* Complaint Counsel does not cite to any evidence in the record indicating how, if at all, "educated, affluent, health-conscious consumers" would be more capable or more likely than ordinary consumers to infer the alleged disease claims from the Challenged Advertisements. *See* CCB at 18-19. In fact, what little evidence there is on the characteristics of this group indicates, if anything, that educated, affluent, health-conscious consumers are more likely to be more discerning and careful readers of an advertisement, and more likely to better understand an advertisement, F. 521-522, all of which weigh against a conclusion that such consumers would be more susceptible to inferring disease claims.

In addition, the only evidence of a "distinctive reaction to particular advertising claims" among educated, affluent, health-conscious consumers is the opinion of Complaint Counsel's rebuttal expert on, *inter alia*, advertising and consumer behavior, Dr. David Stewart (*see* F. 285, 288), that such consumers are more likely to be "more attentive to health claims" and more likely to "draw pragmatic inferences" about the benefits of the POM Products. F. 517. However, Dr. Stewart defined such "pragmatic inferences" as meanings that are neither expressed in the advertisements, nor implied by the advertisements, and may or may not even follow, logically. F. 517. Finally, as Dr. Stewart also noted, consumers are not simply passive recipients of messages, but are active processors, and in determining how a consumer would interpret an advertisement, it is critical to consider prior beliefs, prior knowledge, what the consumer may regard as relevant, how the consumer will process the information, and generally what the consumer brings to the viewing situation. F. 542-543. Complaint Counsel introduced no evidence on these considerations cited by Dr. Stewart.

In summary, while the evidence shows that Respondents' advertising may have been geared, at least in part, toward educated, affluent, health-conscious consumers, Complaint Counsel has failed to prove that this group would be more likely to interpret, or in fact did interpret, the Challenged Advertisements differently than ordinary consumers, or in what manner that group would do so. Accordingly, to meaningfully analyze the Challenged Advertisements from the perspective of the asserted target group would require unacceptable speculation, because what constitutes such perspective, or how such perspective would be applied to the group's interpretation of advertising, has not been proven.

2. Respondents disseminated advertisements making the claims alleged in the Complaint

a. Summary of findings

***184** As noted above, the determination of what claims are made in an advertisement is a factual one. *Removatron Int'l Corp.*, 884 F.2d at 1496;*AHP*, 695 F.2d at 686;*Nat'l Urological Group*, 645 F. Supp. 2d at 1189;*QT*, 448 F. Supp. 2d at 957-58. In *Thompson Medical*, the Administrative Law Judge ("ALJ") described the approach that he employed in making such determination as follows:

In determining the meaning of individual advertisements, I have primarily relied on my knowledge and experience to determine what impression or impressions an advertisement as a whole is reasonably likely to convey to a consumer. When my initial determination is confirmed by the expert testimony of complaint counsel or respondent, I rested. When my initial determination disagreed with that of expert testimony, which was often conflicting, I reexamined the advertisement in question, and further considered other record evidence such as copy tests and other consumer research before reaching a final determination. I have not relied on such extrinsic evidence when, after careful study and reflection, I found it to be unpersuasive and contrary to the weight of evidence.

Thompson Medical, 1984 FTC LEXIS 6, *82-83 (Initial Decision).

Employing and applying the above methodology, based upon a facial analysis and having considered all applicable extrinsic evidence, this Initial Decision finds that certain Challenged Advertisements disseminated by Respondents made the claims alleged in the Complaint. F. 579-584. Therefore, Complaint Counsel has satisfied the first element of its deceptive advertising claim. *See Kraft*, 970 F.2d at 314. Detailed findings of fact are set forth in Section II.D, *supra* and summarized, as applicable, in the following analysis. *See also* Initial Decision Appendix (containing advertisements found to have made the alleged claims). The reasoning for these findings is further explained below. The evidence upon which Respondents rely to argue that none of the Challenged Advertisements should be interpreted as making the challenged claims, including the opinions of their linguistics expert, Dr. Ronald Butters (F. 259-263), have been fully considered. F. 579. With respect to those Challenged Advertisements found to have made the alleged claims, such evidence fails to outweigh the evidence demonstrating that the claims were in fact made, including the overall net impression of the advertisements themselves. F. 584. Respondents' arguments are further addressed in Section III.E.2.f, *infra*.

As to those of the Challenged Advertisements that were not found to have made the challenged claims, this Initial Decision finds that such claims were not reasonably clear or conspicuous on the face of the advertisements, and that considering the interplay of all the elements of such advertisements, it could not be concluded with confidence, on the face of the advertisements alone, that a significant minority of reasonable consumers would interpret the advertisements to make the claims alleged in the Complaint. F. 585, 587. Among other reasons, these advertisements: do not mention heart disease, prostate cancer, or erectile dysfunction; use vague, non-specific, substantially qualified, and/or otherwise non-definitive language; use language and/or images that, in the context of the advertisement, are inconsistent with the alleged claim; and/or do not draw a connection for the reader, such as through associated explanatory text, between health benefits, or study results, and effectiveness for heart disease, prostate cancer, or erectile dysfunction. F. 588; *see also* F. 585. *See In re Sterling Drug, Inc.*, No. 8919, 102 F.T.C. 395, 1983 FTC LEXIS 66, at *477-78 (July 5, 1983) (holding that claim that Bayer aspirin relieved tension was not apparent in advertisement depicting Bayer relieving a headache caused by tension). In the context of these advertisements, the nature of the transaction, *i.e.*, the purchase of a food product, or a supplement derived therefrom, as opposed to the purchase of a drug (F. 57, 65-68, 70-72), further weighs against interpreting such advertisements as making the alleged claims. *See Deception Statement*, 103 F.T.C. 110, 1984 FTC LEXIS 71, at *172 (noting that in evaluating whether implied claim was made, the Commission will consider, among other factors, the nature of the transaction). To this extent, the facial analysis is confirmed by the opinion of Respondents' expert, Dr. Butters, that an advertisement promoting the consumption of food is far less likely to be interpreted by a reasonable consumer as conveying a treatment claim, than an advertisement promoting a drug. F. 491-492.

***185** Furthermore, as to those of the Challenged Advertisements, described above, for which the alleged claims are not reasonably clear from a facial analysis, the weight of the applicable extrinsic evidence also fails to demonstrate that such advertisements would be reasonably interpreted to make the claims alleged in the Complaint. F. 589; *see also* F. 585. For example, Complaint Counsel relies on the Bovitz Survey, a 2009 study of billboard headlines, commissioned by Respondents to assess the impact of their advertising campaigns. F. 544-548; *see* CCFF 588. In particular, Complaint Counsel relies on the fact that forty-three percent of survey respondents in POM's general target audience and forty-eight percent of those survey respondents that were POM Juice users, when shown an advertisement picturing a POM Juice bottle saying, "I'm off to save PROSTATES!" and a sub-headline "The Antioxidant Superpower," said the advertisement's main idea was "good for prostates." F. 557. However, this vague and general interpretation is not persuasive evidence that a significant minority of reasonable consumers would draw the further inference, when viewing an advertisement containing such language and imagery, that the POM Products treat, prevent, or reduce the risk of "prostate cancer." *See also* F. 524 (In linguistic terms, "I'm off to save prostates" would not imply that a product will protect or rescue one from disease). Similarly, Complaint Counsel relies on the fact that fourteen percent of survey respondents in POM's general target audience, when shown an advertisement picturing a POM Juice bottle inside a blood pressure cuff, with the headline "Decompress" and a sub-headline "POM Wonderful Pomegranate Juice [ ] The Antioxidant Superpower," said the advertisement's main idea was "helps/lowers blood pressure." F. 555. This vague and ambiguous conclusion is not enough to support a finding that a significant minority of reasonable consumers would draw the further inference, when viewing an advertisement containing this language and imagery, that the POM Products treat, prevent, or reduce the risk of "heart disease." None of the survey respondents in the Bovitz Survey answered that the main idea of these billboard advertisements was prevention, risk reduction, or treatment of any specific disease. F. 555-558, 572. The most common "main idea" communicated (at least 90%) was that POM Juice had general health benefits. F. 572. Moreover, the Bovitz Survey examined only advertisement headlines and images, as shown on the billboard advertisements. F. 547. Thus, the Bovitz Survey did not examine the headlines, images and text, as shown on any of the Challenged Advertisements. F. 547. As Complaint Counsel's rebuttal expert, Dr. Stewart, acknowledged, other text that is added in a lengthier print advertisement might modify a message communicated by the image and headline of a billboard. F. 561. For this reason as well, the findings of the Bovitz Survey are entitled to little weight.

***186** Complaint Counsel also places too much weight on opinions that Complaint Counsel obtained from Dr. Butters on cross-examination that phrases such as "prostate health" and "heart health" would be interpreted to mean the absence of disease. F. 538-539. While the meaning of "health" may well include the absence of disease, the meaning of "health" is surely not so limited as to include only treatment, prevention or reduction of the risk of disease, and to the extent Dr. Butters opined as such, that opinion is rejected.

Accordingly, because, as to certain Challenged Advertisements, the alleged claims are not reasonably clear or conspicuous on the face of the advertisements themselves, and because the applicable extrinsic evidence of the meaning of those advertisements is insufficient or unpersuasive, this Initial Decision finds that the evidence fails to demonstrate that such advertisements made the claims alleged in the Complaint. F. 587-590; *see also* F. 585. *See Sterling Drug*, 1983 FTC LEXIS 66, at *477-78 (stating Commission was "unwilling in the absence of extrinsic evidence to find that consumers infer from these ads that Bayer will relieve tension" where such claim was "not apparent ... from a careful examination of the ads"); *Thompson Medical*, 104 F.T.C. at 339-40 (holding that Commission "cannot find the ad to convey" implied claim that Aspercreme contained aspirin where Commission was unable to "conclude with adequate confidence" based on the advertisement itself "whether or not one message conveyed to consumers" was that Aspercreme contained aspirin and where extrinsic evidence was insufficient to find such claim). It is worth emphasizing that this is not a finding that the advertisements *do not* convey the alleged claims, but merely that the evidence was insufficient to conclude that they do. As the Commission stated in *Thompson Medical*:

Here we merely say that complaint counsel failed to provide extrinsic evidence demonstrating that [the advertisements] created a net impression which did [make the challenged claim]. We do not attempt to use our judgment to reach any substantive conclusion. Where the implied meanings of an advertisement are unclear absent extrinsic evidence, our expertise is no more reliable in permitting conclusions that an interpretation is unreasonable than that it is reasonable.

Thompson Medical, 1984 FTC LEXIS 6, at *371.

To be clear, Complaint Counsel has demonstrated, based on a number of the Challenged Advertisements, that Respondents *did*, in fact, disseminate some advertisements making the claims alleged in the Complaint. It is not necessary to find that all the Challenged Advertisements made the alleged claims in order to warrant injunctive relief for deceptive advertising. *Bristol-Meyers*, 1983 FTC LEXIS 64, at *250-51 (disagreeing with ALJ findings that certain advertisements made the challenged claims, and stating: "Although we find a smaller number of violative ads than did the ALJ, there is certainly an adequate number to support the order ..."); *Fedders Corp.*, No. 8932, 85 F.T.C. 38, 71-72, 1975 FTC LEXIS 282, *72 (Jan. 14, 1975) ("The Commission has previously issued orders in cases involving no more than one or a few deceptive advertisements.").

b. "Establishment" claims vs. "efficacy" claims

***187** Advertisements that claim a certain type or level of support are considered "establishment claims." *Thompson Medical*, 791 F.2d at 194. An establishment claim includes a claim that the effectiveness of a product has been shown by clinical proof. *Removatron*, 884 F.2d at 1492 n.3. As the Commission stated in *Thompson Medical*: "There is no conceptual or practical reason to single out such claims [ ] for special treatment. They are but one example of an express or implied claim that an advertiser possesses a particular level of substantiation." 1984 FTC LEXIS 6, at *387 n.59; *see also Bristol-Meyers*, 1983 FTC LEXIS 64, at *253 (noting that a claim of clinical proof can be express or implied). A claim that a product is effective, without expressly or impliedly representing a particular level of support, is not an establishment claim, but is an efficacy claim. *Removatron*, 884 F.2d at 1491 n.3.

The majority of the Challenged Advertisements that have been found herein to have made the claims alleged in the Complaint represented that clinical studies supported the claimed effectiveness of the POM Products, and, therefore, are referred to herein as "establishment claims." The remainder of the Challenged Advertisements found to have made the claims alleged in the Complaint made non-establishment, "efficacy" claims.

c. Heart disease claims

The evidence shows that Respondents disseminated advertisements that impliedly represented that the POM Products treat, prevent, or reduce the risk of heart disease and, in many of these same advertisements, are clinically proven to do so, by lowering blood pressure, reducing arterial plaque, and/or increasing blood flow to the heart. F. 580, 583. Respondents made these claims indirectly and obliquely, typically by presenting, through words and images, a logical syllogism that: free radicals cause or contribute to heart disease; the POM Products contain antioxidants that neutralize free radicals; and, therefore, the POM Products are effective for heart disease. F. 294-295, 301-303, 348, 374, 394-396, 398, 407, 414, 444, 452-453, 460-462. Against this background, many of the advertisements further state or represent that the POM Products have been shown in one or more clinical, medical, or scientific studies, to reduce plaque, lower blood pressure, and/or improve blood flow to the heart, in a context where it is readily inferable that the referenced study results involve heart disease risk factors and, therefore, constitute clinical support for the effectiveness claim. F. 295, 301, 303, 349, 373, 376, 379, 395-397, 400, 407, 414, 420.

For example, in April 2009, the "Cardiovascular" section of the health benefits webpage of pomwonderful.com had a "read more" link that took the viewer to text stating that "heart disease" is a leading killer of men and women in the United States, that "atherosclerosis," which is defined for the reader as too much "plaque," is a leading factor in "heart attacks," and further describes the role of antioxidants in reducing LDL (defined as "bad" cholesterol) oxidation. F. 373-374. The "read more" links from this page connect to a 2005 study on the effect of pomegranate juice on myocardial perfusion published in the *American Journal of Cardiology*; a 2004 study on reduction of carotid intima-media thickness, blood pressure (CIMT-BP) and LDL oxidation; and a 2001 study on reduction of systolic blood pressure. F. 374. The "Cardiovascular" section of the health benefits webpage of pomwonderful.com also advised the reader that POM Juice was shown in one study to improve blood flow to the heart in "coronary heart disease" "patients"; and, in another study, to reduce arterial plaque. F. 373. In this context, asserting clinical proof of a beneficial effect on the underlying conditions of the body (blood flow, arterial plaque, CIMT-BP, and LDL) would reasonably be interpreted as representing clinical proof of effectiveness for heart disease. F. 373-375, 381.

***188** Another example is the Heart Newsletter (CX1426 (Compl. Ex. M); F. 346-350), which states or represents that (1) "58.8 million Americans suffer from some form of heart disease"; (2) supplementation with antioxidants is "your ally" in fighting "heart disease"; (3) antioxidants fight free radicals and help prevent cell and tissue damage that lead to "disease"; (4) POM Juice and POMx have polyphenol antioxidants, which are unique and superior; and (5) POMx provides antioxidant supplementation without adding the calories of POM Juice. F. 348. The Heart Newsletter further states that POM's "scientists have found" that POM Juice "may help counteract factors leading to arterial plaque buildup, as well as inhibit a number of factors associated with heart disease." F. 349. The text then proceeds to describe these findings, from "new research," including (1) a "pilot" study involving 19 "patients" with "clogged arteries" which found a "30% decrease in arterial plaque" among those drinking eight ounces of POM Juice daily; and (2) a study involving 45 "patients" with "impaired blood flow to the heart," showing "17% improved blood flow" among those who consumed eight ounces of POM Juice daily. F. 349. By connecting POM-provided antioxidants to benefits for "heart disease," and by further connecting the study results to heart disease risk factors, the advertisement implies that the POM Products are effective for heart disease, and that such effectiveness is based upon clinical testing. F. 350. *See also* F. 301 (CX0029 print advertisement representing, *inter alia*, that "heart attacks are due to ... plaque in the arteries" and "scientific research shows" that POM Juice prevents LDL oxidation and reduces plaque); F. 414 (CX0473 Ex. E-1 (pomegranatetruth.com)), representing that "atherosclerosis," which is defined for the reader as too much "plaque," is a leading factor in "heart attacks" and linking to research studies on the effects of pomegranate juice on myocardial perfusion, reduction of carotid intima-media thickness, blood pressure, and LDL oxidation); F. 339-340, 419-420.

The Challenged Advertisements that were not found to have made establishment claims, as alleged by Complaint Counsel, but which were found to have made heart disease efficacy claims only, either do not reference any clinical testing or refer to clinical testing in such a way, and in such context, that it cannot be concluded with confidence that a significant minority of reasonable consumers would take away the message that the efficacy claim is "clinically proven." *See* F. 440-448 (CX0031 ("Floss your arteries")); F. 456-468 (CX0034 ("Amaze your cardiologist")). For example, CX0031 represents that "clogged arteries lead to heart trouble," free radicals cause "artery clogging plaque," and that drinking eight ounces of POM Juice a day "can reduce plaque up to 30%!*" F. 444. While this advertisement makes an efficacy claim, the only reference to any scientific support is in very small print, at an asterisk at the bottom of the page, which states: "Aviram, M. Clinical Nutrition, 2004. Based on a clinical pilot study." F. 447. CX0034 is a similar advertisement. F. 466.

***189** As the Commission stated in *Bristol Meyers*, not "every reference to a test necessarily gives rise to an establishment claim. The key, of course, is the overall impression created by the ad." 1983 FTC LEXIS 64, at **253*. In CX0031 and CX0034, this small print, single reference to a study, particularly in the context of a qualified assertion that POM Juice "can" reduce plaque, is insufficient to conclude with confidence that a

significant minority of reasonable consumers would interpret these advertisements to be claiming that POM Juice is "clinically proven" to be effective for heart disease. F. 446-447, 466-467. Moreover, the applicable extrinsic evidence does not support a conclusion that consumers would interpret these advertisements to be making a "clinically proven" claim. F. 579, 585. Accordingly, the evidence fails to demonstrate that these advertisements, which do make efficacy claims, convey the additional message that POM Juice's efficacy is demonstrated by clinical proof. F. 448, 468, 585.

d. Prostate cancer claims

The evidence shows that Respondents disseminated advertisements that impliedly represented that the POM Products are clinically proven to treat, prevent, or reduce the risk of prostate cancer, by prolonging prostate-specific antigen ("PSA") doubling time. F. 581. These advertisements typically communicate the claim by juxtaposing statements and representations that prostate cancer is a leading cause of death in men; antioxidants, such as those provided by the POM Products, may help prevent cancer; that PSA is an indicator of prostate cancer; that PSA doubling time is an indicator of prostate cancer progression; and that the POM Products have been shown in clinical testing to slow PSA doubling time. F. 310-318, 332, 334-336, 352-353, 371, 381, 389-392, 398, 400-405, 409, 429-430. Thus, similar to those advertisements found herein to have made heart disease claims, these advertisements specifically refer to prostate cancer, and connect both POM-provided antioxidants, and the study results, to effectiveness for prostate cancer. *Id.*

For example, CX1426 (Compl. Ex. I) (POMx Pill package insert) juxtaposes statements and representations that: (1) antioxidants fight free radicals, which may be linked to "serious health threats like cancer ..."; (2) "Prostate cancer is the most commonly diagnosed cancer ... and the second-leading cause of cancer death" among men in the United States; (3) POMx is a "time pill" because "stable levels of PSA," which is defined for the reader as "prostate-specific antigens," "are critical for men with prostate cancer," and "[p]atients with quick PSA doubling times are more likely to die from their cancer"; (4) "[a]ccording to a UCLA study of 46 men age 65 to 70 with advanced prostate cancer, drinking an 8**oz** glass of POM Wonderful 100% Pomegranate Juice every day slowed their PSA doubling time by nearly 350%. 83% of those who participated in the study showed a significant decrease in their cancer regrowth rate"; and (5) "basic studies" indicate POMx may have the same effects as POM Juice. F. 332, 334.

***190** Similarly, the Prostate Newsletter (CX1426 (Compl. Ex. N)) states and represents that: (1) "Prostate cancer is the second leading cause of cancer related death in men in the United States ..."; (2) "risk factors" for prostate cancer include "diet," and advises a diet that includes, among other things, "fruits rich in antioxidants"; (3) a "preliminary UCLA medical study" on 46 men treated for prostate cancer, showed that a majority of those consuming eight ounces of POM Juice daily "experienced a significantly extended PSA doubling time. Doubling time is an indicator of prostate cancer progression — extended doubling time may indicate slower disease progression"; testing on "patient" blood serum showed a decrease in "cancer cell proliferation," and "increase in cancer cell death"; (4) in another study, "in vitro laboratory testing at UCLA showed that POMx significantly decreased human prostate cancer cell growth and increased cancer cell death"; and (5) POMx has the same active ingredients in POM Juice. F. 352-353. *See also* F. 311 (regarding CX0314, CX0372, CX0379, CX0380, representing, *inter alia*, that according to a published study on men treated for prostate cancer, those consuming POM Juice "experienced significantly slower" "PSA doubling times," and that PSA "is a biomarker that indicates the presence of prostate cancer. 'PSA doubling time' is a measure of how long it takes for PSA levels to double. A longer doubling time may indicate slower progression of the disease"); F. 371, 380-381, 403-404, 409, 430.

e. Erectile dysfunction

The evidence demonstrates that Respondents disseminated advertisements that impliedly represented that the POM Products are clinically proven to treat, prevent or reduce the risk of erectile dysfunction ("ED"). F. 582. Respondents disseminated print advertisements that stated and represented, for example, that: (1) the superior antioxidants in the POM Products protect against free radicals, which can damage the body; (2) powerful antioxidants enhance the actions of nitric oxide in vascular endothelial cells, showing potential for management of "ED"; and (3) a preliminary study on "erectile function" showed that men who consumed POM Juice reported "a 50% greater likelihood of improved erections," as compared to a placebo. F. 323-324. Similarly, in April 2009, the "Erectile Function" section of the health benefits webpage on pomwonderful.com reported that a 2007 "pilot" study, published in the *Journal of Impotence Research*, involving 61 male subjects with "mild to moderate erectile dysfunction," showed that those men drinking eight ounces of POM Juice daily for four weeks were "50% more likely to experience improved erections." F. 372. *See also* F. 380-381, 433-437. Presenting a study on "erectile function" showing "improved erections" is reasonably read to imply effectiveness for erectile dysfunction, particularly when juxtaposed to an express reference to management of "ED." F. 323-325. *See also* F. 408 (response to the FAQ "Erectile Dysfunction" "Can pomegranate juice benefit men with erectile dysfunction?" stating, "Initial results linking POM Wonderful 100% Pomegranate Juice and erectile performance are promising. In a soon-to-be-published clinical study on men with erectile dysfunction, the group who consumed 8**o**z. of POM Juice daily experienced better erectile performance than the group who drank a placebo"). Moreover, as Respondents' expert, Dr. Butters, acknowledged, contemporary speakers of American English could interpret the phrase "erectile function" to relate to the ability of men to achieve and maintain erections. Erectile function and the absence of erectile dysfunction are closely related. F. 537.

f. Respondents' arguments as to advertisement interpretation

***191** As noted above, the determination of whether any of the Challenged Advertisements conveyed the implied claims alleged in the Complaint is a question of fact. *Removatron*, 884 F.2d at 1496;*AHP*, 695 F.2d at 686;*Nat'l Urological Group*, 645 F. Supp. 2d at 1189;*QT*, 448 F. Supp. 2d at 957-58. As to those Challenged Advertisements found herein to have made the challenged claims, this factual question has been resolved against Respondents. This determination is based upon all the evidence, including full consideration and weighing of all the evidence, inferences, and arguments raised by Respondents in opposition to finding that the challenged claims were made. As to those Challenged Advertisements found herein to have made the challenged claims, Respondents' opposing evidence, inferences and arguments, have been rejected as unpersuasive, unsupported, or otherwise outweighed by other evidence, including the overall net impression of the advertisements themselves. Respondents' contentions that require further elaboration are discussed below.

Respondents contend that the challenged claims are not reasonably clear or conspicuous on the face of any of the Challenged Advertisements, and that Complaint Counsel failed to present any reliable extrinsic evidence showing that reasonable consumers would interpret the advertisements to make the alleged claims. Therefore, Respondents argue, Complaint Counsel failed to meet its burden of proving that the challenged claims were made. *See, e.g.*, RB at 71-74. Respondents accurately assert that Complaint Counsel did not offer a copy test on the Challenged Advertisements. Complaint Counsel also did not proffer any expert opinion or analysis of the Challenged Advertisements to demonstrate that reasonable consumers would interpret the Challenged Advertisements as making the alleged claims. F. 513. As to those Challenged Advertisements for which the alleged claims were not reasonably clear or conspicuous on the face of the advertisements alone, *see* F. 587-588; *see also* F. 585, such a copy test or expert analysis provided by Complaint Counsel might have made a material difference. However, the failure of Complaint Counsel to proffer such extrinsic evidence is not fatal to Complaint Counsel's case because, for those Challenged Advertisements found to have made the alleged claims, the claims are, in fact, apparent from the overall, common-sense, net impression, of the words and images of the advertisements themselves. F. 293, 299, 310, 325, 331, 338, 346, 351, 368, 387, 411, 417, 422, 429, 433, 443, 455, 463, 474.

Moreover, Complaint Counsel adduced some extrinsic evidence relevant to consumer interpretation, albeit on cross-examination and rebuttal, which has also been considered. F. 579; *see, e.g.*, F. 527, 533-537, 540-541.

***192** Respondents further contend that the Challenged Advertisements must be interpreted in the context of the purchase of food, or a food-derived product, as opposed to the purchase of a drug, and that when viewed from this perspective, the advertisements are not reasonably interpreted, including by a facial analysis alone, as conveying the claim that the POM Products "prevent," "treat," or "reduce the risk" of any disease. *See, e.g.*, RB at 72, 78-82. Respondents argue in the alternative that, to the extent consumers would interpret the Challenged Advertisements as claiming that the POM Products "may help prevent" or "reduce the risk" of heart disease, prostate cancer or erectile dysfunction, it is in the same sense that broccoli, a healthy diet, or exercise "reduce the risk" of disease, and not in the sense of a drug, with a single target of action. *Id.*; *see also* RRB at 20-22. Further, Respondents argue that to the extent reasonable consumers would interpret the Challenged Advertisements as making a "treatment" claim, it would not be in the sense of a substitute for medical treatment. RB at 72. Respondents fail to explain how such a limited interpretation is legally significant since such claims would still appear to be within the scope of the claims alleged in the Complaint. In any event, Dr. Butters, whose testimony Respondents cite, did not testify to the interpretation urged by Respondents. RB at 73-74, 78-82 (citing Butters, Tr. 2817-18, 2821). In the cited testimony, Dr. Butters opined that what people might infer with respect to a food product might be different than what they might infer with respect to a drug; that an advertisement promoting the consumption of food is far less likely to be interpreted by a reasonable consumer as conveying a treatment claim; and that the word "treatment" means medical treatment. *See* F. 491-492. Dr. Butters simply did not opine that consumers would interpret the Challenged Advertisements in the manner claimed by Respondents. Moreover, as noted above, the nature of the transaction (*i.e.*, the purchase of a food product or food-derived supplement) has been considered in determining the meaning of the Challenged Advertisements. With respect to those of the Challenged Advertisements for which the challenged claims were not reasonably clear or conspicuous on the face of the advertisements themselves, the opinions of Dr. Butters, set forth above, have been taken into account. As to other advertisements, the nature of the POM Products as food, or food-derived, was insufficient to outweigh the overall net impression that such advertisements conveyed the alleged claims. *See, e.g.*, F. 296, 305. [8]

Respondents argue that the Challenged Advertisements are not reasonably interpreted as making "broad" establishment claims, because they simply report study results, in a qualified manner with words such as "preliminary," "promising," "encouraging," or "hopeful," and are not reasonably interpreted as implying that the study results prove that the POM Products treat, prevent, or reduce the risk of disease. *See, e.g.*, RB at 75-82; RRB at 10-15. However, in the context of the Challenged Advertisements found to have made establishment claims, the foregoing language fails to materially alter the overall net impression that such advertisements were claiming clinical proof. *E.g.*, F. 300-301, 312, 333, 342, 349-350, 354; *see also* F. 519 (Dr. Stewart opining that the typical consumer would likely have little understanding of what "initial" or "pilot" means, particularly in the context of being referred to as having been published in a major journal).

***193** Similarly, Respondents assert that advertising that a study on POM Juice showed "prolongation of PSA doubling times" does not convey the claim that POM Juice has been clinically proven to treat, prevent, or reduce the risk of "prostate cancer," and that advertising a study that POM Juice consumption resulted in "significant reduction of ... arterial plaque" or "improvement in blood flow" does not convey a claim of clinical proof of prevention, treatment, or reduction of the risk of "heart disease." RRB at 10. However, as explained above, those of the Challenged Advertisements found to have made "clinically proven" claims expressly referred to "heart disease," *e.g.*, F. 294, 301, 348, 374, 407, 414, "prostate cancer," *e.g.*, F. 334, 352, 381, 403, and "erectile dysfunction," F. 408, 413, or "erectile function" together with the phrase, "ED," F. 324, 434, and drew a logical connection for the reader, including through associated explanatory text, between the study results and effectiveness for the referenced maladies. *E.g.*, F. 301-303, 323-325, 348-350, 353, 374, 379-380, 414. Thus, in

the context of these advertisements, reasonable consumers would readily infer that the study results constituted clinical proof of effectiveness for the referenced maladies.

In addition, contrary to Respondents' argument, the preponderance of the evidence does not support a finding that the use of qualified language, such as “may” or “can” necessarily prevents communication of a more definitive claim. To the extent Dr. Butters opined to this effect, *see* F. 497, that opinion is rejected as unsupported and inconsistent with common-sense. First, there is academic literature in the record indicating that qualifiers such as “can,” “could,” “might,” or “up to” can create the inference of a stronger claim. F. 589. Moreover, whether a consumer will interpret “may” or “can” to mean “will” depends on the context, and the totality of the advertisement. F. 527.

Finally, Respondents contend that interpreting any of the Challenged Advertisements to make the alleged claims ignores the role of humor, parody, or hyperbole present in Respondents' advertising. Notwithstanding Dr. Butters' opinion on this issue, F. 487-489, the preponderance of the evidence demonstrates that humor, parody, or hyperbole within an advertisement does not necessarily “block” communication of a serious message within that advertisement. Rather, as Dr. Butters acknowledged, parody and humor have the effect of capturing the attention of the advertisement viewer, to help the viewer connect with the message in the printed portion of the advertisement. F. 534. Humor can induce further processing of an advertisement and a search for further information. F. 535. While readers may discount puffery and hyperbole as an exaggeration, the fact that puffery and hyperbole are not to be taken literally does not mean that advertisements using such elements cannot convey a serious claim. F. 532-533. Thus, the fact that a number of the Challenged Advertisements found to have made the alleged claims made partial use of humor or hyperbole is insufficient, in the context of the other elements of those advertisements, to prevent conveying the challenged claims. *See, e.g.*, F. 300-301, 320, 327, 464, 476. [9]

F. Whether the Challenged Claims are False or Misleading

1. Overview of applicable legal standards

***194** Having found that Respondents disseminated advertisements making the claims alleged in the Complaint, the next step is to determine whether the claims are false or misleading. *Kraft*, 970 F.2d at 314;*Pantron I Corp.*, 33 F.3d at 1095;*Direct Marketing Concepts*, 569 F. Supp. 2d at 297. Two theories have been used to prove that an advertisement is deceptive or misleading: (1) the “falsity” theory or (2) the “reasonable basis” theory. *Pantron I*, 33 F.3d at 1096;*Thompson Medical*, 1984 FTC LEXIS 6, at *380-81. Complaint Counsel contends that Respondents' claims are deceptive because they are both “false” and “unsubstantiated.” CCB at 36. Notwithstanding Complaint Counsel's contention, as further explained below, the issue of whether Respondents' claims were deceptive turns on the nature and quality of Respondents' substantiation, and, therefore, “the falsity and reasonable basis theories collapse into the same inquiry: did [Respondents] possess adequate substantiation to make such a claim?” *QT, Inc.*, 448 F. Supp. 2d at 966.

The Complaint charges that Respondents have represented that clinical studies, research, and/or trials prove that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, and/or erectile dysfunction, when in fact, studies, research and/or trials do not prove such claims, and, therefore, Respondents' representations are false or misleading. Complaint ¶¶ 12-18. Complaint Counsel refers to these claims as “false establishment claims.” CCB at 20-24. The Complaint also charges that Respondents represented that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, and/or erectile dysfunction without a reasonable basis to substantiate those representations. Complaint ¶¶ 19-21. Complaint Counsel refers to these charges as “unsubstantiated efficacy claims.” CCB at 25-26.

Establishment claims are those that contain representations regarding the amount and type of evidence the advertiser has for its product claims. *In re Daniel Chapter One*, No. 9329, 2009 FTC LEXIS 259, at *55 (Dec. 24, 2009); *Direct Marketing Concepts*, 569 F. Supp. 2d at 298 (citing FTC Policy Statement on Advertising Substantiation, appended to *Thompson Medical*, 104 F.T.C. at 839, 1984 FTC LEXIS 6, at *434). The establishment claim theory "is based on the straightforward notion that when an advertiser represents in its ads that there is a particular level of support for a claim, the absence of that support makes the claim false." *Sterling Drug*, 1983 FTC LEXIS 66, at *436. Common examples of establishment claims include statements such as "tests prove," "doctors recommend," or "studies show." *Direct Marketing Concepts*, 569 F. Supp. 2d at 298-99 (citing Policy on Advertising Substantiation; *Thompson Medical*, 791 F.2d at 194) (other citations omitted). Complaint Counsel bears the burden of demonstrating that the level of support represented by Respondents was false, *i.e.*, that Respondents did not have the amount and type of substantiation they claimed to have had. *See Sterling Drug*, 1983 FTC LEXIS 66, at *437; *Thompson Medical*, 791 F.2d at 194;*Bristol-Meyers*, 1983 FTC LEXIS 64, at *252.

***195** Non-establishment claims, or "efficacy claims," are those about a product's attributes, performance, or efficacy, without indicating any particular level of support for such claim. *Thompson Medical*, 1984 FTC LEXIS 6, at *368; *Removatron* 884 F.2d at 1492 n.3 ("'Non-establishment' claims are statements to the effect that a product works."). Under the reasonable basis theory of deception, because claims about a product's attributes, performance, or efficacy carry with them the express or implied representation that the advertiser had a reasonable basis substantiating such claims, failure to have a reasonable basis for the claim is deceptive or misleading. *Pantron I*, 33 F.3d at 1096;*QT, Inc.*, 448 F. Supp. 2d at 959-60;*Direct Marketing Concepts*, 569 F. Supp. 2d at 298; *Thompson Medical*, 1984 FTC LEXIS 6, at *367; *Daniel Chapter One*, 2009 FTC LEXIS 157, at *222 (Initial Decision). Under the reasonable basis theory, the government has the burden of proving by a preponderance of evidence that the Respondents did not have a reasonable basis for asserting that the challenged claims are true. *Pantron I*, 33 F.3d at 1096;*QT, Inc.*, 448 F. Supp. 2d at 959;*Thompson Medical*, 1984 FTC LEXIS 6, at *379. Thus, as to both the alleged "false establishment claims" and the alleged "unsubstantiated efficacy claims," proof of deception requires proof that Respondents' substantiation failed to meet the level of substantiation required.

The district court in *FTC v. QT, Inc.* described the shifting burdens as follows:
[T]he Court must first determine what level of substantiation Defendants were required to have for their advertising claims, and this determination is a question of fact. Then, the Court must determine whether Defendants possessed that level of substantiation .... Defendants have the burden of establishing what substantiation they relied on for their product claims. The FTC has the burden of proving that Defendants' purported substantiation is inadequate, and the FTC need not conduct or present clinical studies showing that the product does not work as claimed.

448 F. Supp. 2d at 959 (citations omitted).

For efficacy claims, the Commission, in *Thompson Medical*, held that determining the appropriate level of substantiation requires weighing the following factors: (1) the product involved; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation experts in the field would agree is reasonable. 1984 FTC LEXIS 6, at *387 (citing *In re Pfizer, Inc.* No. 8819, 81 F.T.C. 23, 1972 FTC LEXIS 13, at *91 (July 11, 1972)). Those factors, known as the "*Pfizer* factors," have been applied to determine the appropriate level of substantiation for non-establishment claims in numerous cases since *Pfizer* was decided. *E.g., Direct Marketing Concepts*, 569 F. Supp. 2d at 299 (citing *Removatron*, 884 F.2d at 1492 n.3);*QT, Inc.*, 448 F. Supp. 2d at 959 (citing Policy on Advertising Substantiation).

***196** For establishment claims, the Commission does not require application of the *Pfizer* factors to determine the required level of substantiation, on the theory that the advertiser must be held to whatever level of substantiation is represented in the advertisement. *In re Removatron Intl Corp.*, No. 9200, 111 F.T.C. 206, 1985 FTC LEXIS 21,

at *190 (Sept. 30, 1985); *Thompson Medical*, 1984 FTC LEXIS 6, at *387 n.59. If an advertisement represents that a particular claim has been scientifically established, the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claim's truth. *Removatron*, 1985 FTC LEXIS 21, at *191 (citing *Thompson*, 104 F.T.C. at 821-22 n.59; *Bristol-Meyers*, 102 F.T.C. at 321, 331).

Complaint Counsel charges that Respondents knew that their scientific studies were insufficient to support their efficacy and establishment claims. CCB at 3. *See also e.g.*, CCB at 41 (Complaint Counsel contending that Respondents "recognize[d] that they lack[ed] proof that the POM Products prevent or treat" heart disease). However, any opinions Respondents may have had regarding the adequacy of their substantiation do not constitute expert opinion on what "experts in the field would agree is reasonable" or on whether "the level of proof [relied upon is] sufficient to satisfy the relevant scientific community of the claim's truth." Accordingly, such evidence is not material or probative to the issue of whether Respondents possessed an adequate level of substantiation.

With these generally applicable principles in mind, to determine whether the challenged claims are false or misleading, it must first be determined what level of substantiation Respondents were required to have for their advertising claims. *QT, Inc.*, 448 F. Supp. 2d at 959. This determination is a question of fact to be determined based upon the evidence adduced at trial. *QT, Inc.*, 448 F. Supp. 2d at 959;*FTC v. Braswell*, CV 03-3700 DT, 2005 U.S. Dist. LEXIS 42976, at * 35 (C.D. Cal. 2005). Next, it must be determined whether Respondents possessed that level of substantiation. *QT, Inc.*, 448 F. Supp. 2d at 959. Respondents have the burden of establishing what substantiation they relied on for their product claims. *Id.* Complaint Counsel has the burden of proving that Respondents' purported substantiation is inadequate. *Id.*

2. Appropriate level of substantiation generally

***197** A review of the briefs in this case reveals that there is no dispute that the appropriate level of substantiation is "competent and reliable scientific evidence," both for Respondents' establishment claims and for Respondents' efficacy claims. The parties' dispute centers upon what constitutes "competent and reliable scientific evidence." *See, e.g.*, CCB at 2-3, 30, 40; CCRB at 18; RB at 32-38.

Complaint Counsel asserts that competent and reliable scientific evidence must include "RCTs," which experts define as well-designed, well-conducted, randomized, double-blind, placebo-controlled human clinical trials, (F. 608) in order to provide adequate substantiation for both the alleged establishment claims and efficacy claims in this case. CCB at 32; CCRB at 18. Respondents dispute this notion, asserting that, in examining the totality of the evidence, basic science and "pilot" studies, not just RCTs, can be relied upon as competent and reliable evidence. RB at 32-38. "Basic science" refers to test-tube (*in vitro*) studies, *in vivo* animal studies, and pre-clinical research. F. 593.

As explained below, neither the FTC Act nor applicable case law imposes a requirement of RCTs to substantiate all "health-related efficacy claims," as urged by Complaint Counsel. CCB at 32. Rather, and as Complaint Counsel's cited cases make clear, the determination of the appropriate level of substantiation is a question of fact to be determined based upon the expert testimony adduced at trial. *QT, Inc.*, 448 F. Supp. 2d at 959;*FTC v. Braswell*, 2005 U.S. Dist. LEXIS 42976, at *35.

a. RCTs are not a legal requirement

In its Post-Trial Brief, Complaint Counsel asserts that "[c]ourts have consistently found or upheld that double-blind, randomized, placebo-controlled trials ("RCTs") are required to provide adequate substantiation for the truthfulness of health-related claims." CCB at 32. As a matter of law, "[n]othing in the Federal Trade Commission Act ... requires placebo-controlled, double-blind studies." *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008).

Further, contrary to Complaint Counsel's assertion, the cases upon which Complaint Counsel rely do not compel a conclusion that RCTs are required.

Complaint Counsel cites *FTC v. Direct Marketing Concepts, Inc.*, 569 F. Supp. 2d at 303, for the proposition that double-blind, placebo controlled studies are required to substantiate health-related efficacy claims. Although the district court in *Direct Marketing* stated, "it seems well-accepted that double-blind, placebo-controlled studies are necessary to substantiate health-related efficacy claims," *id.* at 303, the First Circuit Court of Appeals, when reviewing the district court's opinion, expressly noted that while the FTC had argued and produced expert testimony that the claims at issue should be substantiated by double-blind, placebo-controlled studies, "there may be other scientific evidence that could be sufficient, and we may assume for these purposes that a double-blind study is not necessarily required." *FTC v. Direct Marketing Concepts, Inc.*, 624 F.3d 1, 9 (1st Cir. 2010).

***198** Complaint Counsel next cites *National Urological Group*, 645 F. Supp. 2d at 1202-03. However, in that case, which was before the court on the FTC's motion for summary judgment, the court did not hold that claims for erectile dysfunction "required" double-blind placebo-controlled studies, as Complaint Counsel suggests. Instead, the court stated, "what constitutes competent and reliable scientific evidence in this case is a question of fact for expert interpretation." *Id.* at 1190. In *National Urological Group*, the expert testimony was undisputed that the erectile dysfunction claims made in that case required well-designed, placebo-controlled, randomized, double-blind clinical trials for substantiation. Because the "defendants ha[d] not countered the testimonies of the FTC's expert regarding what level of substantiation is required for the claims made," the court concluded that there was no genuine dispute of fact on the requisite level of substantiation. *Id.* at 1202. In the instant case, by contrast, expert testimony on whether RCTs are required was clearly disputed and conflicting.

In *FTC v. Braswell*, 2005 U.S. Dist. LEXIS 42976, also cited by Complaint Counsel, defendants advertised the dietary supplements Lung Support Formula, AntiBetic Pancreas Tonic and Gero Vita GH3, one of which was advertised as a substitute for medical treatments. *Id.* at *4, *20-21 (AntiBetic). The court found that, by offering unrefuted evidence that the standard should be double-blind, placebo-controlled tests, the FTC had offered sufficient evidence to withstand summary judgment. *Id.* at *35. The court further noted that the ultimate determination of the level of substantiation required would be determined by the court based upon the evidence at trial. *Id.*

Complaint Counsel also relies on *Removatron*, 884 F.2d 1489 (1st Cir. 1989), where the Court of Appeals upheld the Commission's determination that a well-controlled scientific study was necessary to substantiate the respondent's claims that a radio frequency energy hair removal device would permanently remove hair. *Id.* at 1498. The court explained the basis for its holding as follows: "The FTC's expert, Dr. Van Scott, testified that, in this field, at least one well-controlled test would be needed to establish a permanency claim. He also testified that two tests would be better and three superb. The ALJ found that petitioners needed two well-controlled tests in order to establish their claims; the Commission decided one was sufficient. Thus, petitioners needed to present evidence that they possessed at least one well-controlled scientific study that supported their permanency claim." *Id.* Since the only substantiation evidence in that trial was a single experiment which, according to the doctor who conducted it, did not actually demonstrate permanent hair removal, the respondent's substantiation was found to be inadequate. *Id. Removatron*, therefore, is consistent with the requirement that the appropriate level of substantiation is determined by the evidence, and does not hold that RCTs are required as a general matter.

***199** Additionally, in another case relied upon by Complaint Counsel, *Thompson Medical* 1984 FTC LEXIS 6, which involved an arthritis medication, Aspercreme, the Commission evaluated the efficacy of an over-the-counter analgesic drug, utilizing the six *Pfizer* factors, to conclude that the proper level of substantiation was two well-controlled clinical tests. 1984 FTC LEXIS 6 at *291, 398. However, there the Commission also noted,

"we do not preclude ourselves from also permitting advertisers to use other types of evidence to comply with our substantiation requirement." *Id.* at *399.

Finally, Complaint Counsel relies on *QT, Inc.*, 448 F. Supp. 2d at 961. In determining the appropriate level of substantiation in that case, the court stated at the outset: "The Court must first determine what level of substantiation Defendants were required to possess for [the claim that an 'ionized' bracelet was proven, by scientific tests, to provide immediate pain relief]. *This is a question of fact*." *Id.* (emphasis added). The expert testimony in that case was that "at least one well-conducted, placebo-controlled, randomized, double-blind or sham-controlled clinical trial would be required by qualified experts in the field of pain due to rheumatic disease to support a claim that a product relieves or treats musculoskeletal pain," and that "a placebo-controlled, randomized, double-blind trial is the gold standard in the scientific community and depending on the claims an advertiser wishes to make, such a gold-standard study should be attempted to support those claims." *Id.* at 961-62. The court concluded that "with medical, health-related claims, a well-conducted, placebo-controlled, randomized, double-blind study, the gold standard, should have been conducted." *Id.* at 962. On appeal, the court expressly rejected the notion that RCTs are required as matter of law, stating: "Placebo-controlled, double-blind testing is not a legal requirement for consumer products." *QT, Inc.*, 512 F.3d at 861. Thus, *QT* does not stand for the proposition that RCTs are necessarily required, but is consistent with the proposition that the appropriate level of substantiation is determined by what the evidence shows that experts in the relevant field would deem adequate.

b. Summary of expert testimony on the appropriate level of substantiation

Detailed findings of fact on the expert testimony adduced at trial on the appropriate level of substantiation are set forth in Section II.F, *supra.* In summary, Complaint Counsel's experts in the fields of antioxidants and epidemiology (Dr. Meir Stampfer), heart disease (Dr. Frank Sacks), prostate cancer (Dr. James Eastham), and erectile dysfunction (Dr. Arnold Melman) each separately opined on the level of substantiation they would expect, as experts in their respective fields, to support claims that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction, and claims that Respondents' clinical research proves such benefits. These experts all testified that well-designed, well-conducted RCTs showing statistically and clinically significant improvements in valid endpoints are necessary to make claims that: (1) the Challenged Products treat, prevent, or reduce the risk of heart disease, prostate cancer, and/or erectile dysfunction; or (2) studies show that the Challenged Products treat, prevent, or reduce the risk of heart disease, prostate cancer, and/or erectile dysfunction. F. 626, 638, 648, 654.

***200** Respondents' experts in the fields of the design of clinical research protocols (Dr. Denis Miller), nutrition (Dr. David Heber), cardiovascular health (Dr. Dean Ornish), urology and prostate health (Dr. Jean deKernion), and urology and sexual medicine (Dr. Arthur Burnett and Dr. Irwin Goldstein) offered rebuttal to Complaint Counsel's experts' testimony. Dr. Miller testified that Respondents do not need RCTs to substantiate POM's claims because the POM Products are absolutely safe, pure fruit products and Respondents have not suggested that the Challenged Products be used as substitutes for conventional medical treatment. F. 661; *see also* F. 662-670. Dr. Heber opined that experts in nutrition evaluate whether competent and reliable science supports health claims for safe, pure fruit products, such as pomegranate juice, based on the totality of evidence, which does not necessarily include RCTs. F. 671-673. Dr. Ornish testified that, in a nutritional context, *in vitro* and animal studies may be more effective in testing the efficacy of a nutrient and that the totality of Respondents' scientific evidence must be considered in evaluating cardiovascular health claims, which need not be substantiated by expensive RCTs. F. 674; *see also* F. 675-679. Dr. deKernion testified that in the case of a fruit juice, which has low or no toxicity, it is not necessary to use an RCT. F. 682. Dr. Burnett opined that a safe pure fruit juice, like pomegranate juice, which is not used as a substitute for proper medical treatment, does not require RCTs to substantiate health claims. F. 683. Dr. Goldstein testified that RCT studies are not required to substantiate claims that pomegranate juice can aid in erectile health. F. 685-686.

c. Overview as to the appropriate level of substantiation

i. Expert testimony does not establish that RCTs are required in this case

The expert testimony in this case demonstrates that competent and reliable scientific evidence is required for claims about nutritional supplements when such products are advertised to treat diseases or medical conditions. *E.g.*, F. 662, 711, 964. *See also Daniel Chapter One*, 2009 FTC LEXIS 157, at *233-35 (Initial Decision) (summarizing expert testimony and citing *Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *11-12; *National Urological Group*, 645 F. Supp. 2d at 1190;*Direct Marketing Concepts*, 569 F. Supp. 2d at 300, 303). The greater weight of the persuasive expert testimony adduced at trial does not, however, support Complaint Counsel's position that, in order to have the required competent and reliable scientific evidence, Respondents must have had RCTs. F. 706, 707. Instead, the more persuasive expert testimony shows that RCTs are needed for a nutrient supplement if one makes a claim that the product causes the effect of treating, preventing, or reducing the risk of a disease and one offers the nutrient supplement as a replacement to medical care to treat, prevent, or reduce the risk of diseases. F. 706. The evidence further shows that RCTs are not required to convey information about a food or nutrient supplement where, as here, the safety of the product is known; the product creates no material risk of harm; and the product is not being advocated as an alternative to following medical advice. F. 707.

ii. Expert testimony on the appropriate level of substantiation

***201** Having determined that RCTs are not required in this case, the next step is to determine what level of substantiation Respondents were required to have for their advertising claims. *QT, Inc.*, 448 F. Supp. 2d at 959. As stated above, for efficacy claims, the appropriate level is determined by weighing the six *Pfizer* factors, one of which is "the amount of substantiation experts in the field would agree is reasonable." *Thompson Medical*, 1984 FTC LEXIS 6, at *387. For establishment claims, the appropriate level of substantiation is determined by what would "satisfy the relevant scientific community that the claim[s are] true." *Removatron*, 111 F.T.C. at *246, 1985 FTC LEXIS 21 at *195.

As asserted by Complaint Counsel, by virtue of their very nature, the advertisements containing establishment claims also make the efficacy claims that are challenged as unsubstantiated in the Complaint. CCB at 31. Experts in the relevant scientific communities would require the same level of evidence to support claims that a product treats, prevents, or reduces the risk of a disease or dysfunction, as they would require to support claims that clinical studies, research, or trials prove the same claims. *E.g.*, F. 713. All four of Complaint Counsel's experts in the relevant fields applied the same standards in evaluating Respondents' level of substantiation without regard to whether the claims at issue were "clinically proven" establishment claims or whether the claims at issue were efficacy claims without reference to any studies. *E.g.*, F. 190, 199, 207, 214. As discussed below, the experts, including Complaint Counsel's experts, considered evidence relating to the nature of the product, the nature of the claim, and the feasibility of conducting RCTs. *See* F. 688-705. Thus, while application of the *Pfizer* factors is not necessarily required, because the experts considered essentially the same factors in determining the "proof sufficient to satisfy the relevant scientific community of the claim's truth" (*Removatron*, 1985 FTC LEXIS 21 at *190), and because, with respect to Respondents' heart disease claims, Respondents did make non-establishment claims, a review of the *Pfizer* factors is appropriate.

Under *Pfizer*, "the amount of substantiation experts in the field would agree is reasonable," is one of six factors that must be evaluated to determine the appropriate level of substantiation for non-establishment claims. *Thompson Medical*, 1984 FTC LEXIS 6, at *387. That evaluation is discussed in the three subsequent sections of the Initial Decision specific to what experts in each of the relevant fields believe to be reasonable substantiation for claims regarding heart disease, prostate cancer, and erectile dysfunction, respectively. The remaining five *Pfizer* factors

are applicable in determining the required level of substantiation regardless of the relevant field, and are, therefore, addressed below as a preliminary matter, before the evaluation of the evidence on what experts in the fields of heart disease, prostate cancer, and erectile dysfunction would agree is reasonable substantiation. Those five *Pfizer* factors, analyzed below, are: (1) the products involved; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; and (5) the consequences of a false claim. *Thompson Medical*, 1984 FTC LEXIS 6, at *387.

(a) The products involved

***202** The POM Products are either food products or dietary supplements wholly derived from the pomegranate fruit. F. 57-58, 61, 67, 70-71. POM Juice is produced by pressing the whole fruit containing both arils (pomegranate berries) and the peel (husk) and internal membrane. F. 57-58. POMx is an extract from the pomegranate, made through a process by which POMx Liquid is first derived from the whole fruit, and then POMx is extracted from the POMx Liquid. F. 67, 70. POM Juice is sold in the refrigerated produce section of grocery stores. F. 65.

Pomegranate juice and its extract have a “high degree” of safety and are safe for human consumption. F. 78. Humans have consumed pomegranates for centuries as a safe and nutritious food. F. 77. The U.S. Food and Drug Administration (“FDA”) identifies pomegranate as being “generally recognized as safe” for human consumption. F. 82, 84; *see* 32 U.S.C. § 231(s). To establish such recognition, it must be shown that there is a consensus of expert opinion regarding the safety of the use of the substance. 21 C.F.R. § 170.30(a); *see* F. 83. Respondents' expert, Dr. Heber, confirmed that pomegranate juice has no adverse side effects, in contrast to drugs. F. 85-88.

Complaint Counsel's expert, Dr. Sacks, testified that the issue of the safety of the POM Products was not within the scope of his assignment in this case, that his expert report contains no opinions on the safety of the POM Products, and that he has “no opinion about whether [the POM Products are] safe or not.” F. 93. Complaint Counsel's expert, Dr. Stampfer, admitted that there are no safety concerns with consuming pomegranate juice apart from “the usual harm that comes with fruit juice, sugary beverages ... but that is not specific to pomegranate juice.” F. 94.

Scientific studies also confirm that POM Juice and POMx are safe for human consumption. F. 87, 88. Researchers validated the safety of POMx Pills in a clinical study where no adverse events or changes in blood count, serum chemistry or urinalysis were observed in the human subjects after consuming the extract for four weeks. F. 92. Researchers confirmed in a clinical study that the consumption of pomegranate juice had no drug interaction in the human volunteers. F. 91.

Complaint Counsel's experts agreed that the level of scientific evidence required to support a claim considers the product being promoted. F. 695. The greater weight of the persuasive expert testimony is that RCTs are needed for pharmaceutical drugs to assess safety and efficacy because pharmaceutical drugs are unnatural, developed in laboratories, and have toxicities. F. 666, 675, 682, 686, 696. Pharmaceutical drugs, which are not known to be safe and always have toxicities and side effects, are held to a higher standard than a juice that is derived from a fruit that has been around for thousands of years. F. 666, 675, 682, 686, 697. Complaint Counsel's expert, Dr. Sacks, testified that you do not need RCT trials to test the benefit of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. F. 645. Complaint Counsel's expert, Dr. Stampfer, conceded that RCTs are not required (or better) for nutritional-based research and admitted that he has made public statements or recommendations that food and beverage products lower the risk of certain diseases in the absence of RCTs. F. 631, 632.

***203** The standard applied to new drugs should not be applied to nutrients as long as the product is not claimed to be a substitute for conventional drug therapies or medical care and is shown to be safe. F. 666, 682, 697, 698.

Thus, the facts that the POM Products are derived from a fruit and are known to be safe weigh in favor of a standard for substantiation that is less than that required for pharmaceutical drugs.

(b) The type of claim

The type of claim Respondents have been found to have made — that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction and that the POM Products are clinically proven to do so — weighs in favor of a high standard for substantiation. Where defendants make a "medical, health-related claim, ... such a claim must be based on a heightened level of substantiation." *QT*, 448 F. Supp. 2d at 962. In *QT*, where the expert testimony established that "a well-conducted, placebo-controlled, randomized, double-blind study, the gold standard, should have been conducted," the court held that "Defendants would not be required to have a gold-standard study to substantiate the Q-Ray bracelet if they did not make such a strong, medical claim." *QT*, 448 F. Supp. 2d at 962. In addition, where defendants claim that a product's efficacy has been "test-proven," such a statement must be substantiated by "a reliable test" with "statistically significant results achieved." *QT*, 512 F.3d at 862;*Removatron*, 884 F.2d at 1498 ("reasonable basis" for establishment claims meant well-controlled scientific studies).

While Respondents here have been found to have made claims that the POM Products treat, prevent, or reduce the risk of diseases or dysfunction, it is significant to note that Respondents did not advertise or market the POM Products as an alternative to medical treatment. "The Complaint does not allege, and it is neither Complaint Counsel's contention nor its burden, to demonstrate that Respondents are selling the POM Products as a substitute for conventional medical treatment." CCRB at 40 n.36.

The greater weight of the persuasive expert testimony in this case confirms that the appropriate level of substantiation depends on the claims. If the claim does not suggest that an individual should forgo conventional medical care or treatment based on the consumption of a safe product and does not imply that a causal link between the product and the effect has been established, then evidence short of RCTs can be sufficient. F. 631, 707. Complaint Counsel's expert, Dr. Stampfer, testified that if, for example, nuts are not being offered as a substitute to medical care, and the claim is that there is some evidence to suggest the possibility that nuts may reduce the risk of diabetes, then evidence short of RCTs can support that claim. F. 631. While claims of efficacy can be made only when a causal relationship with human disease is established by competent and reliable scientific evidence (F. 627; *see also* F. 629-631), based on the evidence and the law as applied to this case, competent and reliable scientific evidence does not mean RCTs.

(c) The benefits of a truthful claim and the ease of developing substantiation for the claim

***204** "These two factors -- the benefits of a truthful claim and the ease of developing substantiation for the claim -- are typically considered together." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *232-33 (Initial Decision). "The consideration of these factors seeks to ensure that the level of substantiation required is not likely to deter product development or prevent disclosure of potentially valuable information about product characteristics to consumers." *Id.* at *233 (citing *Removatron*, 1985 FTC LEXIS 21, at *212 n.20; *Thompson Medical*, 104 F.T.C. at 823-24, 1984 FTC LEXIS 6, at *391).

The fact that individuals could benefit from truthful claims about a product's ability to treat, prevent, or reduce the risk of diseases or medical conditions is obvious. Complaint Counsel's expert, Dr. Stampfer, conceded that he "believe [s] that it may be appropriate to use evidence short of an RCT for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, because everyone eats and the public should be given advice based on the best evidence available." F. 631. Dr. Stampfer further testified that the failure to act, in the absence of conclusive RCT evidence, increases the risk of forgoing benefits to the public

that might have been achieved with little risk and little cost and that one should "definitely" make that potential benefit available to the public rather than withhold it. F. 633. Although advertising is not a "public health recommendation," it does convey a message and provides "potentially valuable information" about products. *Thompson Medical*, 1984 FTC LEXIS 6, at *391.

In a nutritional context, RCTs are prohibitively expensive and often not feasible because of the costs of conducting them. F. 632, 647, 673, 704. Complaint Counsel's expert, Dr. Eastham, testified that disease prevention studies should involve ten to thirty thousand participants which are "incredibly expensive" and in the range of $600 million. F. 704. Foods, unlike pharmaceutical drugs, are not patentable, and manufacturers cannot recoup the costs of conducting RCTs through profits from exclusive intellectual property rights. F. 705.

Complaint Counsel's expert, Dr. Sacks, acknowledged that RCTs may also not be feasible because of logistical and ethical considerations. F. 641, 704. In studying a fruit or food, it is difficult to do double-blind, randomized, placebo-controlled trials because the subjects know what they are consuming. F. 641, 679, 703. Once a participant is assigned to the control group and they know what the intervention is, the participant can consume the food or juice anyway, whereas one would not be able to do so with an experimental drug. F. 703. Moreover, in a nutritional context, a hypothesis about disease causation can rarely, if ever, be directly tested in humans using the RCT design. F. 701.

***205** The greater weight of the persuasive expert testimony in this case leads to the conclusion that where the product is absolutely safe, like the POM Products, and where the claim or advertisement does not suggest that the product be used as a substitute for conventional medical care or treatment, then it is appropriate to favor disclosure. *See* F. 633, 709; *see also Pearson*, 164 F.3d at 657 (under the First Amendment commercial speech doctrine, there is a "preference for disclosure over outright suppression").

(d) The consequences of a false claim

The consequences of a false claim do not compel requiring a high level of substantiation. As analyzed above, there is no evidence to suggest, and Complaint Counsel does not argue, that Respondents urge individuals to consume the POM Products in place of conventional medical treatment. CCRB at 40 n.36. *Compare Daniel Chapter One*, 2009 FTC LEXIS 157, at *234, *282 (Initial Decision) (finding that where representations in some instances suggested that individuals forego traditional cancer treatments in favor of purchasing and consuming the challenged products and evidence showed that foregoing a proven cancer treatment in favor of an ineffective treatment would be injurious to a patient's health, the consequences of a false claim required a higher level of substantiation). Moreover, the evidence shows that the POM Products are safe. F. 77-78. *See also* F. 94.

In *Pearson v. Shalala*, 164 F.3d 650, 656 n.6 (D.C. Cir. 1999), the court of appeals explained that courts should distinguish between products (*e.g.*, dietary supplements) that do not "in any fashion threaten consumer's health and safety" and "drugs," "wherein the potential harm presumably is much greater," when evaluating restrictions on commercial speech. The court in *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002) further explained:
It is especially important to recognize that, in the present case, the potential harm to consumers from deception is severely limited ... At worst any deception resulting from Plaintiffs' health claim will result in consumers spending money on a product that they might not otherwise have purchased.

Id. at 16 (noting also that the economic injury is not insignificant).

Spending money on an ineffective remedy is considered an economic injury for purposes of this *Pfizer* factor. *Daniel Chapter One*, 2009 FTC LEXIS 157, at *234 (Initial Decision) (citing *In re Schering Corp.*, No. 9232, 1991 FTC LEXIS 427, at *134 (Sept. 16, 1991)); *Removatron*, 1985 FTC LEXIS 21, at *212 n.20). In this case,

for the 52 weeks ending July 20, 2008, the weighted average base price per unit for POM Juice was $2.93 for an 8-ounce bottle or $4.29 for a 16-ounce bottle. F. 97. A serving size of POM Juice is eight ounces and, thus, a one year supply costs at least $780. *See* F. 64, 97. A one year supply of POMx costs approximately $315. *See* F. 97. Although the cost of the POM Products may not be insignificant, when you take into account the fact, at least with respect to POM Juice, that consumers are buying what is considered to be a premium fruit juice (F. 95), the economic injury to consumers is not a material factor in determining the required level of substantiation.

(e) The amount of substantiation experts in the field would agree is reasonable

***206** The last of the six *Pfizer* factors, the amount of substantiation experts in the field would agree is reasonable, must be examined in relation to each field being evaluated. In addition, for Respondents' claims that were establishment claims only, Respondents must "satisfy the relevant scientific community that the claim is true." *Removatron*, 1985 FTC LEXIS 21, at *195. Accordingly, the amount of substantiation experts would agree is reasonable, the amount of evidence that would satisfy the relevant scientific community, and whether Respondents possessed that level of substantiation in regard to each of the three diseases or dysfunction, is evaluated in the following three sections of the Initial Decision.

3. Substantiation for Respondents' heart disease claims

a. Overview

As discussed in Section III.E.2.c, *supra*, the evidence demonstrates that Respondents disseminated advertisements that impliedly represented that the POM Products treat, prevent, or reduce the risk of heart disease and, in many of these same advertisements, are clinically proven to do so, by lowering blood pressure, reducing arterial plaque and/or increasing blood flow to the heart. Complaint Counsel contends that (1) Respondents did not possess and rely upon a reasonable basis to substantiate their efficacy claims that the POM Products treat, prevent, or reduce the risk of heart disease; and (2) clinical studies, research, and/or trials do not prove Respondents' establishment claims that the POM Products treat, prevent, or reduce the risk of heart disease. CCB at 37-44.

i. Summary of expert opinions

In support of its position, Complaint Counsel submitted the expert report and testimony of Dr. Meir Stampfer and Dr. Frank Sacks. Dr. Stampfer is a Professor of Epidemiology and Nutrition, Harvard School of Public Health; Faculty Member, Division of Biological Sciences, Harvard School of Public Health; Professor of Medicine, Harvard Medical School; and Faculty Member, Dana Farber Harvard Cancer Center. F. 182. Dr. Stampfer has been an investigator in several large studies focused on the relationship between nutrition and cardiovascular disease and has published more than 850 articles in medical journals. F. 183, 184. Dr. Sacks is a Professor of Cardiovascular Disease Prevention, Department of Nutrition, Harvard School of Public Health, and Professor of Medicine, Harvard Medical School. F. 191. Dr. Sacks has researched cardiovascular disease ("CVD") and coronary heart disease ("CHD") and their risk factors, including lipid profiles, hypertension, obesity, and diabetes, and the effects of potential risk-modifying diets, foods, food components, and drugs. F. 192. Dr. Sacks has published more than 160 articles in peer-reviewed scientific journals relating to CVD, CHD, and the relationship between nutrition and these diseases. F. 193.

***207** According to Dr. Stampfer, for products such as the POM Products, claims of efficacy can be made only when a causal relationship with human disease has been established and the RCT is the best study design that permits a strong causal inference concerning the relationship between an administered agent and any specific outcome. F. 631, 632. According to Dr. Sacks, to substantiate a claim that a product, including a conventional food or dietary supplement, can treat, prevent, or reduce the risk of heart disease, one must rely on appropriately

analyzed results of well-designed, well-conducted RCTs. F. 638. Dr. Sacks further opined that the findings of the RCTs must be statistically significant (*i.e.*, have strong "*p*" values). F. 711. In addition, Dr. Sacks opined that the results of the RCTs must demonstrate significant changes in valid surrogate markers of cardiovascular health, such as blood pressure and LDL cholesterol (two surrogate markers recognized by the FDA) or Creactive protein, HDL cholesterol, and triglycerides (three surrogate markers recognized by many experts in the field). F. 712, 761-763, 765-766.

In Dr. Sacks' opinion, the same level of evidence is needed to show that clinical studies, research, or trials prove that a product treats, prevents, reduces the risk of heart disease, as is needed to substantiate a heart disease efficacy claim. F. 713.

Dr. Sacks acknowledged that there are common clinical recommendations today that have not been proven by RCTs, that in some instances, such as studies on foods, the blinding of patients is not possible, and that if a study becomes unblinded or does not have a placebo, the study can still have value. F. 641, 647. Moreover, Dr. Sacks testified that you do not need RCTs to test the benefit of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. F. 645. These positions weaken Dr. Sacks' opinion in this case that Respondents must have had two RCTs to support their claims.

In support of their position that they possessed and relied upon a reasonable basis to substantiate their claims, Respondents submitted the expert reports and testimony of Dr. David Heber and Dr. Dean Ornish. Dr. David Heber is a practicing physician, Professor of Medicine and Public Health at UCLA, and the founding Director of the UCLA Center for Human Nutrition, a center for clinical research, education, and public health endeavors. F. 221, 222. Dr. Heber has co-authored over 200 peer-reviewed publications in the field of nutrition and its relation to various diseases and written 25 chapters in other scientific texts. F. 224. Dr. Ornish is a well-known medical doctor and Clinical Professor of Medicine at the University of California at San Francisco. F. 227. Dr. Ornish is also the founder and President of the Preventative Medicine Research Institute ("PMRI"). F. 228. Dr. Ornish has directed clinical research on the relationship between diet and lifestyle and coronary heart disease for over 34 years and has written numerous books and articles for peer-reviewed journals. F. 229, 230.

***208** Both Dr. Heber and Dr. Ornish opined that there is credible scientific evidence showing that pomegranate juice and pomegranate extracts have significant health benefits for human cardiovascular systems, including: (1) decreases in arterial plaque; (2) lowering of blood pressure; and (3) improvement in cardiac blood flow, based on the biological mechanism of prolonging the half-life of nitric oxide in the vasculature. F. 956, 960. Dr. Ornish opined that, taken as a whole, the preponderance of the scientific evidence from basic scientific studies, animal research, and clinical trials in humans reveals that the pomegranate in its various forms (including POM Wonderful 100% Pomegranate Juice, POMx Pills, or POMx Liquid) is likely to be beneficial in maintaining cardiovascular health and is likely to help reduce the risk of cardiovascular disease. F. 959. Dr. Heber also opined that the body of research on pomegranate juice and extract provides support for potential heart benefits for heart disease. F. 954. Dr. Heber explained that although claims that pomegranate juice and extract have not been proven absolutely effective to treat, prevent, or reduce the risk of heart disease, the entire body of scientific evidence should be considered when evaluating nutritional science. F. 957.

Dr. Ornish disagreed that study results must be "statistically significant" with "strong '*p*' values" (*i.e.*, *p* # 0.05 or a 5 percent or less chance that the change is due to chance), testifying that: (1) in evaluating scientific research related to a whole food, it is not necessary to reach statistical significance, as opposed to a prescription drug with potential side effects; and (2) the convention that there be a five percent or less finding due to chance is an arbitrary number. F. 958. Respondents' experts further dispute Dr. Sacks' opinion that significant changes must be shown in valid surrogate markers and opine that myocardial perfusion (or blood flow to the heart) and carotid intima-

media thickness are more closely related to, and predictive of, cardiovascular disease than blood pressure or LDL cholesterol. F. 764, 765, 771.

ii. Standard for substantiation

Having considered the evidence on all the relevant factors, including the other five *Pfizer* factors analyzed in Section III.F.2, *supra*, the evidence demonstrates that competent and reliable scientific evidence is required to support claims that the POM Products treat, prevent, or reduce the risk of heart disease and that they have been clinically proven to do so. F. 711, 713; *see also* F. 710, 712. Based on the greater weight of the persuasive evidence from the experts at trial, to support claims that the POM Products treat, prevent, or reduce the risk of heart disease, or have been clinically proven to do so, competent and reliable evidence must include clinical studies, although not necessarily RCTs, that show that the POM Products did treat, prevent, or reduce the risk of heart disease. *See id.* As analyzed below, Complaint Counsel has demonstrated that Respondents did not possess adequate competent and reliable scientific evidence to substantiate the implied claims that the POM Products treat, prevent, or reduce the risk of heart disease or that clinical tests show the same. Complaint Counsel has, therefore, met its burden of proving that Respondents' claims are false or misleading. *See* *QT*, 448 F. Supp. 2d at 959.

b. Scientific evidence relied upon

i. Overview of cardiovascular heart disease

***209** Heart disease, including heart attacks or angina, occurs as the result of decades-long damage to blood vessels. F. 715, 716. The process begins with the oxidation of the protein known as low density lipoprotein ("LDL" or bad cholesterol) which circulates in the blood. F. 716. Once LDL becomes oxidized, the chemical nature of the protein changes, causing it to reside and accumulate in the blood vessel. F. 717. Macrophages, white blood cells that respond to inflammation by digesting cellular debris, begin to engulf and devour the oxidized cholesterol. F. 719. These macrophages continue to accumulate until they develop into "foam cells." F. 720. These foam cells become full of cholesterol and actually burst, bringing in more macrophages and more inflammation. F. 720. As this process progresses, plaque begins to form as yellow streaks in the coronary arteries. F. 721.

Antioxidants play an important role in mitigating heart disease by, among other things, inhibiting oxidative stress, including reducing LDL oxidation (and its uptake) and inflammation. F. 726, 727. In addition, the presence of nitric oxide in the body also helps offer protection against atherosclerosis by regulating blood flow and contributing to smooth muscle relaxation. F. 723-725, 751. Nitric oxide helps maintain healthy blood vessels, which improves blood flow to almost every organ in the body, including the heart. F. 731. Several studies have indicated that pomegranate juice has antioxidant and anti-atherosclerotic properties due to the presence of multiple polyphenols such as tannins, flavonols, anthocyanins and ellagic acid. F. 725.

ii. *In vitro* and *in vivo* studies

Respondents sponsored several *in vitro* and *in vivo* animal studies to examine the effect of POM Juice and POMx Pills on cardiovascular health. *In vitro* studies are those where blood elements or cells are removed from the body and tested in a controlled laboratory environment, such as a test tube. F. 593. *In vivo* studies are those conducted within the living. Respondents acknowledge that their *in vitro* and *in vivo* studies are "basic science" or "pre-clinical." RRCCFF 1083. Detailed findings on these studies are set forth in Section II.G.3, *supra*, and are summarized below.

Respondents have sponsored many published studies in cellular and animal models evaluating the effects of pomegranate juice and/or its extracts on cardiovascular function. F. 732. Beginning around 2000, and continuing

to the present time, Dr. Michael Aviram began studies investigating pomegranate juice's potential benefits to the cardiovascular system. F. 744. Dr. Aviram and his colleagues observed several beneficial effects of pomegranate juice and its extracts at the cellular and animal stage including, but not limited to: (1) reduction in oxidation of LDL cholesterol; (2) lessening the "uptake" of oxidized LDL by macrophage foam cells; (3) decrease in size of atherosclerotic lesions and foam cells; and (4) diminishing of platelet aggregation. F. 744.

***210** Respondents have also sponsored research in the area of nitric oxide and understanding its role in cardiovascular health *in vitro* and in animals. F. 747. Dr. deNigris, Dr. Napoli, and, Dr. Ignarro conducted a number of studies in which they found that POM Juice and/or POMx Pills demonstrated: increasing and preserving levels of nitric oxide, decreasing expression of genes associated with stress, and progression of atherosclerosis; reducing LDL oxidation, size of atherosclerotic plaques, and formation of foam cells; reversing effects of shear stress, which can damage the endothelial cells or thin layer of cells that line the interior of blood vessels; decreasing cellular production and release of oxygen radicals in the vascular wall; inhibiting activation of oxidation-sensitive genes; and improving biological activity of nitric oxide. F. 751.

Complaint Counsel's expert, Dr. Sacks, acknowledges that some of Respondents' *in vitro* studies have shown pomegranate juice's favorable effects on the mechanisms involved in cardiovascular disease and that *in vitro* studies, like Dr. Aviram's, can be competent and reliable scientific evidence of an agent's effect on a particular mechanism. F. 745, 746. However, Dr. Sacks also opined regarding Respondents' basic research that *in vitro* and animal studies do not provide reliable scientific evidence of what effects a treatment will have inside the human body and, thus, do not provide reliable scientific evidence on whether an agent can treat, prevent or reduce the risk of cardiovascular disease in humans. F. 752. Respondents' expert, Dr. Ornish, testified that *in vitro* and animal studies are important in considering the totality of evidence in determining whether or not pomegranate juice in its various forms is beneficial, but that there are limitations to extrapolating from *in vitro* and animal studies to humans. F. 753.

Respondents' basic science indicates that pomegranate juice may be beneficial to cardiovascular health. F. 754. The basic research relied upon by Respondents is part of the totality of evidence that must be examined in evaluating the effects of the POM Products. F. 755. However, experts in the field agree that *in vitro* and animal studies need to be replicated in humans to show an effect on preventing or treating a disease. F. 755.

iii. Clinical trials; overview

Complaint Counsel charges that Respondents did not have a reasonable basis and did not have clinical studies, research, or trials to prove that the POM Products prevent, reduce the risk of, or treat heart disease, by: (1) lowering blood pressure; (2) decreasing arterial plaque; and/or (3) improving blood flow to the heart. (Complaint ¶¶ 17-19). Respondents have sponsored approximately 10 published and several unpublished studies on humans, evaluating the effect of pomegranate juice and/or its extracts on cardiovascular health. F. 756. The results of the studies relied upon by Respondents and the conflicting expert opinions on these studies are found in Section II.G.5, *supra*, and discussed below.

iv. Clinical trials; improving blood pressure

***211** In support of claims that the POM Products treat, prevent, or reduce the risk of heart disease by lowering blood pressure, in addition to the basic science discussed above, Respondents rely on the Aviram ACE/BP Study [10] and the Aviram CIMT/BP Study [11] of POM Juice. RRB at 106.

(a) About the studies

The Aviram ACE/BP Study was a study with ten elderly, hypertensive patients who drank 50 ml. of pomegranate concentrate daily, for two weeks. F. 774. The Aviram ACE/BP Study was unblinded and had no control group; instead, each patient's "before" measures were compared to his or her "after" measures. F. 776. The Aviram ACE/BP Study indicated that all ten patients experienced a statistically significant 5% reduction in systolic blood pressure from their baseline blood pressure measure. F. 778. The Aviram ACE/BP Study concluded that "pomegranate juice consumption can offer a wide protection against cardiovascular disease." F. 779.

In the Aviram CIMT/BP Study, a group of ten patients with severe carotid artery stenosis consumed 50 ml. of concentrated pomegranate juice daily for one year and five of them continued for up to three years. F. 790. A second group of nine patients who did not consume pomegranate juice acted as a control. F. 790. The Aviram CIMT/BP Study indicated that the pomegranate juice group members' systolic blood pressure was significantly ($p < 0.05$) reduced by 12% after one year of pomegranate juice consumption, compared to their baseline values. F. 794. In the group that did not consume pomegranate juice, blood pressure was unchanged. F. 794.

(b) Expert opinions on the studies

Complaint Counsel's experts criticized the Aviram ACE/BP Study on the following grounds: the sample size of ten patients was too small to provide reliable evidence that the observed effects would be generally applicable to a larger population; the two-week period of the study was too short to provide reliable evidence that the indicated improvement in blood pressure would be enduring; and the Aviram ACE/BP Study did not have a control group, thus, it is not possible to conclude what caused the indicated improvements in the subjects' blood pressure levels. F. 780. Complaint Counsel's experts criticized the Aviram CIMT/BP Study for the lack of a randomized, placebo-controlled group; the fact that the patients in the active and control groups received different treatment; the small sample size; and the lack of any between-group statistical analysis. F. 798.

Respondents' expert, Dr. Ornish, responded that there is a common misconception that a larger study is a better study, but the opposite can be argued; with a smaller number of patients, the treatment has to be more powerful and consistent in order to show a statistically significant effect. F. 783, 803; s*ee also* F. 785. Dr. Aviram testified that it is entirely appropriate for each patient to serve as his or her own control and that if a study is conducted without a placebo, that fact does not weaken its importance. F. 784.

***212** Complaint Counsel's experts additionally opined that one cannot extrapolate the results of the two Aviram studies of POM Juice to the POMx products. *See* F. 948. Respondents counter this criticism by stating that, with respect to POMx Pills and POMx Liquid, Respondents detailed the findings of eight scientific studies that document the beneficial effects of POMx Pills and POMx Liquid on cardiovascular health. RRCCFF 965 (citing CX0053; PX0057; PX0056; PX0008; PX0017; PX0038; PX0139; PX0127; RFF 831-840, 924, 930-957, 1100). Furthermore, Dr. Heber, the only expert who opined on the bioavailability of pomegranate polyphenols, explained that because both the 100% Pomegranate Juice product and the POMx products contain ellagitannins that contribute to the antioxidant activity of the products (and because both are bioavailable (absorbed) in humans), there is no difference in the antioxidant effect between POM Juice and POMx products in laboratory studies. F. 953.

Lastly, Complaint Counsel charges that five subsequent RCTs sponsored by Respondents showed no benefit to blood pressure. These include the Ornish MP Study;[12] the Ornish CIMT Study;[13] the Davidson BART/FMD Study;[14] the Davidson CIMT Study;[15] and the San Diego Study.[16] Complaint Counsel's expert, Dr. Sacks, opined that the Ornish CIMT Study's and the Davidson BART/FMD Study's findings of no statistically significant difference in blood pressure due to POM Juice consumption undermine the credibility of the results of the Aviram ACE/BP Study and Aviram CIMT/BP Study. F. 862, 909.

Respondents counter this criticism by stating that none of Respondents' subsequent studies examined blood pressure as a primary endpoint and, as a result, one cannot conclude that there was no effect of POM Juice or POMx on blood pressure. RRB at 94; F. 864, 866, 912. In any clinical study, it is routine to record blood pressure, pulse, body temperature, among other measurements, to make sure patients are healthy. F. 842. Although blood pressure is measured in many studies, a specific claim on blood pressure requires a very specific study involving special equipment and personnel. F. 842. Thus, Dr. Heber testified, where blood pressure was not the endpoint, any results for blood pressure cannot be relied upon as negative evidence. F. 841, 912. Complaint Counsel's expert, Dr. Sacks, concedes that in subsequent studies showing no statistically significant changes in blood pressure, the absence of such evidence is not proof that there is no effect. F. 867, 911.

(c) Determination

As discussed above, the expert testimony regarding the Aviram ACE/BP Study and Aviram CIMT/BP Study is conflicting. The greater weight of the persuasive expert testimony on the studies sponsored by Respondents measuring blood pressure demonstrates that the scientific evidence relied upon by Respondents is not adequate to substantiate a claim that the POM Products treat, prevent, or reduce the risk of heart disease through reducing blood pressure, or that clinical studies show the same.

v. Clinical trials; reducing arterial plaque

(a) About the Aviram CIMT/BP Study

***213** In support of claims that the POM Products treat, prevent, or reduce the risk of heart disease by reducing arterial plaque, in addition to the basic science discussed above, Respondents rely on the Aviram CIMT/BP Study and the Davidson CIMT Study. RRB at 106.

Carotid intima media thickness (“CIMT”) testing measures the combination of the vessel muscle and atherosclerosis (arterial plaque). F. 767. Measures of CIMT are usually relevant to cardiovascular health, and if CIMT measures show consistent improvement, this would be an indicator that a treatment may be beneficial. F. 769. However, such measures alone are not conclusive evidence that an intervention treats existing heart disease. F. 769.

In the Aviram CIMT/BP Study, a group of ten patients with severe carotid artery stenosis (“CAS”) consumed 50 ml. of concentrated pomegranate juice daily for one year and five of them continued for up to three years. F. 790. A second group of nine patients who did not consume pomegranate juice acted as a control. F. 790. The results of the Aviram CIMT/BP Study showed that, in the control group that did not consume pomegranate juice, the patients' CIMT increased by 9% during one year, whereas, pomegranate juice consumption resulted in a significant CIMT reduction, by up to 30%, after one year. F. 791. The Aviram CIMT/BP Study concluded that the “results of the present study ... suggest that [pomegranate juice] consumption by patients with CAS decreases carotid IMT and systolic blood pressure and these effects could be related to the potent antioxidant characteristics of [pomegranate juice] polyphenols.” F. 797.

(b) Expert opinions on the Aviram CIMT/BP Study

Complaint Counsel's expert, Dr. Sacks, testified that a qualified scientist would not be able to conclude with any credibility that the improvements in the treatment group indicated by the Aviram CIMT/BP Study were caused by the group's consumption of pomegranate juice and not some other factor because of: the lack of a randomized, placebo-controlled group; the fact that the patients in the active and control groups received different treatment; the small sample size; and the lack of any between-group statistical analysis. F. 798.

Dr. Ornish testified that the findings in the Aviram CIMT/BP Study suggest that oxidative stress may have been reduced by pomegranate juice consumption in these patients. F. 793. Respondents assert that the fact that the Aviram CIMT/BP Study is considered "unblinded and uncontrolled" by Complaint Counsel does not invalidate the results. RRB at 95. However, Respondents' expert, Dr. Ornish, agreed that the Aviram CIMT/BP Study was limited in scope and opined: "Thus, while not at all conclusive, the study suggests a benefit." F. 802. He further testified that the Aviram CIMT/BP Study was "very provocative and interesting and laid the groundwork for even more conclusive studies." F. 802.

(c) About the Davidson CIMT Study

***214** The Davidson CIMT Study was an 18-month, 289-person randomized, double-blinded, placebo-controlled clinical trial conducted at two clinical research sites in accordance with good clinical practice guidelines and under a protocol approved by an institutional review board. F. 872. Participants in the Davidson CIMT Study drank eight ounces of pomegranate juice or placebo juice daily. F. 876. Adherence to product consumption was assessed at each visit by reviewing daily consumption diaries maintained by the subjects. F. 876. The protocol for the Davidson CIMT Study called for ultrasound testing of the carotid artery at baseline, at 12 months, and at 18 months. F. 877.

Among other findings, the Davidson CIMT Study indicated the following:
• Anterior and posterior wall CIMT values and progression rates did not differ significantly between treatment groups at any time point.

• The composite measurement of CIMT showed a significantly smaller value at 12 months in the pomegranate juice group compared to the control group ... However, this difference was no longer significant at the end of the treatment period [18 months].

• Results of the present study showed no significant influence of 18 months of pomegranate juice consumption on CIMT progression in the overall study sample. However, results from *post hoc* exploratory analyses, which should be interpreted with caution, suggest that the rate of CIMT progression may have been slowed in subgroups characterized by more rapid CIMT progression, including those with increased levels of TG-rich lipoproteins, low levels of HDL cholesterol, and greater oxidative stress.

• Whether possible benefits of pomegranate juice consumption on CIMT progression in some subgroups relate to antioxidant activity is uncertain. A lack of significant improvements in most markers of oxidative stress argues against an important role for antioxidant activity. However, specific reactive oxygen/nitrogen species may be scavenged by pomegranate unique polyphenolic hydrolysable tannins. Indeed, a subgroup for whom there was an apparent benefit was the top tertile for baseline PD — AAPH, suggesting that antioxidant effects may have played a role in the protection against CIMT progression by pomegranate juice consumption.

F. 878.

(d) Expert opinions on the Davidson CIMT Study

Complaint Counsel charges that Respondents "cherry-picked observations from the Davidson CIMT Study" by, *inter alia*, (1) relying on the results at 12 months, rather than the results at 18 months; and (2) focusing on results

of an exploratory sub-group analysis performed *post hoc*. CCB at 38. Respondents rejoin that: (1) the fact that differences in the composite measurement of CIMT were not statistically significant at 18 months does not change the fact that these differences were statistically significant at 12 months; and (2) findings related to subgroups cannot be ignored merely because they were formed in a *post hoc* analysis. RRB at 94-95.

***215** Complaint Counsel's expert, Dr. Sacks, testified that the Davidson CIMT Study is the largest of the heart studies conducted on pomegranate juice; was carefully designed, in that the protocol identified the endpoints to be measured, the procedures to be followed, inclusion and exclusion criteria, and the statistical analysis to be conducted; and that there was no evidence of critical problems in the conduct or analysis of the study (except its over-emphasis on the subgroup results). F. 884. Based on the findings of the Davidson CIMT Study (summarized above), particularly that, at the end of the study, there were no significant differences in CIMT progression rates between the subjects in the pomegranate juice and control groups, Dr. Sacks concluded that the Davidson CIMT Study is "competent and reliable evidence that consumption of pomegranate juice did not improve CIMT in subjects with one or more cardiovascular risk factors." F. 884. Dr. Stampfer agreed and opined that that the main result from the Davidson CIMT Study provides substantial evidence *against* the hypothesis that pomegranate juice can reduce the progression of CIMT. F. 892.

Respondents' experts opine that the Davidson CIMT Study constitutes competent and reliable scientific evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, reducing arterial plaque. F. 885. Dr. Ornish stated that the bottom line of the Davidson CIMT Study is that pomegranate juice *did* show a statistically significant improvement in CIMT after 12 months in the measure that was most clinically relevant; the fact that these differences in CIMT measurements were not statistically significant at 18 months does not change the fact that these differences were statistically significant after 12 months. F. 888.

Dr. Ornish explained that a potential reason for lack of a change in the CIMT progression rate at 18 months was that participants in the Davidson CIMT Study may have stopped drinking the juice after 12 months. F. 890. Dr. Ornish observed that it is not unusual for patients to be less than honest in describing their compliance, as patients often describe that it is embarrassing and even humiliating to report that they have not done what they were supposed to do. F. 890. However, Dr. Davidson, who evaluated compliance with the product consumption guidelines during the Davidson CIMT Study, testified that his review of compliance diaries showed high levels of compliance with the product consumption guidelines. F. 891.

Respondents' experts also opine that the Davidson CIMT Study provides supporting evidence that there were statistically significant lower CIMT progression rates for pomegranate versus control in the subgroup of persons with higher cardiovascular disease risk factors. F. 888. The Davidson CIMT Study described the subgroup analyses as "*post hoc* exploratory analyses, which should be interpreted with caution[.]" F. 878. Respondents' experts opined that in scientific research, *post hoc* analysis is routine. F. 896.

***216** Complaint Counsel's expert, Dr. Sacks, opined that a *post hoc* analysis is one that is conceived after the researchers have seen the data and is, thus, generally a less valid approach than one planned for in the protocol, because it is more subject to bias. F. 895. Dr. Sacks further opined: because the subgroup data is hypothesis generating only, and has not been corrected for multiple comparisons, a qualified scientist could not rely on the *post hoc* analysis of the subgroup populations as reliable scientific evidence to support claims that POM Juice or POMx prevent, reduce the risk of, or treat heart disease in the subgroup populations identified. F. 899.

(e) The Ornish CIMT Study

Complaint Counsel further charges that Respondents, in making claims that the POM Products can treat or prevent heart disease by reducing arterial plaque, discount the outcome of the Ornish CIMT Study. CCB at 38. The Ornish

CIMT Study was an unpublished, randomized, double-blind, placebo-controlled 73-person study, conducted by Dr. Ornish, one of Respondents' experts in this case. F. 850. The primary endpoint of the Ornish CIMT Study was to investigate the effects of pomegranate juice on CIMT in patients with at least one cardiovascular risk factor. F. 850. The treatment group drank eight ounces of pomegranate juice concentrate daily, and the control group drank eight ounces of placebo beverage daily, for one year. F. 850. According to the Ornish CIMT Study unpublished final report, there were no significant changes in the treatment group relative to the placebo for CIMT thickness or elastic properties. F. 858.

Dr. Sacks described the results of the Ornish CIMT Study as "convincingly null, showing that pomegranate juice treatment did not improve CIMT" and opined that the Ornish CIMT Study confirmed that the purportedly positive results of Dr. Aviram's unrandomized, uncontrolled 19-patient CIMT/BP Study lacked credibility. F. 861, 862. However, Dr. Sacks admitted that the lack of statistical significance for a positive result in the Ornish CIMT Study is not proof of a negative. F. 867.

Dr. Ornish testified that the Ornish CIMT Study was an indeterminate study that cannot be relied upon; "it neither proves or disproves." F. 864. Dr. Ornish explained that the protocol for the Ornish CIMT Study called for 200 patients, but ultimately, only 73 patients were recruited, 56 of whom completed one-year testing. F. 851. Dr. Ornish further stated: Even in this smaller group, we found improvements in right CIMT that approached statistical significance and that if these changes had been seen in a sample of 200 patients, then it would have been statistically significant. F. 857, 863. Dr. Heber observed that the Ornish CIMT Study "had inadequate power at that number of subjects," so no conclusions could be drawn from the study. F. 865.

(f) Determination

As discussed above, the expert testimony regarding the studies measuring CIMT to support Respondents' claims is conflicting. The greater weight of the persuasive expert testimony on the studies sponsored by Respondents measuring CIMT demonstrates that the scientific evidence relied upon by Respondents is not adequate to substantiate a claim that the POM Products treat, prevent, or reduce the risk of heart disease through reducing arterial plaque, or that clinical studies show the same.

vi. Clinical trials; improving blood flow

***217** In support of claims that the POM Products treat, prevent, or reduce the risk of heart disease by improving blood flow (myocardial perfusion), in addition to the basic science discussed above, Respondents rely on the Ornish MP Study. RRB at 106.

(a) About the Ornish MP Study

In the Ornish MP Study, Dr. Ornish and his colleagues investigated whether the daily consumption of pomegranate juice for three months would affect myocardial perfusion ("MP") in 45 patients who had coronary heart disease and myocardial ischemia (narrowing of the arteries) in a randomized, placebo-controlled, double-blind study, which was subsequently published. F. 805, 808. The Ornish MP Study indicated that after three months there was a significant ($p = 0.05$) improvement of 17% in the summed differences score ("SDS") [17] in the POM Juice group, as compared to an average worsening of 18% in the control group. F. 811. Thus, after three months, the comparative benefit in blood flow of the pomegranate juice group to the placebo group in the Ornish MP Study was about 35 percent. F. 811. The Ornish MP Study concluded: "Although the sample in this study was relatively small, the strength of the design and the clinically significant and statistically significant improvements in myocardial perfusion observed in the experimental group over a rather short period suggest that daily consumption of pomegranate juice may have important clinical benefits in this population." F. 815.

(b) Expert opinions on the Ornish MP Study

Complaint Counsel criticizes the Ornish MP Study, *inter alia*, on the following grounds: (1) change in myocardial perfusion is not a recognized surrogate marker of therapeutic effects on coronary heart disease; (2) the Ornish MP Study indicates significant changes in only one of three measures of blood flow — in summed difference score (SDS), but not summed rest score (SRS) or summed stress score (SSS); (3) the study was designed to last 12 months, but was cut short at 3 months; (4) the study showed no improvement in other measures, such as blood pressure, cholesterol, inflammatory biomarkers, and oxidative stress; and (5) there were problems in the design and conduct of the study. Respondents' replies to each of these challenges to the adequacy of the Ornish MP Study to substantiate claims regarding improving blood flow are addressed, in order, below.

First, the Ornish MP Study measured improvements in myocardial perfusion. F. 808. Complaint Counsel's experts opined that myocardial perfusion is a research tool, but is not recognized as a surrogate marker for heart disease and is not used as the primary outcome in studies of treatment efficacy for coronary heart disease. F. 825. Dr. Sacks further opined that even where blood flow is shown to have been improved, it will not necessarily result in improved cardiovascular health, such as reductions in heart attack and stroke. F. 825. However, Dr. Sacks conceded that proper blood flow from the coronary artery and to the heart is fundamental to lowering the risk of cardiovascular disease. F. 826.

***218** Dr. Ornish, for Respondents, opined that blood flow is essential to life, an important measure of heart disease, and the "bottom line" in coronary heart disease (along with how well the heart is pumping blood) and, thus, when researchers measure myocardial perfusion, researchers are measuring what actually matters most. F. 827. As Dr. Ornish explained, blood carries oxygen and nutrients that feed the heart. F. 828. If the blood flow to the heart (perfusion) is reduced, then the heart is no longer receiving enough blood flow to maintain itself. F. 828. Coronary heart disease, which is the most common form of heart disease, occurs when the heart does not get enough blood to fuel itself and blood carries oxygen, which is the fuel for the heart. F. 828.

In addition, Respondents' experts opined that myocardial perfusion is more closely connected as a surrogate marker for cardiovascular disease than LDL cholesterol, which has been accepted by the FDA as a surrogate marker. F. 829. Dr. Ornish explained that when a person has a biomarker such as high LDL cholesterol, which increases his or her risk, that is far away from the actual event of a heart attack, which may be affected by many other factors, such as inflammation and oxidation. F. 829. There are a number of people who have low cholesterol levels, but get heart disease. F. 829. About 50 percent of the people who die from a heart attack actually have cholesterol in the normal range. F. 829. There are people who have high cholesterol levels who do not have heart disease, and the same is true for blood pressure. F. 829.

Second, the Ornish MP Study report indicates significant changes in only one of three measures of blood flow. F. 833. Complaint Counsel's experts testified that the .05 "*p*" value of the SDS improvement is not very persuasive where, as in the Ornish MP Study, there were three possible outcome measures (SSS, SRS, and SDS), and only one just met significance. F. 833.

Responding to these criticisms, Dr. Ornish explained that he did not ignore the SRS and SSS measures, but that those were not the objective of the Ornish MP Study because they measure infarcted or dead heart tissue. F. 832, 834. SDS is derived by subtracting SRS from SSS and the finding of statistically significant changes in SDS confirmed what the researchers were hoping to find -- an improvement in blood flow to the heart when compared to rest and stress. F. 832, 834.

Complaint Counsel's experts also opined that there was a large discrepancy between the pomegranate juice and the control groups in the baseline values of SRS and SSS, the two components of the SDS. F. 835. The control group's baseline values were worse than those of the pomegranate group, and, thus, it could be predicted that the control group, having worse coronary perfusion than the pomegranate group at baseline, would have a more accelerated form of the disease and show worsening on follow-up, according to Dr. Sacks. F. 836.

***219** Dr. Ornish explained that there was a difference in SSS at baseline, but no statistically significant differences in SRS or SDS. F. 837. Dr. Ornish further testified that the Ornish MP Study employed an "analysis of variance," which took into account any baseline differences. F. 837.

Third, the Ornish MP study was originally designed to last 12 months, with measurements at baseline, 3 months, and 12 months. F. 843. Complaint Counsel charges that the study was cut short when the three-month data came in favorably and Dr. Ornish faced cost overruns. CCB at 39. Dr. Sacks opined that the shortened study period and failure to report the planned duration are inconsistent with widely-accepted standards for conduct of clinical trials and undermine any confidence in the findings. F. 843.

Dr. Ornish testified that the Ornish MP Study was terminated after three months only because the Resnicks did not provide the funding that they had previously committed to this study, not because the *p*-value was statistically significant at three months. F. 844. Dr. Ornish further opined that while he did not have 12 months of follow-up data, this does not reduce the confidence in the three-month findings of the Ornish MP Study. F. 844.

Fourth, Complaint Counsel's expert criticized the Ornish MP Study on the additional basis that blood pressure, cholesterol, inflammatory biomarkers, and oxidative stress were not improved. F. 838. Dr. Ornish himself concluded that "blood pressure ... did not improve" in the Ornish MP Study. F. 839. However, Dr. Ornish explained, the fact that other factors such as blood pressure and cholesterol did not improve does not in any way provide evidence that pomegranate juice was not beneficial, as its effects may have been mediated via other pathways. F. 840.

Fifth, Complaint Counsel's experts point out various other problems in the design and conduct of the study, including providing data on only 39 of the 41 patients and unblinding of 6 patients mid-way through the Ornish MP Study. F. 820, 824. In trial testimony and in his expert report, Dr. Ornish acknowledged that "some problems" occurred during the Ornish MP Study that were not "optimal," but opined that the difference in SDS remained statistically significant and, therefore, the conclusions of the study remain valid. F. 819, 821.

Complaint Counsel's expert, Dr. Sacks, concluded, "the interpretation of [the Ornish MP] study that is most consistent with the principles of clinical study design and conduct is that the treatment had no effect on any measure of cardiac health" and that experts in the field of cardiovascular disease would not consider the Ornish MP Study to support the proposition that pomegranate juice provides a heart disease benefit. F. 845.

Respondents' expert, Dr. Ornish, the author of the study, concluded that the Ornish MP Study constitutes credible and reliable science showing that pomegranate juice lessens the risk of cardiovascular problems; that in people who have already had heart disease, it improves blood flow and reverses the progression of heart disease; and if you can begin to reverse a disease, it would only make sense that pomegranate juice would work even better to help prevent heart disease in the first place. F. 847.

(c) Determination

***220** As discussed above, the expert testimony regarding the Ornish MP Study is conflicting. The greater weight of the persuasive expert testimony on the Ornish MP Study demonstrates that the scientific evidence relied upon

by Respondents is not adequate to substantiate a claim that the POM Products treat, prevent, or reduce the risk of heart disease through improving blood flow, or that clinical studies show the same.

c. Conclusion

Having fully considered and weighed all the evidence and the conflicting expert testimony on Respondents' basic science and clinical trials, the greater weight of the persuasive expert testimony demonstrates that there is insufficient competent and reliable scientific evidence to substantiate a claim that the POM Products treat, prevent, or reduce the risk of heart disease, by lowering blood pressure, reducing arterial plaque and/or increasing blood flow to the heart, or are clinically proven to do so. F. 962. Accordingly, Complaint Counsel has met its burden of proving that Respondents' substantiation was inadequate to make the implied heart disease claims found to have been made in this case, and that, therefore, such claims were false or misleading.

4. Substantiation for Respondents' prostate cancer claims

a. Overview

As discussed in Section III.E.2.d, *supra*, the evidence demonstrates that Respondents disseminated advertisements that impliedly represented that the POM Products are clinically proven to treat, prevent, or reduce the risk of prostate cancer, by prolonging prostate-specific antigen ("PSA") doubling time. Complaint Counsel contends that (1) Respondents did not possess and rely upon a reasonable basis to substantiate their efficacy claims that the POM Products treat, prevent, or reduce the risk of prostate cancer; and (2) clinical studies, research, and/or trials do not prove Respondents' establishment claims that the POM Products treat, prevent, or reduce the risk of prostate cancer. CCB at 44-50. With respect to claims made about prostate cancer, although Respondents have been found to have made establishment claims only, by virtue of their very nature, the advertisements containing establishment claims also make the efficacy claims that are challenged as unsubstantiated in the Complaint. CCB at 31.

i. Summary of expert opinions

In support of its position, Complaint Counsel submitted the expert report and testimony of Dr. James Eastham and Dr. Stampfer. Dr. Eastham is Chief of Urology, Department of Surgery, and Director of Clinical Research, Urology Department at Memorial Sloan Kettering Cancer Center. F. 200. He is a board-certified urological surgeon who has treated more than 2,000 patients with prostate cancer and has extensive experience, including as an investigator, in the design and conduct of clinical trials studying prostate cancer. F. 200, 201. Dr. Eastham is an expert in the fields of urology, including the prevention and treatment of prostate cancer, as well as clinical testing related to the prevention and treatment of prostate cancer. F. 204. Dr. Stampfer has participated in research investigating risk factors (including food intake and dietary factors) associated with prostate cancer. F. 183. An expert in nutrition, including its relation to the prevention and treatment of prostate cancer, and clinical testing related to the prevention of prostate cancer, Dr. Stampfer also reviewed Respondents' prostate cancer research and provided his independent opinion. F. 190.

***221** Dr. Eastham and Dr. Stampfer state that to support claims that the POM Products prevent prostate cancer, or that they have been clinically proven to do so, experts in the field of prostate cancer would require at least one well-designed, randomized, double-blind, placebo-controlled clinical trial involving an appropriate sample population and endpoint. F. 626, 648. Dr. Eastham opined that the appropriate sample population for a cancer prevention trial "would involve more than 10,000 healthy men, ages 50 to 65, having no sign of prostate cancer." F. 1092. Dr. Eastham also testified that "[a] prostate cancer prevention study must be conducted over a long enough period of time to see an effect over time." F. 1093. Dr. Eastham states that "[t]he primary endpoint in a

prostate cancer prevention trial for measuring whether a product has been effective is the prevalence or incidence of prostate cancer between the treatment and placebo groups at the conclusion of the study." F. 1089.

Dr. Eastham and Dr. Stampfer also state that to support claims that the POM Products treat prostate cancer, or that they have been clinically proven to do so, experts in the field of prostate cancer would require a randomized, placebo-controlled, double-blind clinical trial with an appropriate sample population and endpoint. F. 626, 648. Dr. Eastham and Dr. Stampfer further opine that PSA doubling time is not recognized by experts in the field as a surrogate endpoint in prostate cancer clinical trials. F. 1100.

Complaint Counsel's experts concluded that evidence relied upon by Respondents does not constitute adequate substantiation for claims that the POM Products treat, prevent, or reduce the risk of prostate cancer or have been clinically proven to do so. F. 1019, 1086-1094, 1096-1099.

In support of their position that they possessed and relied upon a reasonable basis to substantiate their claims, Respondents submitted the expert reports and testimony of Dr. David Heber and Dr. Jean deKernion. Dr. Heber is a practicing physician, Professor of Medicine and Public Health at UCLA, and the Director of the UCLA Center for Human Nutrition. F. 221, 222. Dr. Jean deKernion is the Chairman of the Department of Urology and Senior Associate Dean for Clinical Affairs at the UCLA School of Medicine and served as the Dean of Urology at the UCLA School of Medicine for twenty-six years. F. 251. Dr. deKernion is also a practicing urologist certified by both the American Board of Surgery and the America Board of Urology. F. 250.

Dr. Heber reviewed Respondents' science in the area of prostate cancer and testified at trial that there is competent and reliable science showing that POM Juice and POMx Pills lengthen the PSA doubling time for men who have had prostate cancer and, thus, it is likely for those men to have a deferred recurrence or death from that disease; and that POM Juice and POMx Pills are likely to lower the risk of prostate problems for men who have not yet been diagnosed with prostate cancer. F. 1120. Dr. Heber's expert report, however, was more limited than his trial testimony, opining: the statistically significant prolongation of PSA doubling time, coupled with corresponding laboratory effects on prostate cancer *in vitro* cell proliferation and apoptosis [programmed cell death], as well as oxidative stress and inflammation, provides strong scientific rationale for the statement that pomegranate juice promotes prostate "health." F. 1121.

***222** Dr. deKernion testified that the POM Products are beneficial to prostate health. F. 1124. Dr. deKernion opined that although there is not 100% proof that the POM Products reduce the risk of prostate cancer, the same mechanism shown in the *in vitro* and animal studies and in the Pantuck and Carducci human studies (discussed below) showed, with a "high degree of probability," that POM Juice and POMx would inhibit the clinical development of prostate cancer in men who have not been diagnosed with that disease. F. 1124. Dr. deKernion testified also that there is a high probability that the POM Products provide a special benefit to men with detectable PSA after radical prostatectomy. F. 1125.

ii. Standard for substantiation

Having fully considered and weighed the evidence adduced at trial, the evidence demonstrates that competent and reliable scientific evidence is required to support claims that the POM Products treat, prevent, or reduce the risk of prostate cancer, or that they have been clinically proven to do so. *See* F. 963-966. Based on the greater weight of the persuasive evidence from the experts at trial, to support claims that the POM Products treat, prevent, or reduce the risk of prostate cancer, or that they are clinically proven to do so, competent and reliable evidence must include clinical studies, although not necessarily RCTs, that show that the POM Products did treat, prevent, or reduce the risk of prostate cancer. *See id.* As analyzed below, Complaint Counsel has demonstrated that Respondents did not possess adequate competent and reliable scientific evidence to substantiate the implied claims that the

POM Products treat, prevent, or reduce the risk of prostate cancer or that clinical tests show the same. Complaint Counsel has, therefore, met its burden of proving that Respondents' claims are false or misleading. *See QT*, 448 F. Supp. 2d at 959.

b. Scientific evidence relied upon

i. *In vitro* and *in vivo* studies

The mechanism by which pomegranates promote prostate health is through potent antioxidant and antiatherosclerotic properties[18] attributed to pomegranates' high content of polyphenols, including ellagic acid and tannins. F. 725. Ellagic acid and tannins have been shown to exhibit *in vitro* and *in vivo* anticarcinogenic properties, such as induction of cell cycle arrest and apoptosis, as well as the inhibition of tumor formation and growth in animals. F. 990. *In vivo* research has demonstrated that pomegranate polyphenols reduce inflammation in prostate tumors. F. 995. *In vitro* and *in vivo* research has also demonstrated that in tumors treated with pomegranate extract, the nuclear factor-*kappa*B decreased (see below), thereby causing decrease of tumor growth. F. 1007.

Working from these foundations, Respondents sponsored several *in vitro* and animal studies to examine the effect of POM Juice and POMx Pills on prostate health. F. 1010. Detailed findings of fact on these studies are set forth in Section II.H.3, *supra.* In summary, in this pre-clinical research, which studied human prostate cancer cells in the lab and inside of mouse models, POM Juice was found to inhibit cancer cell growth, promote prostate cell death, and inhibit the inflammatory process, which is correlated with the growth of cancer. *See id.*

***223** For example, in a study titled, "*Pomegranate Ellagitannin-Derived Metabolites Inhibit Prostate Cancer Growth and Localize to the Mouse Prostate Gland*," Dr. David Heber and colleagues evaluated the effects of pomegranate extract on prostate cancer growth in severe combined immunodeficient mice injected with human prostate cancer cells. F. 1014. The study showed that pomegranate extract significantly inhibited prostate cancer in the mice, as compared to the control. F. 1014. Researchers also found that ellagic acid and synthesized urolithins from the pomegranate extract were shown to inhibit the growth of human prostate cancer cells *in vitro.* F. 1014. The researchers concluded that the chemopreventive potential of pomegranate ellagitannins and localization of their bioactive metabolites in mouse prostate tissue *suggest* that the pomegranate *may play a role* in prostate cancer treatment and chemoprevention. F. 1014 (emphasis added). The researchers also stated that "[t]his warrants future human tissue bioavailability studies and further clinical studies in men with CaP [prostate cancer]." F. 1014.

Another study by Dr. Rettig and Dr. Heber, et al., titled, "*Pomegranate extract inhibits androgen-independent prostate cancer growth through a nuclear factor-kappaB-dependent mechanism*," evaluated POMx Pills and POM Juice and found that their consumption was linked to reduction in cancer growth and decreased plasma PSA levels. F. 1016. The study found that one of the most well-established signaling pathways mediating inflammatory responses relevant to cancer is the nuclear factor-*Kappa*B ("NF-*k*B") pathway, which serves as a predictor for recurrence of prostate cancer after radical prostatectomy, and that POMx inhibited NF-*k*B and cancer cell viability in a dose response fashion *in vitro* and in a human LAPC4 prostate cancer xenograft mouse model. F. 1016. Based on the results, the researchers concluded "that pomegranate juice *could have potential* as a dietary agent to prevent the emergence of androgen-independence," thus, potentially prolonging life expectancy of prostate cancer patients, and suggested "that this may be a high priority area for future clinical investigation." F. 1016 (emphasis added).

As testified to by Dr. deKernion, Respondents' *in vitro* and animal studies showed that pomegranate juice inhibited the growth of prostate cancer cells and actually killed cancer cells from humans that had been inserted into mice. F. 1020. However, as Dr. deKernion also testified, and Complaint Counsel's experts concurred, one cannot always extrapolate from *in vitro* and animal results to what the results would be in humans. F. 1022. Experts in the field

agree that even where the animal and *in vitro* evidence is strong and shows that an agent's mechanism of action works, this evidence alone does not prove that an agent works in humans and, thus, does not show that the POM products treat, prevent, or reduce the risk of prostate cancer. F. 1024.

ii. Clinical trials

***224** Respondents have sponsored one human clinical study, which is completed and published, and one human clinical study that is not yet published. F. 1025. The published study, titled, *Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Following Surgery or Radiation for Prostate Cancer* by Pantuck, et. al, was published in the journal Clinical Cancer Research in 2006. ("Pantuck Study"). F. 1030. The ongoing human clinical study, by Dr. Michael A. Carducci, is completed, and an abstract summarizing the results has been published, but a final, peer-reviewed study report had not been published at the start of trial in this matter. The abstract is titled, *A Phase II Study of Pomegranate Extract for Men with Rising Prostate-Specific Antigen Following Primary Therapy*, J Clin Oncol 29: 2011 (suppl 7; abstr 11) ("Carducci Study"). Detailed findings of fact on the Pantuck Study and the Carducci Study are set forth in Section II.H.4, *supra*, and summarized here.

(a) The Pantuck Study

The Pantuck Study was conducted by Dr. Allan Pantuck, an Associate Professor of Urology at UCLA Medical School who maintains a clinical practice at UCLA. F. 1026. Dr. Pantuck's study was the first clinical trial of pomegranate juice in patients with prostate cancer. F. 1036. According to the published study report, the Pantuck Study was "an open-label, single-arm [one treatment group] clinical trial," meaning it was not an RCT and did not have a placebo group. F. 1037. The Pantuck Study included 46 patients who had been diagnosed with prostate cancer. F. 1039. All 46 patients in the Pantuck Study drank eight ounces of pomegranate juice daily and had their blood drawn every three months to have their PSA determined. F. 1043. The presence of detectable PSA after radical prostatectomy or other radical treatment usually indicates cancer is present. F. 1041. PSA doubling time ("PSADT") is a mathematical expression of the rapidity with which the prostate specific antigen is rising, and an expression of the rapidity of growth and number of prostate tumor cells. F. 1042.

Patients in the Pantuck Study who consumed POM Juice experienced a statistically significant increase in PSADT, when compared to their own baseline pre-treatment PSADT. F. 1044. In the Pantuck Study, the average pre-treatment PSADT before intervention was approximately 15 months, and after 33 months, the average post-treatment PSADT was approximately 54 months. F. 1054. Thus, mean PSADT significantly increased from a mean of 15 months at baseline to 54 months post-treatment. F. 1045. The Pantuck Study concluded that the statistically significant prolongation of PSA doubling time, coupled with corresponding laboratory effects on prostate cancer *in vitro* cell proliferation and apoptosis, as well as oxidative stress, warrant further testing in a placebo-controlled study. F. 1047.

In 2008, Dr. Pantuck presented a follow-up report and released the abstract titled, Pantuck, AJ, et al., "*Long term follow up of pomegranate juice for men with prostate cancer and rising PSA shows durable improvement in PSA doubling times*," American Society of Clinical Oncology ("Pantuck Phase II Follow-Up Results"), which summarized follow-up results for the Pantuck Study. F. 1048. According to the published abstract, fifteen active patients (31%) remained on the study. F. 1049. All of the men who had dropped out of the Pantuck Study did so because their PSA had increased. F. 1049. The Pantuck Phase II Follow-Up Results stated that those who continued on pomegranate juice maintained a lengthening of their PSA doubling time compared to men who did not continue on pomegranate juice. F. 1050. The Pantuck Phase II Follow-Up Results found that long-term follow up of pomegranate juice consumption in men with prostate cancer and rising PSA following primary therapy demonstrates a durable increase in PSA doubling time and concluded that a multi-center, randomized phase III study is ongoing to further evaluate the benefits of pomegranate in a placebo-controlled manner. F. 1052.

***225** When the Pantuck Study report was released in 2006, Dr. Pantuck was quoted in an American Association for Cancer Research press release, as stating: "[w]e don't believe we are curing anyone from prostate cancer." F. 1054. He pointed out that "although a third of patients experienced a decrease in PSA during the study, nobody's PSA went to zero." F. 1054. Dr. Pantuck further explained: "The PSA doubling time, however, was longer. For many men, this may extend the years after surgery or radiation that they remain recurrence free and their life expectancy is extended." F. 1054.

(b) The Carducci Study

The Carducci Study was conducted by Dr. Michael Carducci, a Professor of Oncology and Urology at the Johns Hopkins University School of Medicine, in Baltimore, Maryland. F. 1065. Dr. Carducci has conducted 40 to 50 clinical trials relating to prostate cancer and has published approximately 80 articles related to prostate cancer. F. 1067.

In 2006, Dr. Carducci began working with Respondents to design the Carducci Study. F. 1068. Dr. Carducci submitted a proposed protocol for the Carducci Study to Respondents for a larger randomized three-arm (three groups) study, with two treatment arms and one placebo arm. F. 1068. Respondents conducted a cost and feasibility analysis and decided that the study proposed by Dr. Carducci was too costly, and, thus, the placebo arm was dropped from the study. F. 1069. The Carducci Study began in January 2008. F. 1070. In 2011, Dr. Carducci presented the abstract of his clinical research study titled, "*A Phase II Study of Pomegranate Extract for Men with Rising Prostate-specific Antigen Following Primary Therapy*" at the disease specific meeting of the American Society of Clinical Oncology ("Carducci abstract"). F. 1072.

The Carducci Study was a multi-center, double blind Phase II randomized trial that studied the effect of two different doses of POMx Pills (one or three capsules) on PSADT in men who had received initial therapy for prostate cancer. F. 1070. One hundred and four (104) men were enrolled and treated for up to six months (92%), 12 months (70%), and 18 months (36%). F. 1075. PSA levels were obtained every three months. F. 1074.

The Carducci abstract stated: median PSADT lengthened from 11.9 months at baseline to 18.5 months after treatment, a within group measurement, which showed that POMx treatment significantly increased the PSA doubling time by over six months in both treatment arms. F. 1076. There was no significant treatment difference in PSADT between the group who took one capsule and the group who took three capsules of POMx. F. 1075. The Carducci abstract also stated that 13 patients (13%) had declining PSA levels during the study. F. 1077. The Carducci abstract concluded that POMx demonstrates "promising antitumor effects in prostate cancer." F. 1078.

(c) Expert Opinions of the Pantuck and Carducci Studies

Complaint Counsel's experts, Dr. Eastham and Dr. Stampfer, opined that the Pantuck Study and Carducci Study do not constitute adequate substantiation for Respondents' claims that the POM Products treat, prevent or reduce the risk of prostate cancer, for a number of reasons, including: (1) the studies lacked a placebo-control group; (2) PSA doubling time is not a valid endpoint; (3) the studies do not assess whether the POM Products prevent prostate cancer; and (4) the results of the Pantuck Study on POM Juice cannot be used to support claims made about POMx Pills. Respondents' replies to each of these challenges to the adequacy of Respondents' substantiation are addressed, in order, below.

***226** First, the Pantuck Study and Carducci Study did not have a placebo-control group. F. 1037, 1069, 1070. Complaint Counsel's experts opined that without a control group, it is not possible to conclude that the POM Products alone had an effect on the patients' PSA. F. 1087, 1088, 1096. Respondents' expert, Dr. deKernion

testified that in both the Pantuck Study and the Carducci Study, the control was the previous PSA doubling time prior to treatment. F. 1115. The researchers measured the doubling time before patients took POM Juice or POMx and then measured doubling time afterwards, comparing one to the other. F. 1115. Dr. deKernion further testified that a control arm is often used to control for the placebo effect and that the use of a placebo group is more important when you have a subjective reporting (such as level of pain), as opposed to an objective reporting (such as PSADT). F. 1116, 1117. However, Dr. deKernion also acknowledged that without a placebo, one cannot be certain that the effect on PSA doubling time seen in the Carducci Study is attributable to POMx. F. 1118. Furthermore, Dr. Pantuck testified that the lack of a "blinded control" group was the "greatest limitation" of his study, and Dr. Carducci testified that without a placebo, he cannot be sure that the effect on PSADT observed in the Carducci Study is attributable to POMx. [19] F. 1060, 1083.

Second, the Pantuck Study and the Carducci Study used mean PSA doubling time as the primary endpoint. F. 1040, 1070. The expert testimony on the validity of PSA doubling time as a primary endpoint is conflicting. Complaint Counsel's experts, Dr. Stampfer and Dr. Eastham, both criticized this method, opining that it is unknown if PSADT predicts overall survival in prostate cancer patients throughout its range, PSADT is not a surrogate for overall survival, and PSADT is not a relevant surrogate marker for prostate cancer prevention. F. 1089, 1097. However, Dr. Stampfer also testified that PSA doubling time is a "predictor of disease and mortality" and that, if the extension of PSA doubling time is true, it would substantially prolong lives. F. 1104. Dr. Eastham, too, offered a contradictory opinion to his opinion at trial in an article wherein he concluded, "PSADT is an important prognostic marker in men with biochemical failure after local therapy for prostate cancer, and it predicts the probable response to salvage radiotherapy, progression to metastatic disease and prostate cancer specific death." F. 1102.

Respondents' expert, Dr. Heber, testified that PSA doubling time is a "very important clinically utilized marker of clinical status." F. 1112. *See also* F. 1113 (Dr. Heber testifying that there is a lot of support from the urological community to get the FDA to accept PSA doubling time as a surrogate endpoint). Dr. deKernion testified that given the understanding of PSA doubling time in predicting risk of clinical recurrence and to some extent survival, it is logical to use changes in PSADT as indicative of an intervention's effectiveness regarding prostate tumor behavior. F. 1110. Dr. deKernion also acknowledged, however, that PSA doubling time is not accepted by experts in the field of prostate cancer as a surrogate endpoint for clinical benefit in chemotherapy trials. F. 1111.

***227** As testified to by Dr. Pantuck, "[i]t remains controversial whether modulation of PSA levels represents an equally valid clinical end point." F. 1059. On the one hand, Dr. Pantuck testified that "PSA has not been validated prospectively as a surrogate endpoint for a meaningful prostate cancer outcome." F. 1059. On the other hand, Dr. Pantuck stated that "although PSA changes are thought to be prognostically important, it is based on level 2 evidence, and nobody has ever shown conclusively that changes in PSA kinetics arising from therapeutic intervention is meaningful." F. 1059. Dr. Carducci's testimony on this point also underscores this conflict. While Dr. Carducci testified that the use of PSA doubling time as a primary endpoint to determine if POMx has an effect on the disease state was a scientifically valid way to conduct the Carducci Study, he also acknowledged that PSA doubling time as a marker or surrogate has not been proven and that the endpoint of PSA doubling time is not a standard for regulatory approval of drugs at the FDA level. F. 1079, 1080.

There are no studies proving that changing the rate of PSA doubling time changes the natural history of prostate cancer by delaying the development of metastases or death from the disease. F. 1131. Experts in the field of prostate cancer agree that PSADT is not an accepted surrogate endpoint for survival or prostate cancer-specific mortality in prostate cancer treatment clinical trials. F. 1134. Although this Initial Decision does not require Respondents to meet FDA standards for clinical trials to substantiate claims about a food or food-derived product that is safe and not being sold as an alternative to medical treatment, because the use of PSA doubling time as a valid endpoint is controversial, this factors into evaluating the adequacy of Respondents' substantiation.

Third, Complaint Counsel's experts point out that the clinical studies examining the effect of the POM Products on prostate cancer have been conducted on men who either have prostate cancer, or have been treated for prostate cancer and have experienced a biochemical recurrence. F. 1039, 1070. Because the Pantuck Study and Carducci Study were designed as treatment studies, Dr. Eastham and Dr. Stampfer opine that there is no competent and reliable scientific evidence supporting a claim that the POM Products prevent prostate cancer. F. 1091, 1099.

Respondents' expert, Dr. deKernion, explained that in order to show an effect of POM Products on prostate cancer, the best way to do that research is on patients whose prostate had been removed, because the presence of PSA elevation is almost always an indication of remaining cancer. F. 1122. Dr. deKernion further opined that although there is not proof that POM Products reduce the risk of prostate cancer, the same mechanism shown in the *in vitro* and animal studies and in the Pantuck and Carducci human studies showed, with a "high degree of probability," that POM Juice and POMx would inhibit the clinical development of prostate cancer in men who have not been diagnosed with that disease and that POM Juice and POMx could possibly play a role in preventing them from getting prostate cancer. F. 1124; *see also* F. 1123.

***228** Dr. Pantuck acknowledged that the Pantuck Study did not prove that pomegranate juice prevents or reduces the risk of prostate cancer because all the patients in the study already had prostate cancer and, thus, his study did not address anything related to causation. F. 1055. Dr. Carducci similarly testified that the Carducci Study was never designed to prove, and did not prove, that POMx prevents or reduces the risk of prostate cancer. F. 1084.

Fourth, Complaint Counsel's experts state that the Pantuck Study on POM Juice cannot provide reliable evidence to support claims about POMx Pills' benefit for prostate cancer. F. 1094. According to Dr. Eastham: POM Juice is not identical to POMx Pills and POMx Liquid; POM Juice has more than one active ingredient; processing may result in eliminating a needed ingredient; and even if the active ingredient is known and the alternate compound contains the same amount of active ingredient, the alternate compound may contain some other as yet unknown compound that might counter-act the benefit of the active agent. F. 1094. However, Dr. Eastham is not an expert in bioavailability and did not review the equivalency studies or articles on POM Juice, POMx Pills or POMx Liquid. F. 1095.

Dr. Heber, the only expert who opined on the bioavailability of pomegranate polyphenols, explained that because both the 100% Juice and POMx contain ellagitannins that contribute to the antioxidant activity of the products (and because both are bioavailable (absorbed) in humans), there is no difference in the antioxidant effect between POM Juice and POMx products in laboratory studies. F. 953, 1119. Dr. Heber testified that in laboratory studies he conducted, he found no difference in the antioxidant effect between POM Juice and POMx products and that animal studies indicate that the effects of pomegranate juice and POMx Pills on prostate cancer are equivalent. F. 1119. Moreover, the Carducci Study obtained a result similar to the Pantuck Study regarding the effect of POMx on PSADT. *Compare* F. 1076 *with* F. 1045.

c. Conclusion

As discussed above, the expert testimony regarding the studies relied upon by Respondents is conflicting. The greater weight of the persuasive expert testimony demonstrates the following: The basic research, the Pantuck Study, and the Carducci Study, relied on by Respondents, support the conclusion that pomegranate juice has a beneficial effect on prostate health. F. 1142. Competent and reliable scientific evidence supports the conclusion that the consumption of pomegranate juice and pomegranate extract supports prostate health, including by prolonging PSA doubling time in men with rising PSA after primary treatment for prostate cancer. F. 1142. However, the greater weight of the persuasive expert testimony shows that the evidence relied upon by Respondents is not adequate to substantiate claims that the POM Products treat, prevent, or reduce the risk of

prostate cancer or that they are clinically proven to do so. F. 1143. Indeed, the authors of the Pantuck Study and the Carducci Study each testified that their study did not conclude that POM Juice treats, prevents, or reduces the risk of prostate cancer. F. 1055, 1056, 1084, 1085. And, as Respondents' expert conceded, no clinical studies, research and/or trials show definitively that the POM Products treat, prevent, or reduce the risk of prostate cancer. F. 1135-1138.

***229** Having fully considered and weighed all the evidence and the conflicting expert testimony on Respondents' basic research and clinical trials, the greater weight of the persuasive expert testimony demonstrates that there is insufficient competent and reliable scientific evidence to substantiate a claim that the POM Products treat, prevent, or reduce the risk of prostate cancer or that clinical studies, research, and/or trials prove that the POM Products treat, prevent, or reduce the risk of prostate cancer. F. 1143. Accordingly, Complaint Counsel has met its burden of proving that Respondents' substantiation was inadequate to make the implied prostate cancer claims found to have been made in this case, and that, therefore, such claims were false or misleading.

5. Substantiation for Respondents' erectile dysfunction claims

a. Overview

As discussed in Section III.E.2.e, *supra*, the evidence demonstrates that Respondents disseminated advertisements that impliedly represented that drinking eight ounces of POM Juice daily, or taking one POMx Pill daily, is clinically proven to treat, prevent or reduce the risk of erectile dysfunction. Complaint Counsel contends that (1) Respondents did not possess and rely upon a reasonable basis to substantiate their efficacy claims that the POM Products treat, prevent, or reduce the risk of erectile dysfunction; and (2) clinical studies, research, and/or trials do not prove Respondents' establishment claims that the POM Products treat, prevent, or reduce the risk of erectile dysfunction. CCB at 50-54. With respect to claims made about erectile dysfunction, although Respondents have been found to have made establishment claims only, by virtue of their very nature, the advertisements containing establishment claims also make the efficacy claims that are challenged as unsubstantiated in the Complaint. CCB at 31.

i. Summary of expert opinions

In support of its position, Complaint Counsel submitted the expert report and testimony of Dr. Arnold Melman, M.D., a Professor and Chairman of the Department of Urology at the Albert Einstein College/Montefiore Medical Center in New York. F. 208. Dr. Melman has extensive experience in designing and reviewing protocols for clinical trials. F. 209. Dr. Melman is an expert in the evaluation of whether a product treats, prevents, or reduces the risk of erectile dysfunction, and in the design and conduct of clinical trials involving erectile dysfunction. F. 211. Dr. Melman opined that to constitute a reasonable basis for the claims that the POM Products treat, prevent, or reduce the risk of erectile dysfunction, or have been clinically proven to do so, at least one well-designed, human RCT involving several investigatory sites is required. F. 654. Dr. Melman also opined that a well-designed, human RCT must use a validated tool for measuring treatment outcomes and that the clinical trial must have a total sample population large enough to produce clinically significant results and a statistical significance of $p < 0.05$. F. 655.

***230** Dr. Melman's opinions are attenuated for several reasons. Although Dr. Melman testified that the Global Assessment Questionnaire (“GAQ”) is not a validated measure for assessing erectile function, Dr. Melman had not heard of the term “GAQ” prior to forming his opinions in this case. F. 1196, 1233, 1234. Also, although Dr. Melman testified that Respondents are required to conduct RCTs before making erectile dysfunction claims about the POM Products, Dr. Melman has made claims about a gene transfer therapy for erectile dysfunction called “hMaxi-K,” which he patented and hoped to market, based on an animal study and one study of 11 men. F. 659,

660, 1237. In addition, Dr. Melman testified that a study to support a treatment for erectile dysfunction must show that a man can complete intercourse to orgasm. F. 659.

In support of their position that they possessed and relied upon a reasonable basis to substantiate their claims, Respondents submitted the expert reports and testimony of Dr. Arthur Burnett and Dr. Irwin Goldstein. Dr. Burnett is an expert in the area of erectile health, a Professor of Urology at the Johns Hopkins University School of Medicine/Johns Hopkins Hospital, and is well-known for his groundbreaking work on nitric oxide. F. 234, 238, 239. Dr. Burnett has treated between 10,000 and 15,000 patients for erectile dysfunction. F. 237. Dr. Burnett opined that Respondents' basic scientific and clinical evidence supports the conclusion that pomegranate juice's high antioxidant content improves erectile health and function by increasing the level and preservation of nitric oxide. F. 242. Dr. Burnett also concluded that a safe pure fruit juice, like pomegranate juice, which is not used as a substitute for proper medical treatment, does not require RCTs to substantiate erectile health claims. F. 683, 684.

Dr. Irwin Goldstein is an expert in sexual medicine who opined on the impact of pomegranate juice, antioxidants, and nitric oxide on erectile function and dysfunction. F. 243, 247. Dr. Goldstein is a board certified urologist and sexual medicine physician who has been involved in sexual medicine clinical practice, clinical research, and basic research since 1980. F. 243, 244. Dr. Goldstein testified that competent and reliable scientific evidence fully supports the conclusion that pomegranate juice produces a benefit to proper and effective erectile function. F. 249. Dr. Goldstein opined that RCT studies are not required to substantiate claims that pomegranate juice can aid in erectile health and that *in vitro* and animal studies demonstrated a likelihood that pomegranate juice improves erectile health. F. 686. Dr. Goldstein also opined that the consumption of pomegranate juice is a logical option for men who are not responsive to conventional drugs or who are unwilling to consider invasive or mechanical therapies for treatment of their erectile dysfunction. F. 1307, 1308.

ii. Standard for substantiation

Having fully considered and weighed the evidence adduced at trial, the evidence demonstrates that competent and reliable scientific evidence is required to support claims that the POM Products treat, prevent, or reduce the risk of erectile dysfunction or that they have been clinically proven to do so. *See* F. 1144-1148. Based on the greater weight of the persuasive evidence from the experts at trial, to support claims that the POM Products treat, prevent, or reduce the risk of erectile dysfunction, competent and reliable evidence must include clinical studies, although not necessarily RCTs, that show that the POM Products did treat, prevent, or reduce the risk of erectile dysfunction. *See id.* As analyzed below, Complaint Counsel has demonstrated that Respondents did not possess adequate competent and reliable scientific evidence to substantiate the implied claims that the POM Products treat, prevent, or reduce the risk of erectile dysfunction or that clinical tests show the same. Complaint Counsel has, therefore, met its burden of proving that Respondents' claims are false or misleading. *See QT*, 448 F. Supp. 2d at 959.

b. Scientific evidence relied upon

***231** The mechanism by which pomegranates promote erectile health and function is through potent antioxidant components and the impact on nitric oxide, which is of “paramount importance” to good erectile health and function and is the key molecule that governs penile erections. *See* F. 1165-1184. Detailed findings of fact on Respondents' six *in vitro* and *in vivo* studies and one human clinical study are set forth in Section II.I.3, *supra.* Respondents' studies demonstrate the potential benefits of pomegranate juice on erectile health and function. F. 1310, 1312. These studies do not, however, show that the POM Products treat, prevent, or reduce the risk of erectile dysfunction or show that clinical tests demonstrate that the POM Products treat, prevent, or reduce the risk of erectile dysfunction. F. 1313, 1314.

i. *In vitro* and *in vivo* studies

Dr. Louis Ignarro is highly respected and won a Nobel prize for his discoveries concerning nitric oxide ("NO"). F. 1292, 1297. He conducted an *in vitro* study to evaluate pomegranate juice's capacity to protect NO against oxidative destruction. F. 1292. Based on his findings, Dr. Ignarro concluded that pomegranate juice possesses potent antioxidant activity that results in marked protection of NO against oxidative destruction, thereby resulting in augmentation of the biological actions of NO. F. 1293, 1294. Other studies show similar results. *See* Section II.I.3, *supra.* For example, using an animal model, Dr. Kazem Azadzoi and colleagues found that, due to high antioxidant capacity, long-term pomegranate juice intake increased intracavernosal blood flow in the penis, improved erectile responses, improved smooth muscle relaxation, and decreased erectile tissue fibrosis. F. 1275-1279. In addition to these *in vitro* and *in vivo* studies, multiple other significant scientific studies exist that not only demonstrate the antioxidative powers of pomegranates in enhancing and preserving NO, but also support the general proposition that antioxidants positively influence erectile health. *See* Section II.I.3, *supra.*

Complaint Counsel's expert, Dr. Melman, opined that basic research studies about antioxidants' effects on NO levels may relate to the biochemical process for erectile function, but that basic research studies do not directly involve erectile function in humans and cannot alone prove that POM Juice treats, prevents, or reduces the risk of erectile dysfunction in humans. F. 1301. Respondents' experts reviewed the basic science relied upon Respondents and concluded: basic science alone supports the potential benefit at the human level to improve the physiology of erectile tissue preserving erect tissue health and, thus, suggests a probable benefit of pomegranate juice on erectile health. F. 1298-1300.

ii. Clinical trial

Respondents also sponsored a clinical study, performed by Dr. H. Padma-Nathan, and published in the *International Journal of Impotence Research* in 2007 ("Forest/Padma-Nathan Study). F. 1206. The Forest/Padma-Nathan Study was an RCT of pomegranate juice versus placebo in men with erectile dysfunction. F. 1210. The Forest/Padma-Nathan Study engaged 53 completed subjects with mild-to-moderate erectile dysfunction who underwent two four-week treatment periods separated by a two-week "washout." [20] F. 1211.

***232** Using a global assessment questionnaire ("GAQ"), Dr. Padma-Nathan found that participants rated pomegranate juice 50% more effective than a placebo at improving erections. F. 1212, 1224. The GAQ results achieved a probability value ("*p*-value") of 0.058, meaning that the positive results of the study were 94.2% likely to be the result of something other than "chance." F. 1225. Although the *p*-value was a few thousandths of a percentage point short of achieving statistical significance of 95%, the study has clinical significance in showing a benefit from pomegranate juice on erectile tissue physiology and health. F. 1248, 1250.

Dr. Melman, Complaint Counsel's expert, criticized the Forest/Padma Nathan Study on grounds that the GAQ is not a validated measure and does not provide clinically significant information; the study was not conducted over a sufficient duration to show a sustained clinically significant effect on erectile function; and the study results did not achieve statistical significance. F. 1233, 1235-1236. Respondents' experts reviewed the clinical evidence that Respondents relied upon and concluded that even though statistical significance was not reached, the Forest/Padma-Nathan Study "provides very valuable information" regarding erectile health and function and is "clinically significant" because "it supports the conclusion that the positive results in the basic science are borne out in human function." F. 1238, 1239, 1245. *See also* F. 1240-1245.

c. Conclusion

The greater weight of the persuasive expert testimony demonstrates the following: The basic research relied upon by Respondents and the Forest/Padma-Nathan Study support the conclusion that pomegranate juice has a beneficial effect on erectile tissue physiology, health, and function. F. 1310, 1312. The evidence relied upon by Respondents also supports the conclusion that pomegranate juice is a *potential* treatment for erectile dysfunction. F. 1147, 1243, 1252. The evidence relied upon by Respondents is not, however, adequate to substantiate a claim that clinical studies show that the POM Products treat, prevent, or reduce the risk of erectile dysfunction or that clinical studies show the same. F. 1253, 1313, 1314. Indeed, the authors of the Forest/Padma-Nathan Study each testified that the study did not conclude that POM Juice treats, prevents, or reduces the risk of erectile dysfunction. F. 1230.

Respondents' defense on this issue is that they did not make any claims that the POM Products treat, prevent, or reduce the risk of erectile dysfunction. As such, Respondents' experts did not provide expert opinion on whether Respondents' science was adequate to support a claim that the POM Products treat, prevent, or reduce the risk of erectile dysfunction. Rather, the expert report of Dr. Goldstein states: “The available body of scientific literature — including *in vitro, in vivo*, and preliminary clinical trials — strongly suggests that consuming pomegranate juice promotes erectile health.” F. 249. The expert report of Dr. Burnstein concludes that the basic scientific and clinical evidence is sufficient to support the use of pomegranate juice as a potential benefit for vascular blood flow and the vascular health of the penis. F. 242, 1184. Thus, Respondents have failed to provide expert opinion on the central issue of whether Respondents' science was adequate to support an implied claim that the POM Products treat, prevent, or reduce the risk of erectile dysfunction, or that they are clinically proven to do so. *See Daniel Chapter One*, 2009 FTC LEXIS 157, at *243 (Initial Decision).

***233** Based on the more persuasive expert testimony at trial, competent and reliable scientific evidence demonstrates that pomegranate juice in its various forms provides a positive benefit to erectile health and erectile function. F. 1312. However, as testified to by Respondents' expert, the use of pomegranate juice to promote erectile *health* is a separate and distinct concept from the use of this neutraceutical as a safe and effective treatment for the medical condition of erectile *dysfunction* such as with a PDE5 inhibitor. F. 249, 1311 (emphasis in original).

Having fully considered and weighed all the evidence and the conflicting expert testimony on Respondents' basic science and clinical trial, the greater weight of the persuasive expert testimony demonstrates that there is insufficient competent and reliable scientific evidence to substantiate claims that the POM Products treat, prevent, or reduce the risk of erectile dysfunction or that they are clinically proven to do so. F. 1313, 1314. Accordingly, Complaint Counsel has met its burden of proving that Respondents' substantiation was inadequate to make the implied erectile dysfunction claims found to have been made in this case, and that, therefore, such claims were false or misleading.

6. Summary

To summarize, in finding that Respondents' substantiation was not adequate, the facts that the POM Products are derived from a fruit, are safe, and are not advocated as an alternative to medicine were all considered. In addition, the cost and feasibility of conducting RCTs and the benefits of truthful claims were also considered. Ultimately, however, the determination as to what “amount of substantiation experts in the field would agree is reasonable” and “the level of proof sufficient to satisfy the relevant scientific community of the claim's truth” must, in accordance with applicable law, turn on the nature of the claims made by Respondents.

In this case, as found in Section III.E.2., *supra*, Respondents disseminated advertisements that impliedly represented that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, and/or erectile dysfunction, and/or that “clinical studies, research, and/or trials prove” that the POM Products treat, prevent, or reduce the risk of the same. As to these advertisements, whether or not Respondents' substantiation was adequate

to support general and highly qualified health claims is not the material issue. Having crossed the line from making general and highly qualified health claims to making implied disease claims, "the level of proof sufficient to satisfy the relevant scientific community of the claim's truth" and "the amount of substantiation experts in the field would agree is reasonable" were necessarily heightened. *QT*, 448 F. Supp. 2d at 962 (where defendants make a "medical, health-related claim," ... such a claim must be based on a heightened level of substantiation"). With respect to both the establishment and efficacy claims that Respondents have been found to have made, Respondents' substantiation failed to meet the level of substantiation required. Because Complaint Counsel met its burden of proving that Respondents' substantiation was inadequate, the advertisements compiled in the Appendix to this Initial Decision are false and misleading.

G. Whether Respondents' Claims are Material

1. Overview

***234** Having found that Respondents disseminated advertisements conveying the claims alleged in the Complaint and that those claims were false or misleading, the next step is to determine whether those claims are material to prospective consumers. *Kraft*, 970 F.2d at 314. "The basic question" on the issue of materiality "is whether the act or practice is likely to affect the consumer's conduct or decision with regard to a product or service. If so, the practice is material, and consumer injury is likely, because consumers are likely to have chosen differently but for the deception." *Deception Statement*, 1984 FTC LEXIS 71, at *171; *see also* Joint Stipulations of Law and Facts, Stipulations of Law ¶ 4 (stipulating that "[a] 'material' misrepresentation or practice is one which is likely to affect a consumer's choice of or conduct regarding a product"). In other words, information is material if it is "important to consumers." *Deception Statement*, 1984 FTC LEXIS 71, at *188.

Materiality is a test of the likely effect of the claim on the conduct of a consumer. *Novartis Corp.*, 127 F.T.C. at 691. "Materiality turns upon whether those consumers who have drawn the claim from the advertisement and been misled by it are also likely to have their conduct affected by the misrepresentation." *Id.* To be material, "a claim does not have to be the *only* factor or the *most* important factor likely to affect a consumer's purchase decision, it simply has to be *an* important factor." *Id.* at 683 (emphasis in original).

Complaint Counsel contends that the challenged claims are presumed to be material because, among other reasons, the claims are "health-related efficacy claims." CCB at 26-27. *See Daniel Chapter One*, 2009 FTC LEXIS 157, at *245 (Initial Decision). Moreover, Complaint Counsel asserts, there is evidence, including Respondents' own marketing surveys, demonstrating that the challenged claims are material. CCB at 28-29. Respondents contend that regardless of whether a presumption of materiality applies in this case, Respondents have rebutted the presumption, with survey evidence and expert opinion that the claims are not material to consumers' purchase decisions, and that Complaint Counsel has failed to adduce evidence that the challenged claims are, in fact, material. Therefore, Respondents argue, Complaint Counsel has failed to meet its burden of proof on materiality. RB at 82-92.

The presumption of materiality simply reflects the "general judgment that substantive claims in advertisements (in other words, claims other than "puffery" or window-dressing) would not have been made except to affect a consumer's choice of or conduct regarding a product. Thus, the very existence of the claim ordinarily is sufficient evidence for the Commission to conclude it is material. "However, respondent is always free to counter this evidence either with arguments pertaining to the content of the ad itself or with extrinsic evidence." *Thompson Medical*, 1984 FTC LEXIS 6, at *374 n.45.

***235** In *Novartis*, the Commission explained the operation of the presumption of materiality as follows:
Certain categories of information are presumptively material, including, but not limited to, express claims, claims significantly involving health or safety, and claims pertaining to the central characteristic of the product. *Deception*

Statement, 103 F.T.C. at 182. Similarly, the Commission will infer materiality where the record shows that respondent intended to make an implied claim.

Id. ...

"To establish a 'presumption' is to say that a finding of the predicate fact, here, any of the factors listed above, produces a required conclusion in the absence of explanation," here, materiality. *St. Mary's Honor Ctr. v. Hicks*, 509 U.S. 502, 506 (1993) (internal quotation marks omitted). In order to rebut the presumption, respondent must come forward with sufficient evidence to support a finding that the claim at issue is not material. Respondent can present evidence that tends to disprove the predicate fact from which the presumption springs (*e.g.*, that the claim did *not* involve a health issue) or evidence directly contradicting the initial presumption of materiality. This is not a high hurdle. Unless the rebuttal evidence is so strong that the fact finder could not reasonably find materiality, the fact finder next proceeds to weigh all of the evidence presented by the parties on the issue. *See id.* at 516 (noting that after the presumption drops out, "the inquiry ... turns from the few generalized factors that establish [the presumption] to the specific proofs and rebuttals ... the parties have introduced"). While the presumption itself is negated by sufficient rebuttal evidence, as previously noted, the predicate facts that gave rise to the presumption are not. These facts remain evidence from which materiality can be inferred. *See Boise Cascade*, 113 F.T.C. at 975 (1990). However, this evidence is simply part of the entire body of evidence considered. *See also*21 *Charles Alan Wright and Kenneth W. Graham, Jr., Federal Practice and Procedure: Evidence* §§ 5122 *et seq.* (1977 and 1998 Supp.) (discussing the history and application of presumptions).

Novartis, 127 F.T.C. at 686-87.

Applying the principles of *Novartis* to the evidence in this case, it is unnecessary to rely on any presumption because, as further discussed below, the preponderance of the evidence shows that the challenged claims are material. Even if a presumption arises, and even if Respondents' evidence sufficiently rebuts the presumption, a "weigh[ing] of all of the evidence presented by the parties on the issue" shows that the challenged claims would be important to consumers, and likely to affect consumers' conduct or decisions. *Novartis*, 127 F.T.C. at 686. Accordingly, because the evidence is sufficient to prove materiality in the instant case, irrespective of any legal presumption, logic dictates that this Initial Decision need not, and it does not, analyze the effect of a presumption of materiality in this case.

2. Evidence of materiality

***236** The evidence shows, and Respondents have failed to effectively rebut, the "predicate fact" that the advertising claims at issue involve health-related matters; specifically, efficacy for disease or dysfunction, and clinical proof of such efficacy. F. 580-583; *see Novartis*, 127 F.T.C. at 686-87. Common sense and experience readily support the conclusion that Respondents' claims in this regard would be important to consumers considering a purchase and likely affected consumers' decisions. Such a conclusion requires "no great leap." *Novartis*, 127 F.T.C. at 687.

Moreover, the evidence shows that advertising the results of studies related to heart disease, prostate cancer, and erectile dysfunction resulted in sales and that Respondents were aware of this fact. F. 1317, 1321, 1323-1324, 1326. *See Kraft*, 114 F.T.C. 40, 1991 FTC LEXIS 38, at *46 (finding that materiality was shown by evidence that the challenged advertisement copy led to increased sales). For example, in evaluating how copy-dense or "medically oriented" to make a planned POMx Pill advertisement, Diane Kuyoomjian, Senior Vice President of Marketing for POM from 2008 to 2009, reminded Mrs. Resnick in a January 2009 e-mail: "[y]ou'll recall that a previous ad test with less copy did not generate as many orders. That would suggest we keep the research info in the new ad, which would make it information dense as well." F. 1323. In addition, Ms. Leow, a creative director for Roll, stated

that scientific information in advertising and marketing material helps sell the products, because the scientific information provided the consumer with a "reason to believe." F. 1326. *See also* F. 1321. (September 2006 press article, stating "every time a new study [was] released touting" a health benefit of pomegranate juice, there was a "spike in sales. The study ... linking the consumption of pomegranate juice to a reduction in prostate cancer was especially helpful."). Further, Mr. Resnick testified that POM communicates to consumers the "[company's] belief that pomegranate juice is beneficial in treating some causes of impotence, for the purpose of promoting sales of its product," F. 1316, and he further acknowledged that the kinds of benefits revealed by POM's research results are the primary reason people buy pomegranate juice. F. 1317; *see also* F. 1319 (draft creative brief describing concept behind advertising dollars spent on research as, "We don't just say our product is great, we have clinical studies that prove its efficacy"). Mr. Resnick also acknowledged that consumers buy pomegranate juice "because they believe and in fact it does postpone the onset of prostate cancer, which postpones the onset of death." F. 1317-1318.

In addition, in the ordinary course of business, POM conducted consumer research to understand the characteristics, attitudes and usage habits of POM customers and to identify barriers and opportunities for increasing consumption, particularly in relation to other brands of pomegranate juice. F. 1330. These studies also support a conclusion that the challenged claims are material to consumers. *See Kraft*, 1991 FTC LEXIS 38, at *40 (relying on consumer survey evidence to finding of materiality). The 2009 OTX Attitudes and Usage Study ("OTX A&U Study") (F. 1331) found that, of the survey respondents that identified "health" as a reason for drinking pomegranate juice, 47% of the POM Juice drinkers chose the further response, "helps protect against prostate cancer." F. 1332-1335. Similarly, in August 2007, Respondents commissioned a Zoomerang online survey of the general public, "[t]o better understand pomegranate and non-pomegranate juice consumers," with respect to, among other things, "[i]mportance of certain health benefits." F. 1342. Six health benefits were listed and these survey respondents were asked to rank which was the most important to them personally. F. 1342. For heavy pomegranate juice drinkers, the number one response, for both males and females was "cardiovascular," and the number two choice for men was "prostate." F. 1342. For members of the general public responding to the Zoomerang question regarding ranking of health benefits, 60% ranked cardiovascular health as the first or second most important benefit, 40% of males ranked prostate health as the first or second most important benefit, and approximately 18% of males did so for erectile dysfunction. F. 1343. While Respondents' marketing expert, Dr. David Reibstein, criticized the methodology of using closed-ended questions, such as were used in the OTX A&U Study, because they can "cue" the survey respondent to certain answers and inflate results, F. 1340, closed-ended questions tend to be used when studying purchase motivations and have the advantage of allowing the researcher to obtain specificity in the responses. F. 1341. The materiality survey relied on in *Kraft* also made use of similar closed-ended questions. 1991 FTC LEXIS 38, at *40 (relying on survey asking respondents to rate the importance of a claim that cheese was "a source of calcium").

***237** Additional evidence of the materiality of Respondents' advertising claims is demonstrated by Respondents' "creative briefs," which served to direct the content of their advertising. F. 145-151. For example, a creative brief for the POM Wonderful website, from approximately June 2008, shows that the purpose of the "Health Benefits" section of the POM Wonderful website was to communicate the "heart health," "prostate health," and "E.D." "health benefits," including by explaining how such benefits are provided. F. 1325. Further, in order to engage website viewers, the "Health Benefits" section was to provide "expert" information on heart and prostate matters, as well as a database of studies and results, searchable by subject matter, including heart and prostate. F. 1325; *see also* F. 1327-1328 (creative briefs describing main creative focus for advertising assignments as "prostate cancer"). Respondents' arguments that creative briefs cannot be relied upon because they reflect the opinions of low level employees, is unsupported by the evidence, *see e.g.*, F. 154, 181, and is unpersuasive.

Finally, in over a decade, POM sponsored over 100 studies at 44 different institutions, and over $35 million has been invested in POM's research program. F. 128, 131. POM uses the results of studies it has sponsored

for marketing purposes, as part of POM's "unique selling proposition." F. 113. Considering these circumstances, particularly that POM was aware that among those purchasing the POM Products were "people that have heart disease or prostate cancer in their family, or have a fear of having it themselves," F. 1320, it defies credulity to suggest that Respondents would advertise study results related to these conditions if such advertising did not affect consumer behavior. In fact, Respondents' marketing expert, Dr. Reibstein, stated that it was indeed possible, and he would expect that, to consumers who were concerned about heart disease, prostate cancer, or erectile dysfunction, a claim that drinking a bottle of POM Juice a day was effective for these conditions would be important to their purchasing decisions. F. 1329.

3. Respondents' evidence of immateriality

Respondents rely on the results of the Reibstein Survey, which showed, among other things, that a very small number of survey respondents (12 out of 750), when asked to identify their reasons for purchasing, repurchasing, or recommending pomegranate juice, including POM Juice, identified a specific disease, and of those who did, fewer still mentioned "heart disease" or "cancer." F. 1344, 1351-1365. Based on these study results, Dr. Reibstein expressed the opinion that there is a very small percentage of people that bought, would buy again, or would recommend POM Juice to a friend because they believe that it cures or prevents a specific disease. F. 1372. The Reibstein Survey obtained these results by asking a series of open-ended questions, such as: "Why did you purchase POM Wonderful 100% Pomegranate Juice?" and asking survey respondents to provide "*specific details*." F. 1354. In this regard, the Reibstein Survey was flawed because it only assessed consumer motivations generally; it did not actually assess whether any of the challenged claims in the Complaint would be important to the survey respondent's decision to purchase the products. F. 1373. Moreover, the survey did not ask any follow-up questions, including of the 35.2% of POM Juice purchasers who stated that they bought or would repurchase POM Juice because it was "healthy." F. 1354, 1361, 1375. The failure to probe further as to what these survey respondents meant by "healthy" and whether there were specific reasons or benefits that underlay their "healthy" responses, constitutes methodological flaws that render the Reibstein Survey insufficiently probative to outweigh the substantial, probative evidence, summarized above, showing that disease claims are likely to be important to, and to influence, consumer decision making. *See Kraft*, 1991 FTC LEXIS 38, at *47 (rejecting materiality survey as insufficiently probative because limited response options offered to survey participants failed to adequately elicit all of the ways in which consumer conduct with respect to the product might be affected by the implied claims at issue). A more probative survey on materiality would have provided survey respondents with a statement about what the claim was, and inquired how important they think that claim would be to their potential purchase decision, F. 1374, as did the survey in *Kraft*, 1991 FTC LEXIS 38, at *40. Also affecting the relative weight of the Reibstein Survey is the fact that it was commissioned and designed for use in litigation, F. 1344, while the OTX A&U Study and the Zoomerang online survey were conducted in the ordinary course of business. F. 1330, 1331, 1342.

4. Conclusion

***238** The evidence of materiality in the record outweighs Respondents' evidence of immateriality and, therefore, Complaint Counsel has met its burden of proof on the third element of its deceptive advertising claim. Accordingly, because Complaint Counsel has met its burden as to all three elements of a deceptive advertising claim, liability has been established. The Initial Decision next addresses the appropriate remedy.

H. Remedy

1. General legal principles

Having concluded that Respondents violated the FTC Act, that Act authorizes an order requiring respondents to cease and desist from such acts or practices. 15 U.S.C. § 45(b); *FTC v. Nat'l Lead Co.*, 352 U.S. 419, 428 (1957). "As the Court has said many times before, the Commission may exercise only the powers granted it by the Act. The relevant sections empower the Commission to prevent the use of unfair methods of competition and authorize it, after finding an unfair method present, to enter an order requiring the offender 'to cease and desist' from using such unfair method." *Nat'l Lead Co.*, 352 U.S. at 428 (1957) (internal citation omitted).

The purpose of a cease and desist order is to prevent the violations from being repeated, including by "creating stringent monetary incentives (in the form of civil penalties) for its observance." *In re Litton Indus., Inc.*, No. 9123, 97 F.T.C. 1, 1981 FTC LEXIS 94, at *147 (Jan. 5, 1981); *accord Thompson Medical*, 1984 FTC LEXIS 6, at *405-06 (describing order as appropriate "to prohibit and prevent [the respondent] from engaging in deceptive acts or practices"). Thus, "'[t]he Commission is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past."' *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 395 (1965) (quoting *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952)). The FTC is permitted "to frame its order broadly enough to prevent respondents from engaging in similarly illegal practices in future advertisements." *Colgate-Palmolive Co.*, 380 U.S. at 395. "Having been caught violating the Act, respondents 'must expect some fencing in."' *Id.* (quoting *Nat'l Lead*, 352 U.S. at 431). The cease and desist order must be sufficiently clear so that it is comprehensible to the violator, and must be reasonably related to the violations found to exist. *Colgate-Palmolive*, 380 U.S. at 392, 395.

Applying the foregoing principles, and after consideration of all the arguments of the parties and the entire record of the case, the attached order, to be entered herewith (hereafter, "Order"), will serve to prohibit and prevent Respondents from engaging in deceptive advertising practices in the future, is reasonably related to the unlawful acts or practices found to exist, and is sufficiently clear and precise. The scope and terms of the Order are substantially the same as was entered by the Commission, and upheld on appeal to the United States Court of Appeals, to redress unsubstantiated disease claims in *Daniel Chapter One*, No. 9329, 2010 FTC LEXIS 11 (Jan. 25, 2010), *review denied*, *Daniel Chapter One v. FTC*, No. 10-1064, 2010 U.S. App. LEXIS 25496 (D.C. Cir. Dec. 10, 2010), *cert. denied*, 131 S. Ct. 2917 (2011).

2. Respondents' preliminary arguments

***239** Respondents argue on various grounds that no cease and desist order should issue in this case, despite violations having been found. These arguments are addressed below

a. Outliers

Respondents assert that no cease and desist order may issue in this case based on eight of the Challenged Advertisements, which Respondents assert should be considered "outliers." Respondents define these "outliers" as advertisements run in the 2003-2006 timeframe, and not thereafter, in which the images and the language regarding the health benefits of POM Juice were "more aggressive than was typical of Respondents." RB at 67-68. According to Respondents, no relief can be based upon these "outliers" because such advertisements have stopped and Complaint Counsel has failed to demonstrate that such conduct will be repeated. RB at 68-69, citing *FTC v. Evans Products Co.*, 775 F.2d 1084, 1087 (9th Cir. 1985) (stating that past wrongs are not enough for the grant of an injunction, and that an injunction will issue only if the wrongs are ongoing or likely to recur).

Respondents' argument is unconvincing. Of the eight asserted "outliers," only four are among the Challenged Advertisements found to have made the implied claims alleged in the Complaint: (1) CX0036 ("Cheat Death" print advertisement); (2) CX0016 ("Drink and be healthy" print advertisement); (3) CX0314 (magazine wrap advertisements); and (4) CX0034 ("Amaze your cardiologist" print advertisement). *See* F. 580-583. In addition, even if the exact same advertisements have not been repeated, this does not mean that Respondents' violations

will not be repeated, particularly in light of the fact that numerous advertisements disseminated after 2006 were found to have made implied disease claims, without adequate substantiation. F. 307-308, 321, 328, 344, 365, 432, 580-583, 962, 1143, 1313-1314. That the form of the advertisements communicating these implied claims may have changed is not persuasive evidence that Respondents' past wrongs are not likely to reoccur. Furthermore, even if the "outliers" were not considered violations for purposes of injunctive relief, there would be sufficient violations based upon other advertisements to justify injunctive relief in this case. *Bristol-Meyers*, 1983 FTC LEXIS 64, at *250-51 (finding adequate number of deceptive advertisements to support the order, even though the number was fewer than the number found by the ALJ); *In re Fedders Corp.*, No. 8932, 85 F.T.C. 38, 71-72 (Jan. 14, 1975) (holding that one or two advertisements can be sufficient number of violations to support order).

Accordingly, Respondents' "outlier" defense is rejected.

b. Liability of Roll

Complaint Counsel argues that both POM and Roll are liable for the violations in this case and should both be subject to a cease and desist order, based upon two alternative theories: the "common enterprise" theory, based on the interrelated nature of the two corporate Respondents; and the "active participant" theory, based on Roll's direct activities with regard to POM's advertising, including through Roll's internal advertising agency, allegedly with knowledge of the deceptive nature of the POM advertisements. CCB at 54-56. Respondents contend that no cease and desist order should issue against Roll. RRB at 169-171.

***240** It is well established that "[w]here one or more corporate entities operate in a common enterprise, each may be held liable for the deceptive acts and practices of the others." *FTC v. Bay Area Bus. Council, Inc.*, No. 02-C-5762, 2004 U.S. Dist. LEXIS 6192, at *33-34 (N.D. Ill. Apr. 8, 2004) (finding a common enterprise where the corporate defendants were owned by the same person, were operated by the same people, often shared offices, did business under each other's names, accessed the same customer databases, shared and transferred proceeds as needed, and were considered a collaborative effort by the owner), *aff'd*, 423 F.3d 627 (7th Cir 2005); *Telebrands Corp.*, 140 F.T.C. at 451 (Initial Decision) ("Corporate respondents acting in concert to further a common enterprise are each liable for the acts and practices of the others in furtherance of the enterprise."). To determine whether a common enterprise exists, courts will consider a variety of factors including: "common control; the sharing of office space and officers; whether business is transacted through a maze of interrelated companies; the commingling of corporate funds and failure to maintain separation of companies; unified advertising; and evidence that reveals that no real distinction exists between the corporate defendants." *Nat'l Urological Group*, 645 F. Supp. 2d at 1182. Courts look for vertical or horizontal commonality. *FTC v. Network Servs. Depot, Inc.*, 617 F.3d 1127, 1142-43 (9th Cir. 2010) (noting evidence showing that the companies pooled resources, staff, and funds; shared common owners and managers; and participated to some extent in a common venture).

Applying the foregoing principles, the evidence demonstrates that POM and Roll are a "common enterprise." F. 12, 19-21, 27-28, 1380, 1382, 1384, 1386-1390. Among other things, Respondents Stewart and Lynda Resnick are the sole owners of Roll and its affiliated companies, including POM Wonderful. F. 12. Mr. Resnick is Chairman and President, and Mrs. Resnick is a director and Vice Chairman of Roll. F. 19. Mr. Resnick is also Chairman and Chief Executive Officer of POM. F. 20-21. POM is headquartered in the same building as Roll, in many cases with employees of both companies occupying the same floor. F. 1380. Roll provides risk management, human resources, consulting, and travel services to POM without any reimbursement, and advertising and marketing services have been provided by Roll to POM without necessarily receiving reimbursement. F. 1385. In addition, for accounting purposes, Roll and its affiliated companies, including POM, were represented as being under common control or ownership and have been included together on consolidated financial and tax statements. F. 1387. Moreover, the Resnicks have had ultimate say over all business functions of both Roll and POM, including setting policy and supervising the senior executives of both companies, disregarding corporate formalities. F. 1386.

***241** Respondents fail to make any discernable argument that POM and Roll are not a common enterprise, focusing their argument instead on whether Roll was an "active participant" in POM's advertising and/or had actual or constructive knowledge of any deception. RRB at 169-171. Considering the facts clearly supporting liability of Roll based on the common enterprise theory, Roll is jointly liable with POM and will be held to the provisions of the attached Order. It is, therefore, unnecessary to determine whether or not Roll is also liable under the "active participant" theory. Thus, this Initial Decision need not, and does not, include any conclusions or analysis regarding that issue.

3. Liability of Individual Respondents

a. Applicable legal principles

"To obtain injunctive relief against an individual for a business entity's acts or practices, the FTC first must prove the entity violated § 5. *See* *Federal Trade Comm'n v. Think Achievement Corp.*, 144 F. Supp. 2d 993, 1009-11 (N.D. Ind. 2000), *aff'd*, 312 F.3d 259 (7th Cir. 2002). The FTC must further show the individual participated directly in the business entity's deceptive acts or practices, or had the authority to control them. *See* *Federal Trade Comm'n v. Publishing Clearing House, Inc.*, 104 F.3d 1168, 1170 (9th Cir. 1997)." *FTC v. Freecom Communs., Inc.*, 401 F.3d 1192, 1202-03 (10th Cir. 2005); *FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 573 (7th Cir. 1989). An individual's authority to control the corporation's deceptive acts may be "evidenced by active involvement in business affairs and the making of corporate policy, including assuming the duties of a corporate officer." *Amy Travel Serv.*, 875 F.2d at 573.

b. Stewart and Lynda Resnick

While Respondents assert generally that no liability should attach to any of the individual respondents, Respondents specifically address their argument only to the liability of Respondent Matthew Tupper, which is discussed below. Applying the well-established principles of individual liability, summarized above, the evidence amply supports the conclusion that both Respondents Lynda Resnick and Stewart Resnick actively participated in the acts and practices found to have violated the FTC Act and/or had the authority over them. The Resnicks are the sole owners of POM and Roll. F. 12. Mr. Resnick is the Chairman of both corporate entities, and the Chief Executive Officer of POM with overall responsibility and control over the business, including setting the budgets for marketing, advertising and medical research. F. 19-20, 22-23, 1393. He considers himself ultimately responsible for whether advertising should or should not go out, although he delegated day-to-day responsibility to Mr. Tupper. F. 25. In addition, Mr. Resnick has been involved at a high level with POM's advertising and marketing campaigns, including on occasion seeing headlines before advertisements were disseminated, when Mrs. Resnick has chosen to involve him, and has been intimately involved in POM's scientific research program. F. 23, 26, 1392-1395. The facts support Mr. Resnick being subject to a cease and desist order in this case.

***242** Mrs. Resnick is a director and Vice Chairman of Roll. F. 27-28. According to Mrs. Resnick, when it comes to marketing and creative issues, everyone has a "dotted line" to her. F. 35. Although Mrs. Resnick was not an officer of POM, Mrs. Resnick participated in POM's business on almost a daily basis in the company's early years, and on a weekly or biweekly basis thereafter and through 2010. F. 30. As of 2011, Mrs. Resnick was still the chief marketing person at POM. F. 31. Mrs. Resnick has had a principal role in approving advertising content since POM's inception. F. 143, 160-161, 166-168, 1399. For example, Mrs. Resnick requested that copies of all advertising campaigns be submitted to her for final approval including headlines used in POM's advertisements. F. 1399. Mrs. Resnick held regular creative meetings with the senior in-house representatives of POM and Roll, including representatives of POM's marketing department, Roll's public relations department and Roll's advertising agency, Fire Station, to review and approve advertising concepts. F. 33, 141-143. If there were disputes

or issues to resolve regarding advertising decisions, the final authority was either Mr. or Mrs. Resnick; however, as the overseer of all branding and marketing, Mrs. Resnick had the "final word" on advertising content and concepts. F. 1397, 1400. *See also* F. 33-34. Moreover, Mrs. Resnick was involved in several of the specific advertisements found herein to have violated the FTC Act. Mrs. Resnick was "very involved" in developing the POMx brochure, identified as CX1426, Exhibit I "Antioxidant Superpill" package insert, when it was first produced; Mrs. Resnick was involved in the approval of the print advertisement identified as CX0029 ("10 OUT OF 10 PEOPLE DON'T WANT TO DIE"); Mrs. Resnick approved the headline for the POMx print advertisement headlined "The Only Antioxidant Supplement Rated X"; and Mrs. Resnick approved the print advertisement identified as CX0031 ("Floss your arteries" print advertisement). F. 1401-1404. The evidence is more than sufficient for Mrs. Resnick to be subject to a cease and desist order.

As the Commission stated in *Telebrands Corp.*, "it is not only appropriate but sometimes preferable to make the principal of a corporation subject to fencing-in so that the individual cannot circumvent the order by establishing a new company with a different name." 140 F.T.C. 278, 344 n.62. Accordingly, based on the Resnicks' participation in and control over the acts and practices in this case, it is appropriate for them to be subject to a cease and desist order individually, along with the corporate Respondents. Indeed, as to Mr. and Mrs. Resnick, Respondents fail to articulate any factual or legal basis for a contrary result.

c. Matthew Tupper

i. "Control" as a mandatory prerequisite to finding individual liability of corporate officer

***243** Mr. Tupper has been an officer of POM since 2003, first with the title of Chief Operating Officer and then with the title of President. F. 37-38. Mr. Tupper acknowledges that he was involved in POM's operations, science research, and marketing. However, according to Mr. Tupper, none of these aspects of POM's business were under his ultimate control, but rather were under the ultimate control of Mr. and/or Mrs. Resnick. RTB at 2, 6-8. Mr. Tupper acknowledges, as he must, that the applicable test for individual liability is met by evidence of *either* participation in the deceptive practices at issue *or* authority to control them. RTB at 3-5. *See, e.g.*, *Freecom Communs.*, 401 F.3d at 1203;*Amy Travel Serv.*, 875 F.2d at 573. Mr. Tupper contends, however, that despite being stated in the alternative, "in practice," authority to control is the key factor for liability, not participation. RTB at 3. To the contrary, "[e]ither participation or control suffices." *QT*, 512 F.3d at 864. In *Direct Marketing Concepts*, a case upon which Mr. Tupper relies, the court reaffirmed the "either/or" nature of the individual liability test by rejecting the argument by the defendant co-owner of the corporation "that he did not edit the content of advertising." Relying on *Freecom Communications*, the court held it sufficient that the co-owner controlled the corporations, and, therefore, "could have nipped the offending infomercials in the bud ...." 624 F.3d at 13. Similarly, in *Freecom Communications*, upon which Mr. Tupper also relies, the court held that the lower court's "finding that [the individual defendant] never personally [made the misrepresentations at issue] is beside the point because the law did not require the FTC to make such a showing. To justify the imposition of injunctive relief against the individual, the FTC is required to show the individual participated directly in the business entity's deceptive acts or practices, or had the authority to control such acts or practices." 401 F.3d at 1204. [21]

Mr. Tupper further maintains that, despite the well-established rule that evidence of either participation or control can support imposing individual liability, he is "unaware of any case" in which individual liability of a corporate officer was based on participation alone, and cites cases in which the corporate officer was found liable based on evidence of *both* participation by the corporate officer *and* authority to control the corporation. RTB at 4-5. *E.g.*, *In re Universal Electronics Corp.*, No. 8815, 78 F.T.C 265, 1971 FTC LEXIS 55, at *65-66 (Jan. 28, 1971) (Initial Decision) (finding that evidence demonstrated that officer formulated, directed, and controlled the acts and practices of the corporate respondent; and that he was responsible for, familiar with, and personally participated in, the specific acts and practices at issue); *FTC v. Neovi, Inc.*, 598 F. Supp. 2d 1104, 1117 (S.D. Cal 2008) (stating

that "the Court agrees with the FTC that [the individual defendants] had the authority to control the corporate Defendants' unfair practices, [and] that they participated in those activities ...."); *FTC v. Transnet Wireless Corp.*, 506 F. Supp. 2d 1247, 1271-1272 (S.D. Fla. 2007) (concluding, based on evidence, that individual defendants had "authority to control the corporation" and directly participated in the practices at issue); *Amy Travel Serv.*, 875 F.2d at 574 (affirming individual liability of principal officers and shareholders where it was found they controlled the corporations and where it was also "clear that [the individual defendants] were the ones behind the vacation passport scheme," including writing telemarketing scripts); *FTC v. Publ'g Clearing House, Inc.*, 104 F.3d 1168, 1171 (9th Cir. 1997) (noting that individual defendant's activities as corporate officer "included obtaining and signing PCH's business license and signing the fund-raising agreement between PCH and [a fraudulent charity whose] application to conduct charitable solicitation identified [her] as the person in 'direct charge of conducting the solicitation"'). *See generally* cases cited at RTB 4-5. Mr. Tupper's cited cases do not support interpreting the rule that "[e]ither participation or control suffices," *QT, Inc.*, 512 F.3d at 864, to mean that only "authority to control" will suffice. Furthermore, consistent with the above-cited cases, individual liability is warranted in this case because, as further discussed below, Mr. Tupper both participated in the deceptive advertising practices at issue and had the authority to control POM's practices in this regard. *See also FTC v. Consumer Alliance, Inc.*, No. 02C2429, 2003 U.S. Dist. LEXIS 17423, at *20-22 (N.D. Ill. Sept. 29, 2003) (finding individual liability where the defendants reviewed, approved, and drafted telemarketing scripts used to deceive consumers and had authority to supervise and discipline employees).

ii. Mr. Tupper's participation in and control over the practices at issue in this case

***244** On the issue of participation, the evidence shows that Mr. Tupper's responsibilities within POM included implementing POM's direction with regard to health benefit advertising and the use of science in connection with the advertising. F. 51. With respect to this advertising, Mr. Tupper was the "connecting piece" between the marketing vision and the communication of the science. F. 51-52, 1409, 1411. Mr. Tupper participated in meetings in which Fire Station and POM personnel presented and reviewed advertising concepts and advertising. F. 156, 1419. Mr. Tupper has reviewed and given direction to POM's marketing staff on parts or elements of creative briefs. F. 1417. Mr. Tupper reviewed advertising copy (including headlines), made changes to copy, and, depending on the project, had final say over POM advertising content and which advertisements should or should not run. F. 160, 162, 1420. Mr. Tupper led meetings to review advertising copy from a scientific perspective prior to dissemination of the advertising. F. 1410, 1416. Sometimes, Mr. Tupper would provide the specific words to use when presenting medical research facts, and in other instances, POM Marketing or Fire Station employees would "take a stab at writing [this information] and send it to [Mr. Tupper] to approve." F. 1421. Mr. Tupper participated in drafting the *Time* magazine cover wraps found herein to have made the claims alleged in the Complaint. F. 306-310, 581, 1431. Mr. Tupper also reviewed press releases prior to issuance. F. 1430. In addition, as POM's President, Mr. Tupper attended most of the marketing meetings with Mrs. Resnick, which included discussions of POM's scientific research. F. 142, 144, 1412. In fact, Mr. Tupper had a significant degree of involvement in the research aspects of POM's business, and his responsibilities included discussing which research areas are appropriate for funding, participating in the internal decision-making as to what research to fund, and overseeing for POM the clinical trials on POM's products that were conducted by research institutions. F. 53, 1424-1429; *see also* F. 119 (finding and contacting scientific experts to conduct research). POM's former Senior Vice President of Marketing, Ms. Kuyoomjian, relied on her conversations with Mr. Tupper to understand content in POM's advertising regarding the relationship between POM advertisements and the scientific support for these advertisements. She also relied on Mr. Tupper to be the "arbiter" of whether people felt POM's advertising was accurate. F. 1414, 1418, 1421. Accordingly, Mr. Tupper's level of participation is more than adequate to support individual liability for POM's deceptive advertisements. *See Amy Travel Serv.*, 875 F.2d at 573 (affirming finding proof of participation based on individual defendants' writing telemarketing script used in deception); *Publ'g Clearing House*, 104 F.3d at 1171 (affirming lower court's finding of proof of participation based on individual defendant's signing a contract used in a fraudulent scheme); *Consumer Alliance*, 2003 U.S. Dist. LEXIS 17423,

at *20-22 (finding individual liability where the defendant reviewed, approved, and drafted telemarketing scripts used to deceive); *In re Griffin Sys., Inc.*, No. 9249, 117 F.T.C. 515, 1994 FTC LEXIS 76, at *25 (April 29, 1994) (finding participation based upon individual respondents' preparing solicitation materials that contained misrepresentations, including making changes in the content of those materials). [22]

***245** The evidence also demonstrates that Mr. Tupper had authority to control the practices of POM. Mr. Tupper was an officer of POM and, in his capacity as an officer, Mr. Tupper, together with others, formulated, directed, or controlled the policies, acts, or practices of POM. F. 37-38, 42. Mrs. Resnick considered Mr. Tupper her partner at POM since 2003 and relied on him to oversee POM's marketing when she reduced her day-to-day involvement beginning in 2007. F. 39, 1407. Mr. Resnick delegated the authority to decide which advertisements should run to Mr. Tupper. F. 1406. Mr. Tupper was responsible for managing the day-to-day affairs of POM, including management of the day-to-day operations of the POM marketing team. F. 25, 44. Mr. Tupper oversaw and administered POM's budget for all departments, and had authority to sign checks and contracts on behalf of the company. F. 45. Mr. Tupper had numerous POM employees reporting to him directly, including the vice presidents for marketing, corporate communications, clinical development, and operations. F. 47-50. Mr. Tupper had the authority to hire and fire POM employees, including the head of POM's marketing department, on his own, or, depending on the situation, in consultation with either Mr. or Mrs. Resnick. F. 46. Thus, the evidence is sufficient to show authority to control. *Benrus Watch Co. v. FTC*, 352 F.2d 313, 325 (8th Cir. 1965) (affirming individual liability against officers who "formulated, directed, and controlled" the policies and practices of the corporate respondents); *accord In re Universal Electronics Corporation*, 1971 FTC LEXIS 55, at *65-66 (Initial Decision); *FTC v. World Media Brokers*, 415 F.3d 758, 764-65 (7th Cir. 2005) (finding that individual defendants' assumption of duties of corporate officers, such as corporate signing authority, "establishe[d] a level of corporate involvement sufficient to demonstrate" authority to control); *FTC v. Bay Area Bus. Council, Inc.*, 423 F.3d 627, 636-38 (same); *Consumer Alliance*, 2003 U.S. Dist. LEXIS 17423, at *20-21 (finding liability where individual had authority to control based upon hiring, supervision, and disciplinary authority over employees). *Compare QT, Inc.*, 448 F. Supp. 2d at 973-74 (finding FTC failed to meet burden under test for individual liability where corporate secretary "did not participate directly in the deceptive acts and practices carried out by the corporate Defendants" or "possess 'a level of corporate involvement sufficient to demonstrate the requisite authority to control the corporate defendants.'" (citation omitted)).

Mr. Tupper's contention that he did not have "sole" or "ultimate" control of POM, RTB at 2, 7, even if true, is not determinative. A similar argument was made and rejected in *Griffin Systems, Inc.*, 1994 FTC LEXIS 76. In that case, the evidence showed that the corporate officer, Mr. Giordano, like Mr. Tupper in this case, administered the day-to-day affairs of the office, and, like Mr. Tupper, had duties including, among other things, hiring and supervising employees, and advising employees about the challenged solicitation materials. 1994 FTC LEXIS 76, at *4; *see* F. 25, 44, 46-50, 1414, 1418, 1421. The Commission found these facts sufficient to support individual liability, despite evidence showing that the officer shared his authority with the other individual respondents in that case. *Id.* at *23. The Commission explained:

***246** In support of their argument that it is inappropriate to hold Mr. Giordano individually liable for the actions of Griffin, the respondents emphasize that Mr. Giordano was not in sole control of Griffin. We are not aware of any authority indicating that sole control of a company is necessary to establish individual liability. Indeed, there have been a number of cases in which more than one individual has been held to formulate, direct, and control the practices of a single corporation.

Id. at *24. In the instant case, the evidence, summarized above, amply demonstrates that Mr. Tupper had sufficient authority, particularly with regard to the content of advertisements, to control the practices at issue. Moreover, Mr. Tupper does not cite to any evidence that he ever expressed concerns about, or objections to, the POM advertisements at issue to Mr. or Mrs. Resnick or that any such concerns or objections were overruled by either

of them. As in *Griffin Systems*, the evidence is clear that Mr. Tupper "was part of the inner circle that formulated, controlled, and directed" POM and "therefore it is appropriate to place him under order." *Id.*

iii. Breadth of cease and desist order

Mr. Tupper contends that it is unnecessary and unreasonable to bind him to a cease and desist order in addition to the other Respondents. He asserts that extending the proscriptions in the order to any food, drug, or dietary supplement would "potentially attach to any company he is associated with for the next twenty years" and, thereby, "effectively ensure that no company, with interests in foods, drugs or supplements would ever employ" Mr. Tupper. RTB at 9-10. This argument is unpersuasive. The Order binds Mr. Tupper personally, and his successors or assigns. Order, Definitions para. 2. The cease and desist Order does not, by its terms, bind Mr. Tupper's future employers. [23]

In addition, Mr. Tupper contends that the proposed order is unreasonable and overbroad as applied to him, based upon his asserted limited control over and participation in the challenged practices, when considering the seriousness of the conduct, the deliberateness of the conduct and its transferability to other products. RTB at 10-12; *see* *Telebrands*, 457 F.3d at 358. As noted above, Mr. Tupper's participation in and control over the deceptive practices at issue in this case is more than sufficient to justify a cease and desist order against him. The *Telebrands* factors are analyzed below in Section III.H.4.a.

4. Provisions of the Order

Having determined that a cease and desist order is required against POM, Roll, Mr. and Mrs. Resnick, and Mr. Tupper, this section of the Initial Decision addresses the specific provisions of the Order. The provisions of the Order are substantially the same as Complaint Counsel's proposed order, which is the Notice Order that was attached to the Complaint issued in this case (hereafter, "proposed order"), except that the Order does not include Complaint Counsel's proposed part I, as further explained in Section III.H.4.b.

a. Multi-product coverage (Order, Definitions para. 5)

***247** The FTC's authority includes power to issue orders "encompassing all products or all products in a broad category, based on violations involving only a single product or group of products." *ITT Continental Baking Co. v. FTC*, 532 F.2d 207, 223 (2d Cir. 1976).
Coverage of all products in a broad category is a means of "fencing-in" one who has violated the statute. Fencing-in provisions serve to "close all roads to the prohibited goal, so that (the FTC's) order may not be by-passed with impunity." *FTC v. Ruberoid Co.*, 343 U.S. 470, 473, 72 S. Ct. 800, 803, 96 L. Ed. 1081 (1952) (footnote omitted). Fencing-in provisions must bear a "reasonable relation to the unlawful practices found to exist." *FTC v. Colgate-Palmolive Co.*, 380 U.S. at 394-95, 85 S. Ct. at 1047-1048 (footnote omitted).

Litton Indus., Inc. v. FTC, 676 F.2d 364, 370 (9th Cir. 1982).

In determining whether a fencing-in order bears a "reasonable relationship" to a violation of the FTC Act, courts and the Commission consider: (1) the degree of transferability of the violation to other products; (2) the deliberateness and seriousness of the violation; and (3) any history of prior violations. *Telebrands*, 457 F.3d at 358;*Kraft*, 970 F.2d at 326. "The reasonable relationship analysis operates on a sliding scale -- any one factor's importance varies depending on the extent to which the others are found. In other words, the more serious a violation, the less important transferability and prior history become .... All three factors need not be present for a reasonable relationship to exist." *Telebrands Corp.*, 457 F.3d at 358-59 (citation omitted). "[T]he more egregious

the facts with respect to a particular element, the less important it is that another negative factor be present. In the final analysis, [courts] look to the circumstances as a whole and not to the presence or absence of any single factor." *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 392 (9th Cir. 1982); *see also Kraft*, 970 F.2d at 327.

Applying the foregoing principles to the facts of this case, and as discussed below, the Order's provisions will apply to the POM Products as well as to any other food, drug or dietary supplement products sold by POM and the other Roll entities. *See* Order, Definitions para. 5.

(i) Transferability

As the Commission stated in *Litton Industries*,
The rationale for entry of a multi-product order based upon violations in the advertising of only one or a few products is that many kinds of deceptive advertising are readily transferrable to a variety of products, and it would serve the public poorly to halt the use of a deceptive tactic in the advertising of one product if the respondent remained free to repeat the deceptive practice in another guise, with no threat of sanction save for another order to cease and desist. *FTC v. Colgate-Palmolive Co.*, 380 U.S. at 394-95 (1965).

***248** *Litton Indus., Inc.*, 1981 FTC LEXIS 94, at *147. Indeed, the "prevention of 'transfers' of unfair trade practices is a fundamental goal of the Commission's remedial work." *Sears, Roebuck*, 676 F.2d at 394. Where a violation has been demonstrated, "the Commission need not wait until a 'transfer' occurs" to other products. *Id.* at 395.

A violation is considered transferable when other products could be sold utilizing similar techniques. *Colgate-Palmolive*, 380 U.S. at 394-95;*Sears, Roebuck*, 676 F.2d at 392. For example, "misrepresenting that doctors prefer a product, or that tests prove the product's superiority, is a form of deception that could readily be employed for any non-prescription drug product." *American Home Prods. v. FTC*, 695 F.2d 681, 708 (3rd Cir. 1982). In the instant case, this transferability factor weighs strongly in favor of a multi-product order. As in *Daniel Chapter One*, Respondents' advertising techniques "could readily be employed" for any food, drug or dietary supplement. *Daniel Chapter One*, 2009 FTC LEXIS 157, at *284 (Initial Decision).

Respondents argue that the POM Products are only a small portion of the products Respondents sell. RRB at 204-205. Such assertion, even if true, is not material to whether the advertising claims made for the POM Products are nevertheless transferable to the other categories of products that are covered by the Order and that are sold by POM and/or the affiliated Roll entities, such as other pomegranate-based products (sold by POM); citrus fruits (sold by Paramount Citrus), nuts (sold by Paramount Farms); bottled water (sold by FIJI Water); and wine (sold by Justin Vineyards). F. 56, 1378. *Standard Oil v. FTC*, 577 F.2d 653 (9th Cir. 1978), upon which Respondents rely, is readily distinguishable because in that case, as the court stated, "[t]he over-breadth of the order results from its coverage of "any ... product in commerce" which is advertised by Standard ...." *Id. at* 661. In the instant case, the Order is limited to Respondents' advertising of food, drugs and dietary supplements. Order, Definitions para. 5.

Respondents further contend that their other products that do not involve pomegranates, such as citrus fruits, water, nuts and wine, are so "dramatically different" from the POM Products that Respondents would not use POM research to understand any components of such products. RRB at 205-206. Even if true, this contention is beside the point because the advertising technique, *i.e.*, sponsoring research of a product's health benefits and using the results to make disease claims, is readily transferable to advertising any food, drug or dietary supplement. In this regard, Respondents admit that they have sponsored "research exploring the health benefits of Wonderful Pistachios and Fiji Water" but assert that they have a "history" of "not advertising those benefits until the science is sufficiently developed." RRB at 207. This case demonstrates, however, that Respondents' judgment as to what

constitutes advertising "health benefits" as opposed to what constitutes advertising a scientifically proven effect for disease, has not always been exercised appropriately.

***249** Finally, Respondents assert that the deceptive claims found to have been made in this case are "peripheral" to their advertising strategy, and that their central advertising and marketing strategy has evolved away from health advertising and more toward "history" and "sexuality." RRB at 208. However, Respondents' asserted change of strategy does not make their past advertising themes and techniques any less transferable. As previously noted, such themes and the techniques used to communicate them are fully transferable — whether Respondents may opt to engage in other strategies in the future is not determinative.

Thus, the ease of transferability strongly supports the provisions in the Order making the Order applicable to any food, drug, or dietary supplement products.

(ii) Seriousness and deliberateness

The seriousness of the Respondents' conduct is evidenced by the fact that the deceptive advertising claims found to have been made in this case pertained to serious diseases and dysfunction of the body, including cancer. *See Daniel Chapter One*, 2009 FTC LEXIS 157, at *282 (Initial Decision); *see also Stouffer*, 1994 FTC LEXIS 196, at *39 (holding that deceptive low sodium health claim was serious because of overall health ramifications). The seriousness of Respondents' conduct is further demonstrated by the inability of consumers to evaluate whether Respondents' implied disease claims are true or actually supported by cited studies. *Id.*; *Thompson Medical*, 1984 FTC LEXIS 6, at *417. Thus, Respondents' claims concerning product effectiveness and clinical proof are "ones to which consumers were particularly susceptible." *Id.*; *see also Litton Indus. Inc.*, 1981 FTC LEXIS 94, at *150 (holding that use of survey results to support claim of product superiority has considerable potential to deceive, and, therefore, misuse of surveys in this regard is a serious violation). Respondents' assertion that consumers can access the identified studies themselves, RRB at 181, even if true, is not persuasive evidence that consumers can accurately assess the significance of the studies, much less in relation to Respondents' advertising claims.

The deliberateness of Respondents' conduct is also shown by the consistency of Respondents' advertising themes over the years, which supports a conclusion that the advertisements found herein to have violated the FTC Act did not constitute accident or an "isolated instance." *Thompson Medical*, 1984 FTC LEXIS 6 at *417. Respondents' contention that representations in certain advertisements were the result of mistake, RRB at 182; *see* RB at 67-68, even if assumed to be true, is insufficient to support a conclusion that Respondents' violations on the whole were accidental or inadvertent. Moreover, while it is arguable that the language used to make their advertising claims became less "aggressive" over the years, as Respondents contend, RB at 67-68; RRB at 182, there is little doubt that a central, and persistent, theme of Respondents' advertising was the POM Products' purported ability to affect diseases and dysfunction, and the scientific studies purportedly showing such effects. *See, e.g.*, Appendix to Initial Decision; F. 145-151. In addition, the advertising appeared in a wide variety of national and local media, for multiple years. F. 169-170, 291, 297, 307-308, 321, 328, 344, 365, 416, 421, 428, 432, 440, 449, 456, 469, 580-583. *See* *Sears, Roebuck*, 676 F.2d at 394 (in upholding multi-product order, noting that advertising campaign cost $8 million, ran for four years, and appeared in magazines, newspapers and on television throughout the country); *Daniel Chapter One*, 2009 FTC LEXIS 157, at *281 (Initial Decision) (noting that respondents made numerous deceptive representations over the Internet, in their publications, and through the DCO radio program, over the course of several years).

***250** Respondents contend that POM's internal procedures for evaluating its advertisements and science should also be considered. Specifically, Respondents point to testimony that since 2007, POM has implemented a more formalized vetting process for advertisements relating to the health benefits of its products, which requires multiple stages of review that ultimately culminate in approval by the legal department before any advertisement is run.

(Tupper, Tr. 2977-78). The evidence shows, however, that a number of the advertisements found to have violated the FTC Act were disseminated after 2007, when Respondents' review process was purportedly implemented. F. 307-308, 321, 365, 580-583, 962, 1143, 1313-1314. Therefore, it cannot be concluded, as Respondents urge, that their internal processes will ensure that only accurate information will be presented to the public in the future. [24]

(iii) Prior violations

There is no evidence of prior violations of the FTC Act by Respondents. However, as noted above, all of the three relevant elements need not be present to warrant a multi-product order. *Telebrands Corp.*, 457 F.3d at 358-59. Courts look to the circumstances as a whole "and not to the presence or absence of any single factor." *Sears, Roebuck*, 676 F.2d at 392. In *Telebrands*, the Court of Appeals upheld the Commission's conclusion that the strength of the evidence as to the first two factors sufficiently established that there was a reasonable relationship between the remedy and the violation, and it was not necessary to also consider any prior consent orders. *Telebrands Corp.*, 457 F.3d at 362. Thus, while here there is no history of violations in this case, that factor is less important, taking into account the strength of the other relevant factors, particularly the ease of transferability to other products.

b. Part I of the Order

Part I of the Order prohibits Respondents from making representations that any Covered Product, as defined in the Order, "is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including, but not limited to, any representation that the product will treat, prevent, or reduce the risk of" heart disease, prostate cancer, or erectile dysfunction, "unless, at the time it is made, the representation is non-misleading and, Respondents possessed and relied upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true." Order, Part I. "Competent and reliable scientific evidence" is defined in the Order to mean "tests, analyses, research, or studies, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." Definitions, para. 4. Commission orders requiring respondents to have competent and reliable scientific evidence, as defined in this Order, that is based on the expertise of professionals in the relevant area and that has been conducted and evaluated by persons qualified to do so, are typical and have been consistently upheld by the appellate courts. *E.g.*, *Daniel Chapter One*, 2010 FTC LEXIS 11, *review denied*, 2010 U.S. App. LEXIS 25496 (D.C. Cir. 2010); *Telebrands Corp.*, 140 F.T.C. at 347, *aff'd*, 457 F.3d 354 (4th Cir. 2006); *In re Kraft*, 1991 FTC LEXIS 38, at *59-60, *aff'd*, 970 F.2d 311 (7th Cir. 1992). Such a requirement in this case serves the purpose of preventing future violations, is reasonably related to the violations found to exist, is sufficiently clear and precise, and is amply supported by legal precedent and the facts of this case.

c. Part I of the proposed order (FDA pre-approval substantiation requirement)

(i) Overview

***251** Part I of the Order entered herewith differs from Part I of Complaint Counsel's proposed order. Part I of the proposed order would prohibit Respondents from making any representation that any POM Product "is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including, but not limited to, any representation that the product will treat, prevent, or reduce the risk of" heart disease, prostate cancer, or erectile dysfunction, unless, at the time it is made, the representation is non-misleading and:
A. the product is subject to a final over-the-counter ("OTC") drug monograph promulgated by the Food and Drug Administration ("FDA") for such use, and conforms to the conditions of such use;

B. the product remains covered by a tentative final OTC drug monograph for such use and adopts the conditions of such use;

C. the product is the subject of a new drug application for such use approved by FDA, and conforms to the conditions of such use; or

D. the representation is specifically permitted in labeling for such product by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990 [“NLEA”].

As Complaint Counsel explains, part I of the proposed order:
provides that the necessary substantiation for future claims that any POM Product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease — including heart disease, prostate cancer, or erectile dysfunction — is FDA approval, which may be provided in the form of a tentative final or final over-the-counter (“OTC”) drug monograph, a new drug application, or labeling approval under regulations promulgated pursuant to the Nutrition Labeling and Education Act of 1990 (“NLEA”). For example, a claim that POM Juice reduces the risk of heart disease would need to be supported by an FDA regulation authorizing such a claim in labeling.

CCB at 62-63. Complaint Counsel refers to these provisions as the “requirement of FDA preapproval.” CCB at 64-65. (hereafter, “FDA pre-approval requirement”).

Complaint Counsel further explains that, under the proposed order, if Respondents “make a *qualified* claim, one that characterizes the limited scientific evidence supporting a relationship between a POM product and reductions in disease risk in a careful manner that eliminates any misimpression that a POM product actually reduces risk,” then the substantiation they must possess is “competent and reliable scientific evidence,” as provided under part III of Complaint Counsel's proposed order. CCRB at 50-51 (emphasis in original). However, “[i]f Respondents make [an] *unqualified* disease claim” in the future that any POM Product “*is effective* in the diagnosis, cure, mitigation, treatment, or prevention of any disease,” then the “substantiation [Respondents] must possess for their claims would be FDA preapproval.” CCRB at 50 (emphasis in original). Thus, pursuant to part I of the proposed order, the FTC would determine (and ultimately have to prove at a contempt proceeding in court) whether Respondents made an “unqualified” disease claim, as opposed to a “qualified” “limited” and “careful” claim, and unless the FDA has already determined, applying FDA regulations, that Respondents' substantiation was adequate for that claim, then Respondents would be in violation of the FTC order. March 6, 2012 Tr. 67 (closing arguments).

***252** As more fully discussed below, Complaint Counsel argues that its proposed FDA pre-approval framework is a form of fencing-in that is reasonably related to the violations in this case, is clear and concise, and provides a necessary “bright-line” rule for future claims. *Id.* at 66-67; CCB at 62-65. Respondents oppose the FDA pre-approval requirement on a variety of grounds, including that the requirement is unlawful because it exceeds the authority granted the FTC under the FTC Act and would violate Respondents' First Amendment freedom to engage in commercial speech. RB at 98-99; RRB at 210-218. Complaint Counsel has failed to demonstrate that the proposed FDA pre-approval requirement is necessary or appropriate for this case, as further explained below.

No previous decision by the Commission or any court has required FDA pre-approval as the required level of substantiation, including for purposes of a cease and desist order. Most recently, in *Daniel Chapter One*, in which

the respondents were found to have made unsubstantiated disease claims in violation of Sections 5 and 12 of the FTC Act, the Commission entered an order prohibiting them from making such claims in the future "unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation." 2010 FTC LEXIS 11, at *3. This is also the standard adopted in the Order entered herewith. *See* Order Parts I and III. "Competent and reliable scientific evidence" was defined in the order entered in *Daniel Chapter One*, as in the instant Order, as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." 2010 FTC LEXIS 11, at *1.[25] *See* Order, Definitions para. 5. *Daniel Chapter One* is clear authority for entering an order in this case requiring competent and reliable scientific evidence to substantiate disease claims. Indeed, the competent and reliable scientific evidence standard was deemed sufficient to redress the conduct in *Daniel Chapter One*, which was arguably more egregious than that presented by the instant case. The implied claims in *Daniel Chapter One*, unlike the instant case, were found to have been "so strongly implied as to be virtually express." 2009 FTC LEXIS 157, at *53, 55 (Initial Decision). In addition, unlike the instant case, the respondents in *Daniel Chapter One* conducted *no* testing on the effects of the challenged products, much less clinical testing, and the scientific substantiation relied upon by those respondents consisted of nothing more than compilations of citations to literature, mostly non-peer-reviewed papers, on the use of herbal medicines for a number of different diseases. *Id.* at *237-39; *compare* F. 732, 756, 1010, 1185. Moreover, in *Daniel Chapter One*, unlike the instant case, the respondents urged their customers to forgo medical treatment and instead use their products to treat cancer as an alternative to pursuing established medical treatments. *Id.* at *282-83. Complaint Counsel's arguments in support of deviating from the order entered and upheld in *Daniel Chapter One* are addressed below.[26]

(ii) Complaint Counsel's "reasonably related" justification for FDA pre-approval requirement

***253** Complaint Counsel contends that requiring FDA pre-approval for disease claims is "reasonably related" to the violations in this case because (1) the FDA's standard for labeling approval for a food-disease relationship claim under NLEA ("significant scientific agreement" by experts that the claim is supported) is "cited" in the FTC *Enforcement Policy Statement on Food Advertising*; and (2) the FDA standard for drug approval under the Food, Drug and Cosmetic Act ("adequate and well-controlled" clinical investigations by experts demonstrating effectiveness), is "similar" to the "competent and reliable scientific evidence" standard applied in *Daniel Chapter One*, and referred to in the FTC publication, *Dietary Supplements: An Advertising Guide for Industry*. However, the foregoing FTC publications do not constitute regulatory law, which is made either by adjudication, 15 U.S.C. §45(b); 5 U.S.C. § 556, or by promulgated regulation, 15 U.S.C. §57b-3; 5 U.S.C. §553.[27] *See Ford Motor Co. v. FTC*, 673 F.2d 1008, 1009 (9th Cir. 1981) (noting that an administrative agency such as the FTC may announce principles through adjudication or rulemaking (citing *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974)). The standard for substantiation for disease claims that has been reflected in adjudication is the "competent and reliable scientific evidence" standard, based on the opinions of experts in the relevant fields, as applied in this case and as affirmed most recently in *Daniel Chapter One*.

Moreover, as explained in Section III.F.2 of this Initial Decision, applicable case law clearly establishes that the required level of substantiation is a question of fact, based upon evidence on numerous factors, including the nature of the product, the safety of the product, the overall context in which the transaction occurs, and what experts in the relevant field would consider sufficient to support the claim at issue. *E.g.*, *QT, Inc.*, 448 F. Supp. 2d at 959;*FTC v. Braswell*, 2005 U.S. Dist. LEXIS 42976, at *35; *Thompson Medical*, 1984 FTC LEXIS 6, at *387. In the instant case, after conducting the trial, and thoroughly reviewing the evidence and the voluminous transcript and record, it has been determined that the required level of substantiation for Respondents' implied disease claims is "competent and reliable scientific evidence," as defined by experts in the respective fields, and that such evidence does not require RCTs, such as those that would be required under FDA standards, because

such claims were made for a safe food product that was not being urged as a substitute for medical treatment or advice. *See* F. 693, 694-710, 963, 1147-1148. This Initial Decision has not determined that FDA standards are the required level of substantiation for the implied disease claims found to have been made in this case, nor have Respondents been held liable herein for failing to meet FDA standards. Rather, it has been determined that, applying the competent and reliable scientific evidence standard, as defined by the experts in the respective fields, Respondents' substantiation was inadequate to support the implied disease claims found to have been made in this case and, therefore, Respondents violated the FTC Act. To the extent that part I of the proposed order seeks to impose a different and/or higher level of substantiation for future implied disease claims, which it effectively would do, part I of the proposed order is not reasonably related to the violations found to exist. *See Daniel Chapter One*, 2009 FTC LEXIS 259, at *70 (stating that order's requirement that "Respondents possess and rely upon competent and reliable scientific evidence that substantiates" their claims "only obliged [them] to do that which the case law under Sections 5 and 12 of the FTC Act has defined as necessary to avoid deception"). [28]

***254** Similarly, Complaint Counsel asserts that it is proper to defer to FDA standards and evaluation of scientific evidence because such deference "is consistent with prior Commission practice." CCB at 63-64. Complaint Counsel cites *Thompson Medical*, in which the Commission noted that it was "additionally persuaded" that two well-controlled clinical tests was the correct level of substantiation for drug efficacy claims because "this is the standard currently being required ... by the FDA" and advertisers of drug products will benefit from "greater regulatory certainty." *Thompson Medical*, 104 F.T.C. at 826, 1984 FTC LEXIS 6, at *398. In the instant case, however, as noted above, the evidence failed to show that RCTs were required to substantiate Respondents' implied claims because, among other reasons, the POM Products are food, or food-derived products, and were not being urged as an alternative to medical care or advice. F. 693, 694-710, 963, 1147-1148. Thus, *Thompson Medical* does not support imposing the proposed FDA pre-approval requirement in the Order in this case. [29]

(iii) Complaint Counsel's "bright-line rule" justification for FDA pre-approval requirement

Complaint Counsel further argues that the FDA pre-approval requirement is justified because it is "clear and precise," as required under *Colgate-Palmolive*. According to Complaint Counsel, FDA pre-approval is a "bright-line rule" that will "significantly increase ... enforceability," "eliminate any confusion or ambiguities over the appropriate standard that Respondents must have to make disease claims" and prevent litigation. CCB at 64-65, 67. However, neither FDA pre-approval, nor FDA standards for obtaining such approval, constitutes the required level of substantiation under the FTC Act or applicable case law. Nor have FDA standards been found to constitute the required level of substantiation based on the evidence in the instant case. Thus, the "bright-line" proposed by Complaint Counsel would be imprudently drawn in this case. Moreover, "the complexity of the scientific issues, the unquestioned expertise of the FDA to evaluate scientific evidence relating to disease claims, and the Commission's interest in harmonizing with the FDA," CCB at 67, do not constitute sufficient reasons to create a new level of substantiation, through a cease and desist order against Respondents, *a fortiori*, considering the level of substantiation found to be required in this case. Indeed, the Second Circuit Court of Appeals has indicated that a "bright-line" of FDA approval for FTC cease and desist orders is "unnecessary, if not undesirable." *Bristol-Meyers Co. v. FTC*, 738 F.2d 554, 560 (2d Cir. 1984). In that case, the court rejected Bristol-Meyers' request to modify the FTC's cease and desist order to permit it to rely on demonstrating FDA approval of claims for its over-the-counter analgesics, stating: "FDA determinations are usually complex and subject to varying interpretations. To allow [respondents] to rely on its evaluation of these determinations could conceivably lead to more deceptive advertisements and to more disputes with the FTC." *Id.* The reasoning in *Bristol-Meyers* is equally applicable in the instant case, where Complaint Counsel seeks to replace the governing "competent and reliable scientific evidence" standard with FDA approval standards. [30]

***255** In addition, Complaint Counsel misconstrues the purpose of the requirement that FTC orders be "clear and precise." The Court in *Colgate-Palmolive* explained that "an order's prohibitions 'should be clear and precise in

order *that they may be understood by those against whom they are directed* ....”’ 380 U.S. at 392 (emphasis added) (citation omitted). This language does not indicate that the “clarity and precision” requirement is designed for the benefit of the FTC in litigating potential future enforcement actions. Moreover, some level of uncertainty is contemplated by the FTC Act, as noted by the Supreme Court in *Colgate-Palmolive*: “If, however, a situation arises in which respondents are sincerely unable to determine whether a proposed course of action would violate the present order, they can, by complying with the Commission's rules, oblige the Commission to give them definitive advice as to whether their proposed action, if pursued, would constitute compliance with the order.” 380 U.S. at 394;*Kraft*, 970 F.2d at 326 (citing the ability to seek an advisory opinion under 16 C.F.R. § 2.41(d) as a method of reducing advertiser uncertainty). [31] Moreover, whatever bright-line rule might be applied to substantiation will not necessarily reduce the risk of future litigation over whether Respondents made disease claims in the first place. As this case demonstrates, there is ample room for disagreement over whether or not advertisements make “unqualified” disease claims, as opposed to “qualified” “health benefit” claims, and the task of interpreting advertisements clearly does not lend itself to a bright-line rule.

In any event, Complaint Counsel cites no authority supporting a conclusion that the competent and reliable evidence standard, as provided in the Order upheld in *Daniel Chapter One*, is insufficiently clear or precise. In *Colgate-Palmolive*, the Supreme Court upheld the FTC order's requirement of a “test, experiment or demonstration” to substantiate future claims, and rejected the lower court's finding that such provision was invalid as too difficult to interpret. 380 U.S. at 393-94. The Court stated: “We believe that respondents will have no difficulty applying the Commission's order to the vast majority of their contemplated future commercials.” *Id.* at 394.*See also Bristol-Meyers Co.*, 738 F.2d at 560 (rejecting argument that order's requirement of “reasonable basis” substantiation “to consist of ‘competent and reliable scientific evidence”’ was unduly vague). Indeed, Complaint Counsel's proposed order expressly relies on the competent and reliable evidence standard, albeit for claims other than disease claims, pursuant to proposed part III, and this standard has been incorporated into the Order for all claims governed by the Order. For all the foregoing reasons, there is no basis for concluding that the competent and reliable evidence standard is insufficiently clear or precise for purposes of enforcement.

***256** Complaint Counsel further argues that a “bright-line” rule is necessary because, according to Complaint Counsel, Respondents have shown a willingness to “flout the law,” including, among other allegations, that Respondents failed to make any specific changes to their advertising in response to an FTC warning letter sent to Respondents in January 2008 and an FDA warning letter sent in January 2010. CCB at 65-66. The evidence upon which Complaint Counsel relies, even if true, indicates a disagreement between the Respondents and regulatory authorities regarding whether Respondents' advertising made disease claims and if so, whether those claims were adequately substantiated. *See id.* The disagreement with the FTC culminated in this litigation, in which neither side's position, as to the claims made or the adequacy of the substantiation, has been totally vindicated. Under these circumstances, Respondents' choice not to “heed warnings” and instead to litigate is not fairly interpreted as a willingness to “flout the law” but could be interpreted as an allowable choice made within the system as it exists.

(iv) Summary

Considering the entire record in this case, implementing Complaint Counsel's proposed FDA pre-approval requirement would constitute unnecessary overreaching. The competent and reliable evidence standard is established precedent, is reasonably related to the violations found to exist, and is sufficiently clear and precise to guide Respondents' future advertising practices. Precedent does not support implementing an FDA pre-approval requirement as a “bright-line” rule in this case. If Respondents choose to go “perilously close to an area of proscribed conduct,” then they will “take the risk that [they] may cross the line.” *Colgate-Palmolive*, 380 U.S. at 393. [32]

d. Part II of the Order

Part II of the Order, consistent with the proposed order, prohibits Respondents from misrepresenting "the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research." One of the violations alleged and proved in this case is that Respondents impliedly represented they had clinical proof of the effectiveness of the POM Products, when such clinical proof was not, in fact, adequate to substantiate this implied claim. Requiring Respondents to ensure that any advertised research results are fully accurate and non-misleading is reasonably related to this violation. In their Post-Hearing Briefs, Respondents do not articulate any argument for concluding that the provision is not reasonably related to the violations found in this case.

e. Part III of the Order

Part III of the Order, consistent with the proposed order, prohibits Respondents from making any representation about the "health benefits, performance, or efficacy of any Covered Product" unless the claim is not misleading, and supported by "competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true." This provision is reasonable and appropriate, and obliges Respondents only "to do that which the case law under Sections 5 and 12 of the FTC Act has defined as necessary to avoid deception." *Daniel Chapter One*, 2009 FTC LEXIS 259, at *70. Respondents, in their Post-Hearing Briefs, do not articulate any argument against applying this standard to future advertising claims within the scope of Part III.

f. Miscellaneous provisions

***257** Part IV of the Order, consistent with the proposed order, provides that nothing in the Order prohibits Respondents from making claims that are specifically permitted in labeling, pursuant to FDA standards and regulations. In contrast to Complaint Counsel's proposed and rejected FDA pre-approval requirement, which made FDA standards the minimum substantiation for disease claims, this provision properly gives Respondents a "safe harbor" against any future FTC challenge to Respondents' advertising representations, by enabling Respondents to demonstrate FDA approval. Substantially the same provisions were entered in the Order in *Daniel Chapter One*, 2010 FTC LEXIS 11, at *4-5 (Part IV) and are also appropriate in this case.

Parts V-IX of the Order, consistent with the proposed order, impose certain record-keeping, notification, and reporting requirements, and properly serve to facilitate administration of the Order. Finally, part X of the Order, consistent with the proposed order, provides for the termination of the Order in twenty (20) years. Respondents assert that a twenty-year period is "unconscionable" given that a portion of the advertising at issue occurred, and according to Respondents ceased, more than five years ago. However, as indicated in subsection 2.a., above, numerous advertisements disseminated after 2006 were found to have made implied disease claims, without adequate substantiation. F. 307-308, 321, 328, 344, 365, 432, 580-583, 962, 1143, 1313-1314. Accordingly, a twenty-year duration is not unconscionable for the reason asserted by Respondents. *See also Daniel Chapter One*, 2010 FTC LEXIS 11, at *9-10 (Part XI) (providing for termination of order in twenty years).

5. Conclusion

The Order entered herewith will serve to prevent Respondents from engaging in deceptive advertising practices in the future, is reasonably related to the unlawful acts or practices found to exist, and is sufficiently clear and precise.

IV. SUMMARY OF CONCLUSIONS OF LAW

1. Complaint Counsel bears the burden of proving jurisdiction and liability by a preponderance of evidence.

2. Respondents POM Wonderful ("POM") and Roll Global ("Roll") are corporations within the meaning of Sections 4 and 5 of the Federal Trade Commission Act ("FTC Act").

3. Respondents Stewart Resnick ("Mr. Resnick"), Lynda Resnick ("Mrs. Resnick") and Matthew Tupper ("Mr. Tupper"), are "persons" within the meaning of Section 5 of the FTC Act.

4. Respondents' sales of POM Wonderful 100% pomegranate juice ("POM Juice"), and pomegranate extract products known as POMx Pills and POMx Liquid ("POMx") (collectively, the "POM Products"), are in or affecting commerce, as required by the FTC Act, 15 U.S.C. § 45(a)(1).

***258** 5. The Commission has jurisdiction over Respondents, and the conduct challenged in the Complaint, under Sections 4 and 5 of the FTC Act. 15 U.S.C. § 44, 45.

6. Under the Commission's precedent regarding the statutory term "advertisement," the media appearances and interviews by Respondents, challenged in this case as advertisements, do not constitute "advertisements" within the scope of the FTC Act because they were not paid for or sponsored by Respondents. 15 U.S.C. § 45, 52. Respondents do not dispute that the remaining advertisements and promotional materials disseminated by Respondents and challenged in this case (the "Challenged Advertisements") constitute "advertisements" within the meaning of the FTC Act.

7. The POM Products constitute "food" or "drugs," under Section 12 of the FTC Act. 15 U.S.C. § 55.

8. An advertisement is deceptive under the FTC Act if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect. The determination of whether Respondents disseminated false advertisements in violation of the FTC Act requires a three-part inquiry: (1) whether Respondents disseminated advertisements conveying the claims alleged in the Complaint; (2) whether those claims were false or misleading; and (3) whether those claims are material to prospective consumers.

9. An advertisement is deemed to convey a claim if a significant minority of reasonable consumers would interpret the advertisement to contain that message. Whether an advertisement conveys a claim is a question of fact.

10. To determine whether an advertisement conveys an alleged claim, the first step is to examine the advertisement itself (a "facial analysis"). A proper facial analysis requires an evaluation of such factors as the entire document, the juxtaposition of various phrases in the document, the nature of the claim, and the nature of the transaction.

11. If, after viewing the advertisement as a whole, examining the interaction of all the different elements in the advertisement, it can be concluded with confidence that an advertisement can reasonably be read to contain a particular claim, a facial analysis is sufficient basis to conclude that the advertisement conveys the claim. However, an implied claim must be reasonably clear or conspicuous from the face of the advertisement.

12. If, after a facial analysis, it cannot be concluded with confidence that a particular advertisement can reasonably be read to contain a particular implied message, the advertisement will not be deemed to have made the alleged claim unless extrinsic evidence allows the conclusion that such a reading of the advertisement is reasonable.

***259** 13. "Target audiences," for purposes of interpreting advertising, refer to special audiences who as a group have a greater or lesser capability to recognize deceptive advertising than ordinary members of the adult population or have a distinctive reaction to particular advertising claims. Complaint Counsel has failed to prove that its asserted "target audience" of educated, affluent, health-conscious consumers would be more likely to interpret,

or in fact did interpret, the Challenged Advertisements differently than ordinary consumers, or in what manner that group would do so.

14. The evidence demonstrates that Respondents disseminated advertisements that a significant minority of reasonable consumers would interpret to contain an implied claim that drinking eight ounces of POM Juice daily, taking one POMx Pill daily, and/or taking one teaspoon of POMx Liquid daily, treats, prevents, or reduces the risk of heart disease, prostate cancer and/or erectile dysfunction, and/or is clinically proven to do so, as alleged in the Complaint. It is not necessary to demonstrate that every Challenged Advertisement conveyed one or more of the alleged claims. Accordingly, even though the evidence failed to demonstrate that all of the Challenged Advertisements made the alleged claims, Complaint Counsel met its burden of proving the first element of a false advertising claim.

15. Two theories have been used to prove that an advertisement is deceptive or misleading: (1) the "falsity" theory or (2) the "reasonable basis" theory. As to both the alleged "false establishment claims" and the alleged "unsubstantiated efficacy claims," proof of deception requires proof that Respondents' substantiation failed to meet the level of substantiation required. Because whether Respondents' claims were deceptive turns on the nature and quality of Respondents' substantiation, the falsity and reasonable basis theories collapse into the same inquiry: did Respondents possess adequate substantiation to support their claims?

16. To determine whether the challenged claims are false or misleading, it must first be determined what level of substantiation Respondents were required to have for their advertising claims. This determination is a question of fact to be determined based upon the evidence adduced at trial. Next, it must be determined whether Respondents possessed that level of substantiation. Respondents have the burden of establishing what substantiation they relied on for their product claims. Complaint Counsel has the burden of proving that Respondents' purported substantiation is inadequate.

17. Neither the FTC Act nor applicable case law requires well-designed, well-conducted, randomized, double-blind, placebo-controlled human clinical trials ("RCTs") to substantiate all health-related efficacy claims.

18. The evidence shows that the appropriate level of substantiation for the implied claims in this case that a product can treat, prevent, or reduce the risk of a disease is competent and reliable scientific evidence. Where such claims are made in connection with a food, or food-derived product, that is safe, and that is not being offered as a substitute for medical treatment, well-designed, well-conducted, randomized, double-blind, placebo-controlled human clinical trials, such as those required by the Food and Drug Administration are not required. However, for claims that a food or food-derived product treats, prevents, or reduces the risk of a disease, experts in the field would agree that competent and reliable scientific evidence must include clinical studies, although not necessarily double-blind, randomized, placebo-controlled clinical trials, adequate to show that the product did treat, prevent, or reduce the risk of disease.

***260** 19. The weight of the persuasive expert testimony demonstrates that there was insufficient competent and reliable scientific evidence to support the implied claims, made in advertisements disseminated by Respondents, that the POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, or erectile dysfunction, or are clinically proven to do so. Therefore, such claims were false or misleading within the meaning of Section 12 of the FTC Act, and Complaint Counsel met its burden of proving the second element of a false advertising claim.

20. An act or practice is material if it is likely to affect the consumer's conduct or decision with regard to a product or service. Information is material if it is important to consumers.

21. To be material, a claim does not have to be the only factor or the most important factor likely to affect a consumer's purchase decision; it need only be an important factor.

22. The implied claims found to have been made in this case are material because they are health-related and resulted in increased product sales for Respondents. In addition, consumer research of the attitudes and usage habits of POM customers, conducted in the ordinary course of POM's business, shows that such claims are material to consumers. Accordingly, Complaint Counsel has met its burden of proving the third element of a false advertising claim.

23. Because Complaint Counsel has met its burden as to all three elements of a false advertising claim (see Conclusion No. 8, above), liability has been established.

24. Having concluded that Respondents violated the FTC Act, that Act authorizes an order requiring Respondents to cease and desist from such acts or practices.

25. Where one or more corporate entities operate in a common enterprise, each may be held liable for the deceptive acts and practices of the others. POM and Roll are liable as a “common enterprise” and, accordingly, both are held liable herein.

26. Injunctive relief may be obtained against an individual for a business entity's deceptive acts or practices if the individual either participated directly in the business entity's deceptive acts or practices, or had the authority to control them. The evidence demonstrates that Mr. Resnick, Mrs. Resnick, and Mr. Tupper each participated directly in the business entity's deceptive acts or practices, and/or had the authority to control them, and, therefore, each individual is held liable herein, along with POM and Roll.

27. Sole or ultimate control of a company is not necessary to establish individual liability. To establish liability on the basis of authority to control, it is sufficient that Mr. Tupper was part of the inner circle that formulated, controlled, and directed POM.

28. The purpose of a cease and desist order is to prohibit and prevent liable parties from engaging in deceptive acts or practices in the future. The cease and desist order must be sufficiently clear that it is comprehensible to the violator, and must be reasonably related to the violations found to exist.

***261** 29. The Commission's authority includes power to issue cease and desist orders encompassing all products or all products in a broad category, based on violations involving only a single product or group of products. Coverage of all products in a broad category is a means of “fencing-in” one who has violated the statute.

30. In determining whether a fencing-in order bears a “reasonable relationship” to a violation of the FTC Act, courts and the Commission consider: (1) the deliberateness and seriousness of the violation; (2) the degree of transferability of the violation to other products; and (3) any history of prior violations. All three factors need not be present for a reasonable relationship to exist. The more egregious the facts with respect to a particular factor, the less important it is that another negative factor be present.

31. A violation of the FTC Act is considered transferable where other products could be sold utilizing similar techniques. In the instant case, this transferability factor weighs strongly in favor of a multi-product order covering any food, drug or dietary supplement, not just the POM Products. Respondents' advertising techniques could readily be employed for any food, drug or dietary supplement.

32. The seriousness of Respondents' violations is shown by the fact that the claims pertained to serious diseases and dysfunction of the body, including cancer, and the inability of consumers to evaluate whether Respondents' implied disease claims were true or actually supported by cited studies. The deliberateness of Respondents' conduct is shown by the consistency of Respondents' advertising themes over the years and by the fact that Respondents' advertising appeared in a wide variety of national and local media, for multiple years, which facts support the conclusion that the advertisements found herein to have violated the FTC Act did not constitute accident or an "isolated instance."

33. Although Respondents have no prior violations, the strength of the other relevant fencing-in factors, particularly transferability, is sufficient to establish a reasonable relation between the multi-product remedy and Respondents' violations found in this case.

34. The provision in the Notice Order prohibiting Respondents from making any disease claims in the future, unless such claim has been first approved by the Food and Drug Administration ("FDA") (the "FDA pre-approval requirement") is rejected as unsupported by governing precedent and the facts of this case, and is not reasonably related to the violations of the FTC Act found herein.

35. No previous decision by the Commission or any court has required FDA pre-approval as the required level of substantiation for disease claims, including for purposes of a cease and desist order.

36. The required level of substantiation is a question of fact, and the evidence in this case demonstrates that Respondents' implied disease claims require "competent and reliable scientific evidence," which does not necessarily require well-designed, well-conducted, randomized, double-blind, placebo-controlled human clinical trials, such as those required by the FDA.

***262** 37. The requirement in the order that respondents possess "competent and reliable scientific evidence" was deemed sufficient to redress unsubstantiated disease claims in *Daniel Chapter One*, No. 9329, 2010 FTC LEXIS 11 (Jan. 25, 2010), *review denied, Daniel Chapter One v. FTC*, No. 10-1064, 2010 U.S. App. LEXIS 25496 (D.C. Cir. Dec. 10, 2010), in which the violations were arguably more egregious than in the instant case.

38. The requirement in the Order in this case that Respondents possess competent and reliable evidence, as defined in the Order, to substantiate their claims is consistent with established precedent, is reasonably related to the violations found to exist in this case, is sufficiently clear and precise to guide Respondents' future advertising practices, and is adequate to prohibit and prevent Respondents from engaging in the same or similar violations in the future.

39. The Order attached herewith will serve to prohibit and prevent Respondents from engaging in deceptive advertising practices in the future, is reasonably related to the unlawful acts or practices found to exist, and is sufficiently clear and precise.

ORDER

DEFINITIONS

For purposes of this Order, the following definitions shall apply:
1. Unless otherwise specified, "individual respondents" shall mean Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper, individually and as officers of POM Wonderful LLC ("POM Wonderful") and Roll Global ("Roll").

2. Unless otherwise specified, "Respondents" shall mean POM Wonderful and Roll, their officers, agents, successors and assigns; and the individual respondents and each of their successors, assigns, agents, and representatives.

3. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

4. "Competent and reliable scientific evidence" shall mean tests, analyses, research, or studies, conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

5. "Covered Product" shall mean any food, drug, or dietary supplement, including, but not limited to, the POM Products.

6. "Food" and "drug" shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.

7. "Endorsement" shall mean as defined in 16 C.F.R. § 255.0.

8. "POM Product" shall mean any food, drug, or dietary supplement containing pomegranate or its components, including, but not limited to, POM Wonderful 100% Pomegranate Juice and pomegranate juice blends, POMx Pills, POMx Liquid, POMx Tea, POMx Iced Coffee, POMx Bars, and POMx Shots.

***263** 9. The term "including" in this Order shall mean "without limitation."

10. The terms "and" and "or" in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

IT IS ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make any representation in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, that such product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including, but not limited to, any representation that the product will treat, prevent, or reduce the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, or improving blood flow to the heart; treat, prevent, or reduce the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time ("PSADT"); or treat, prevent, or reduce the risk of erectile dysfunction; unless, at the time it is made, the representation is non-misleading and, Respondents possessed and relied upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

II.

IT IS FURTHER ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not misrepresent,

in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, trademark, or trade name, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

III.

IT IS FURTHER ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, about the health benefits, performance, or efficacy of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, Respondents rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

IV.

***264 IT IS FURTHER ORDERED** that:

A. Nothing in this Order shall prohibit Respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990; and

B. Nothing in this Order shall prohibit Respondents from making any representation for any drug that is permitted in the labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

V.

IT IS FURTHER ORDERED that POM Wonderful, Roll, and their successors and assigns, and individual respondents shall, for five (5) years after the last date of dissemination of any representation covered by this Order, maintain and upon request make available to the Commission for inspection and copying:

A. All advertisements, labeling, packaging, and promotional materials containing the representation;

B. All materials that were relied upon in disseminating the representation;

C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations; and

D. All acknowledgments of receipt of this Order, obtained pursuant to Part VI.

VI.

IT IS FURTHER ORDERED that POM Wonderful, Roll, and their successors and assigns, and individual respondents shall deliver a copy of this Order to all of their current and future principals, officers, directors,

and managers, and to all of their current and future employees, agents, and representatives having managerial responsibilities with respect to the subject matter of this Order, and shall secure from each such person a signed and dated statement acknowledging receipt of the Order. POM Wonderful, Roll, and their successors and assigns, and individual respondents shall deliver this Order to such current personnel within thirty (30) days after the effective date of this Order, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that POM Wonderful, Roll, and their successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporations or any business entity that POM Wonderful, Roll, and their successors and assigns, and individual respondents directly or indirectly control, or have an ownership interest in, that may affect compliance obligations arising under this Order, including but not limited to formation of a new business entity; a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor entity; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order; the proposed filing of a bankruptcy petition; or a change in the business or corporate name or address. Provided, however, that, with respect to any proposed change about which POM Wonderful, Roll, and their successors and assigns, and individual respondents learn less than thirty (30) days prior to the date such action is to take place, POM Wonderful, Roll, and their successors and assigns, and individual respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line *FTC v. POM Wonderful*. Provided, however, that, in lieu of overnight courier, notices may be sent by first-class mail, but only if electronic versions of such notices are contemporaneously sent to the Commission at DEbrief@ftc.gov.

VIII.

***265 IT IS FURTHER ORDERED** that each individual respondent, for a period of ten (10) years after the date of issuance of this Order, shall notify the Commission of the discontinuance of any current business or employment, or of an affiliation with any new business or employment. The notice shall include the individual respondent's new business address and telephone number and a description of the nature of the business or employment and all duties and responsibilities. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line *FTC v. POM Wonderful*. Provided, however, that, in lieu of overnight courier, notices may be sent by first-class mail, but only if electronic versions of such notices are contemporaneously sent to the Commission at DEbrief@ftc.gov.

IX.

IT IS FURTHER ORDERED that POM Wonderful, Roll, and their successors and assigns, and individual respondents within sixty (60) days after the effective date of this Order, shall each file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of their compliance with this Order. In addition, within ten (10) days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports.

X.

This Order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the Order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

A. Any Part in this Order that terminates in less than twenty (20) years;

B. This Order's application to any proposed respondent that is not named as a defendant in such complaint; and

C. This Order, if such complaint is filed after the Order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that Respondents did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Part as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

ORDERED:

D. Michael Chappell
Chief Administrative Law Judge

Date: May 17, 2012

APPENDIX TO INITIAL DECISION

FTC DOCKET 9344

TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

FTC

Footnotes

1 Although Commission Rule 3.41(b)(6) states that "[e]ach side shall be permitted to make a closing argument no later than 5 days after the last filed proposed findings," by Order dated January 26, 2012, good cause was found for moving the closing arguments to March 6, 2012.

2 References to the record are abbreviated as follows:
CX — Complaint Counsel's Exhibit
PX — Respondents' Exhibit
JX — Joint Exhibit
Tr. — Transcript of testimony before the Administrative Law Judge
Dep. — Transcript of Deposition
CCB — Complaint Counsel's Post-Trial Brief
CCRB — Complaint Counsel's Post-Trial Reply Brief
CCFF — Complaint Counsel's Proposed Findings of Fact
CCRRFF — Complaint Counsel's Reply to Respondent's Proposed Findings of Fact
RB — Respondents' Post-Trial Brief
RRB — Respondents' Reply Brief

RTB — Respondent Matthew Tupper's Post-Trial Brief
CCRRTB — Complaint Counsel's Reply to Respondent Matthew Tupper's Reply Brief
RFF — Respondents' Proposed Findings of Fact
RRCCFF — Respondents' Reply to Complaint Counsel's Proposed Findings of Fact

3 The following is an image of a caduceus symbol:

TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

4 As explained in Section III.C, *infra*, the four television interviews that Complaint Counsel challenges as "advertisements" (*see* Complaint ¶ 9, I-J; CCB Appendix A) are not actionable as "advertisements" under the FTC Act. *See* Section III.C.1. Thus, the interviews are hereinafter not included in the term, "Challenged Advertisements," and this Initial Decision does not include any findings regarding any claims allegedly made in those interviews.

5 Respondents also assert that an April 2009 discussion by Mrs. Resnick at USC's Annenberg School of Communication with Dean Ernest J. Wilson III, on "How to Uncover the Hidden Gems in Your Business," (CX0472 at 0002), does not constitute "advertising." RB at 92-95. Complaint Counsel responds that it does not challenge CX0472 at 0002 as deceptive under the FTC Act. CCRB at 43, n.41; CCRRFF ¶ 2546. Accordingly, an analysis of that exhibit is not undertaken. Except as described in this section, Respondents do not dispute that the other advertisements and promotional materials challenged in this case are "advertisements" for purposes of Sections 5 and 12 of the FTC Act.

6 In a case it brought against a telemarketer, the FTC, as prosecutor, acknowledged the distinction between "an independent television program," and an infomercial, which was a "paid advertisement." *FTC v. Direct Marketing Concepts, Inc.*, 569 F. Supp. 2d 285, 304-05 (D. Mass. 2008).

7 Complaint Counsel's assertion that advertisements were distributed in the reception area of urologists' offices is not supported by the evidence cited by Complaint Counsel. *See* CCFF 226.

8 The nature of the POM Products as food, or food-derived, is relevant to, and is considered in connection with, the substantiation analysis in Section III.F.2, *infra*.

9 Respondents' contention that the evidence fails to show the date that certain advertisements were disseminated is moot, to the extent that, with one exception, such advertisements are not among those found to have made the challenged claims. *See* RFF 2252. As to that exception, CX0314, the evidence shows that this advertisement was disseminated in 2008. F. 307. Respondents' further contention that some advertisements found herein to have made the challenged claims are "outliers" that cannot support an injunctive order is addressed in Section III.H, *infra*, with respect to remedy. Finally, Respondents assert that certain advertisements should be eliminated from consideration because of an alleged admission by Complaint Counsel's rebuttal expert on marketing and market research, Dr. Michael Mazis, (F. 279-283) that such advertisements were not being challenged. Having fully reviewed the testimony and Dr. Mazis' report in this regard, that assertion is rejected as unsupported by the evidence.

10 The Aviram ACE/BP Study, conducted by Dr. Michael Aviram and his co-workers, was published as "*Pomegranate juice consumption inhibits serum angiotensin converting enzyme activity and reduces systolic blood pressure*," 158 Atherosclerosis 195-98 (2001). F. 774.

11 The Aviram CIMT/BP Study, conducted by Dr. Aviram and his co-workers, was published as, "*Pomegranate juice consumption for 3 years by patients with carotid artery stenosis reduces common carotid intima-media thickness (CIMT), blood pressure and LDL oxidation*" by Aviram M, Rosenblat M, Gaitini D, Nitecki S, Hoffman A, Dornfeld L, Volkova N, Presser D, Attias J, Liker H, and Hayek T, (Clin Nutr. 2004; 23:423-33). F. 789.

12 The Ornish MP Study was conducted by Dr. Dean Ornish and colleagues and published as Sumner M, et al., *Effects of Pomegranate Juice Consumption on Myocardial Perfusion (MP) in Patients with Coronary Heart Disease*, 96 Am. J. Cardiology 810 (2005). F. 805. The Ornish MP Study was a randomized, placebo-controlled, double-blind study of 45 patients. F. 808. The Ornish MP Study indicated that there were no statistically significant differences between the two groups in blood pressure. F. 813.

13 The Ornish CIMT Study was an unpublished, randomized, double-blind, placebo-controlled 73-person study that measured carotid intima-media thickness (CIMT), blood pressure, and other related mechanisms for 12 months. F. 850. The Ornish CIMT Study indicated that there were no significant differences in the treatment group relative to the placebo group, over time, for any of the other heart-related measurements, including systolic and diastolic blood pressure. F. 859.

14 The Davidson BART/FMD Study, titled, *The Effects of Pomegranate Juice on Flow-Mediated Vasodilation*, is a published study. F. 871. Brachial artery reactivity testing ("BART") is a measurement of how much the brachial artery dilates (enlarges) after a blood pressure cuff is inflated, and then released. F. 901. This is also called flow mediated

dilation ("FMD") testing. F. 901. The Davidson BART/FMD Study took measurements of blood pressure, although blood pressure was not a primary or secondary endpoint of the study. F. 905. At the end of the Davidson BART/FMD Study, there were no significant differences between treatment and placebo groups in blood pressure. F. 906.

15 The Davidson CIMT Study, was published as Davidson MH., *et al., Effects of Consumption of Pomegranate Juice on Carotid Intima-Media Thickness in Men and Women at Moderate Risk for Coronary Heart Disease*, 104 Am. J. Cardiology 936 (2009). F. 871. In the Davidson CIMT Study, exploratory endpoints included changes in blood pressure, and the study indicated: "there were no differences between treatment groups for changes from baseline in traditional cardiovascular risk markers, including ... blood pressures ...." F. 877, 878.

16 The San Diego Study was published as Heber D. *et al., Safety and Antioxidant Activity of a Pomegranate Ellagitannin-Enriched Polyphenol Dietary Supplement in Overweight Individuals with Increased Waist Size*, J. Agric Food Chem., Vol. 55, No. 24 (2007). F. 924. The San Diego Study measured blood pressure, but this was not a primary endpoint. F. 927. The study indicated: "[t]here were no apparent treatment related changes in weight, systolic blood pressure, diastolic blood pressure, pulse rate, respirations, or temperature." F. 928.

17 The Ornish MP Study provides data on three imaging measures at baseline and three months for myocardial perfusion: the summed rest score, or "SRS" (imaging results before the pharmacologic or exercise challenge), the summed stress score, or "SSS" (imaging results after the pharmacologic or exercise challenge), and the summed difference score, "SDS" (calculated by subtracting the SRS from the SSS). F. 810.

18 Atherosclerosis is a buildup of plaque in arteries. F. 988.

19 In addition, the Carducci Study showed no difference between a one pill dose and a three pill dose. Complaint Counsel's expert, Dr. Stampfer, testified that the lack of a dose response, despite a three-fold difference in dosage, does not support a causal relationship between POMx and change in PSADT. F. 1075.

20 The Forest/Padma-Nathan Study used a crossover design, and the 53 participants who completed the study received a different beverage during the two 28-day treatment periods. Participants in cohort one consumed POM Juice in period one and then switched to the placebo beverage in period two. Participants in cohort two consumed the placebo beverage in period one and POM Juice in period two. F. 1211.

21 Mr. Tupper also relies on an initial decision in an FTC case from 1974, *In re Auslander Decorator Furniture, Inc.*, 83 F.T.C. 1542, 1974 WL 175916 (April 23, 1974), in which the hearing examiner declined to find individual liability on the part of two nominal officers because "the record [was] devoid of evidence of actual control or responsibility by [the two individuals] ... over the affairs of ADF, and ... their participation in the unlawful acts and practices of ADF was that of employees working under the direction and supervision of" the owner of the company. That case pre-dates by many years the long line of federal appellate court cases, from *Amy Travel* to *QT*, cited above, which make clear that participation is one of two grounds that justify individual liability. *Auslander* is contrary to such cases. Under these circumstances, *Auslander* cannot reasonably be deemed controlling authority. In any event, unlike *Auslander*, both participation and control have been demonstrated in this case, as more fully discussed below, and for that reason as well, *Auslander* is not dispositive.

22 Mr. Tupper also argues that he was less involved in POM's advertising during the period 2003 to 2006, and for this reason, he cannot be deemed to have "participated" in any deceptive advertisements from this period. RTB at 10. However, the evidence shows that Mr. Tupper was, in fact, engaged in the medical research aspect of POM's business from the time he first joined POM full time in 2003, although beginning in late 2006 or 2007, he became more engaged, as the "connecting piece" between research and marketing. F. 37, 1411. In any event, as explained above in connection with Respondents' "outlier" argument, even if advertisements from 2003 to 2006 are not considered, the violations would be sufficient to justify a cease and desist order against Mr. Tupper. *See Bristol-Meyers*, 1983 FTC LEXIS 64, at *250-51; *Fedders Corp.*, 85 F.T.C. at 71-72. Thus, whether or not Mr. Tupper was less involved in these earlier advertisements is not determinative as to whether a cease and desist order may issue against him.

23 Of course, Mr. Tupper's future employers would be bound, as would any business, to compliance with the FTC Act. As noted above, the "competent and reliable evidence" substantiation standard for disease or efficacy claims only obliges advertisers "to do that which the case law under Sections 5 and 12 of the FTC Act has defined as necessary to avoid deception." *Daniel Chapter One*, 2009 FTC LEXIS 259, at *70.

24 Complaint Counsel argues that deliberateness is also demonstrated by what Complaint Counsel asserts is evidence that "[d]espite concerns expressed by the New York State Attorney General's Office, the Council for Better Business Bureaus' National Advertising Division ("NAD"), NBC television, Dr. Pantuck, several IRBs [Institutional Review Boards], the FTC, and the FDA that POM's advertising claims misled consumers, POM continued to make the same or similar claims." CCB 59-60. Complaint Counsel further contends that "Respondents' own internal assessments

recognized that their research was not sufficient to substantiate POM's claims," citing evidence regarding Respondents' evaluation of their research in relation to FDA approval standards. CCB at 60. *See, e.g.*, F. 1133 (internal document stating, "it is unclear whether PSADT is acceptable as a registrational endpoint for a drug designed to prolong the time to disease progression after initial therapy for prostate cancer"). Respondents strongly dispute the evidence upon which Complaint Counsel relies to make these charges, and/or the inferences Complaint Counsel draws from the cited evidence. RRB at 183-201. However, this Initial Decision need not, and does not, decide whether or not these additional potential grounds for finding deliberateness have been demonstrated because the evidence already demonstrating seriousness and deliberateness, and particularly transferability, more than adequately supports the multi-product Order entered in this case. Moreover, whether or not Respondents knew their studies were inadequate to obtain FDA drug approval for the POM Products, as Complaint Counsel contends, is not material since, as this Initial Decision has determined, Respondents were not required to substantiate their claims with the type of clinical trials that might be deemed necessary for drugs. *E.g.*, F. 693, 694-710, 963, 1147-1148; Analysis Section III.F.2-5, *supra.*

25 Complaint Counsel's proposed order would apply the competent and reliable evidence standard, as set forth above, to representations "about the health benefits, performance, or efficacy of any Covered Product" under part III. Thus, Complaint Counsel acknowledges that this standard is sufficient for those claims, but nevertheless contends that FDA pre-approval should be the required substantiation for disease claims.

26 Relying, *inter alia*, on *Jacob Siegel Co. v. FTC*, 327 U.S. 608 (1946), Complaint Counsel appears to argue that the Commission is empowered to include virtually any provision in a cease and desist order, so long as it is "reasonably related" to the violations in the case and is sufficiently clear and precise. CCB at 57-58. It is, of course, well established that Congress, through the FTC Act, has granted the Commission "wide discretion in its choice of a remedy deemed adequate to cope with ... unlawful practices" and that "the courts will not interfere except where the remedy selected has no reasonable relation to the unlawful practices found to exist." *Jacob Siegel Co.*, 327 U.S. at 611-613. However, this should not be seen as a directive that any and all "reasonably related" remedies are to be ordered. The "reasonable relation" test is an outside limit on the permissible exercise of the FTC's discretion, rather than a standard for determining what remedy will serve the purpose of prohibiting and preventing the recurrence of deceptive trade practices. *See In re Litton Indus., Inc.*, 1981 FTC LEXIS 94, at *147 ("The purpose of a cease and desist order is to prevent the violations from being repeated, including by creating stringent monetary incentives (in the form of civil penalties) for its observance.").

27 Complaint Counsel also notes that the Commission has entered into consent orders with other respondents requiring similar FDA pre-approval requirements. CCB at 64. Consent orders do not constitute legal precedent. "The circumstances surrounding ... negotiated [consent decrees] are so different that they cannot be persuasively cited in a litigation context." *United States v. E. I. du Pont de Nemours & Co.*, 366 U.S. 316, 331 n.12 (1961). Rather, as confirmed by the express terms of the consent orders cited by Complaint Counsel, a consent order "is for settlement purposes only and does not constitute an admission by the respondent that the law has been violated." *In re Dannon Co.*, 151 F.T.C. 62, 91 (2011); *In re Nestle Healthcare Nutrition, Inc.*, 151 F.T.C. 1, 10 (2011); *see also In re Iovate Health Sciences U.S.A., Inc.*, No. 10-CV-587 (W.D.N.Y. July 29, 2010) (stating that Commission and Defendants "stipulate and agree to entry of this Order" but "do not admit or deny any of the allegations ....") (available at http:// www.ftc.gov/os/caselist/0723187/100729iovatestip.pdf).

28 In support of its argument that FDA drug approval standards are "similar" to FTC requirements, Complaint Counsel cites to the portion of the *Daniel Chapter One* Initial Decision that found as a fact, based on the weight of the expert testimony presented in that case, that "competent and reliable scientific evidence" to support the respondents' cancer effectiveness claims required "well-designed, controlled, clinical trials ...." 2009 FTC LEXIS 157, at *109-11. Consistent with that evidence, the order in *Daniel Chapter One*, like the Order in this case, defined competent and reliable scientific evidence as "tests, analyses, research, [or] studies, ... conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." Thus, *Daniel Chapter One* is not authority for requiring Respondents in this case to substantiate claims in accordance with FDA approval standards.

29 However, were Respondents to advertise a "drug" in the future, *Thompson Medical* clearly shows how application of the competent and reliable scientific evidence standard, as defined in the Order, could well result in a required level of substantiation that is consistent with FDA standards for drug approval.

30 It must also be noted that there is no evidence in the record of any coordination with, or acceptance by, the FDA with respect to requiring the FDA to pre-approve advertising claims challenged under the FTC Act.

31 Rule 2.41 states in pertinent part: "(d) Any respondent subject to a Commission order may request advice from the Commission as to whether a proposed course of action, if pursued by it, will constitute compliance with such order. The request for advice should be submitted in writing to the Secretary of the Commission and should include full and complete information regarding the proposed course of action. On the basis of the facts submitted, as well as other information available to the Commission, the Commission will inform the respondent whether or not the proposed course of action, if pursued, would constitute compliance with its order." 16 C.F.R. § 2.41(d).

32 Because Complaint Counsel has failed to adequately justify departing from established precedent to provide for the proposed FDA pre-approval requirement, that requirement is not included in the Order. Thus, this Initial Decision need not, and does not, address whether or not the proposed FDA pre-approval requirement should also be rejected because it exceeds the Commission's authority under the FTC Act and/or violates Respondents' First Amendment rights. It should be noted, however, that Respondents' generalized assertion that none of its commercial speech should be "barred" is without merit. RRB at 177. Requiring adequate substantiation for advertising claims does not "bar" commercial speech, but serves to prevent dissemination of misleading claims. *E.g.*, *Bristol-Meyers*, 738 F.2d at 562 ("Even in the absence of a finding of actual deception, agencies may properly regulate speech that is merely potentially deceptive."); *Sears, Roebuck*, 676 F.2d at 399 ("[T]he Commission may require prior reasonable substantiation of product performance claims after finding violations of the Act, without offending the [F]irst [A]mendment."); *Jay Norris, Inc. v. FTC*, 598 F.2d 1244, 1252 (2d Cir. 1979) ("[B]ecause the FTC here imposes the requirement of prior substantiation as a reasonable remedy for past violations of the Act, there is no unconstitutional prior restraint of petitioners' protected speech."). *See also* *Zauderer v. Office of Disciplinary Council*, 471 U.S. 626, 638 (1985) (holding that "[t]he States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading"); *In re R. M. J.*, 455 U.S. 191, 207 (1982) (stating that "the States retain the authority to regulate advertising that is inherently misleading or that has proved to be misleading in practice").

2012 WL 2340406 (F.T.C.)

End of Document

1988 WL 490114 (F.T.C.)

FEDERAL TRADE COMMISSION (F.T.C.)

In the Matter of
R.J. REYNOLDS TOBACCO COMPANY, INC., a corporation.

Docket No. 9206
ISSUED: March 4, 1988

***1** COMMISSIONERS:

Daniel Oliver, Chairman

Patricia P. Bailey

Terry Calvani

Mary L. Azcuenaga

Andrew J. Strenio, Jr.

ORDER

This matter has been heard by the Commission upon the appeal of counsel supporting the complaint from the initial decision, and upon briefs and oral argument in support of and in opposition to the appeal. For the reasons stated in the accompanying opinion, the Commission has determined to reverse the initial decision and remand the matter for further proceedings. Therefore,

IT IS ORDERED that the initial decision of the Administrative Law Judge is reversed and the matter remanded for further proceedings in accordance with this order and accompanying opinion.

By the Commission, Chairman Oliver dissenting.

Benjamin I. Berman

Acting Secretary

OPINION OF THE COMMISSION

By Strenio, Commissioner.

The issue presented here is whether the Administrative Law Judge (“ALJ”) erred when he granted respondent R.J. Reynolds Tobacco Company, Inc.'s (“Reynolds”) motion to dismiss on the ground that “Of Cigarettes and Science” was not commercial speech and, thus, not subject to the Commission's jurisdiction. We find that the ALJ erred when he granted the motion to dismiss. We also find that the ALJ erred when he ruled that further opportunity to discover and present facts relating to jurisdiction was not permitted. His order is reversed and the matter remanded for further proceedings consistent with this opinion.

I. Procedural History.

This case involves an advertisement, entitled "Of Cigarettes and Science," allegedly disseminated by Reynolds in the course of its business of manufacturing, advertising and selling cigarettes. Complaint, ¶ ¶ 2-4. The advertisement discusses, among other things, the procedures that scientists use to test scientific hypotheses and sets forth information about a scientific study known as the Multiple Risk Factor Intervention Trial ("MR FIT"). Complaint, Attachment A.

On June 16, 1986, the Federal Trade Commission ("Commission" or "FTC") issued a complaint alleging that the Reynolds advertisement falsely and misleadingly represents: that the purpose of the MR FIT study was to determine whether heart disease is caused by cigarette smoking; that the MR FIT study provides credible scientific evidence that smoking is not as hazardous as the public or the reader has been led to believe; and that the MR FIT study tends to refute the theory that smoking causes coronary heart disease. Complaint, ¶ ¶ 5-6. In addition, the complaint alleges that the advertisement fails to disclose certain material facts about the MR FIT study. Complaint, ¶ 7.

Respondent filed a motion to dismiss the complaint on June 26, 1986. The motion sought dismissal on the ground that the Commission had no subject matter jurisdiction over the "Of Cigarettes and Science" advertisement because "the acts and practices complained of are expressions of opinion on issues of social and political importance which cannot be regulated by the Federal Trade Commission consistent with the First Amendment." [1] Motion to Dismiss, ¶ 1. According to Reynolds, the ALJ was required to determine the jurisdictional issue on the basis of the pleadings alone; consideration of extrinsic evidence was both irrelevant and itself violative of the First Amendment. [2]

***2** Complaint counsel opposed the motion to dismiss, arguing alternatively that the motion should be denied because the challenged advertisement was properly classified as commercial speech and, thus, properly subject to the Commission's jurisdiction or because the motion raised issues that required further factual development. [3]

After hearing argument on the motion, the ALJ concluded that the advertisement was not commercial speech but rather speech fully protected by the First Amendment. The ALJ thus ruled that the advertisement was outside the jurisdiction of the Commission. Order, dated August 4, 1986. In his decision, the ALJ rejected the argument that complaint counsel should be granted further opportunity to discover and present facts relating to jurisdiction. Id. at 14-15. He concluded that further discovery was "contrary to law and unacceptable" because categorization of speech as either commercial or noncommercial has been "customarily resolved by the courts on the basis of what is contained in the ads" and, in any event, he had already granted complaint counsel "ample time" for discovery. Id.

Counsel supporting the complaint appealed the ALJ's initial decision to the Commission.

II. FTC Jurisdiction.

We agree with the parties and the ALJ that unless the Reynolds advertisement can be classified as commercial speech, it is not subject to the Commission's jurisdiction. Thus, consideration of whether the ALJ erred when he concluded, at this stage of the proceeding, that the complaint should be dismissed necessarily begins with an analysis of the legal standards applicable to classification of speech as commercial or noncommercial.

Following that analysis, the facts of this case will be applied to the legal framework. When making this analysis, the procedural standards applicable to motions to dismiss apply. Under those standards, the complaint must allege facts sufficient to confer jurisdiction. For purposes of this analysis, all of the factual allegations of the complaint concerning jurisdiction are presumed true. See, e.g., Scheuer v. Rhodes, 416 U.S. 232, 236 (1974). See also 2A

J. Moore, J. Lucas & G. Grotheer, Moore's Federal Practice, ¶ 12.07 [2.-1] at 12-46 to 12-47 (2d ed. 1987). If the complaint does not allege sufficient facts to confer jurisdiction, it must be dismissed.

If, on the other hand, the complaint does allege facts which if true would be sufficient to establish jurisdiction, then another inquiry is required. Specifically, the question then becomes whether the facts alleged are supported by the evidence. In making this determination, there is no presumption that the allegations are true, and the burden is on complaint counsel to prove jurisdiction by a preponderance of the evidence. See, e.g., Menchaca v. Chrysler Credit Corp., 613 F.2d 507, 511 (5th Cir.), cert. denied, 449 U.S. 953 (1980); Mortensen v. First Federal Savings & Loan Ass'n, 549 F.2d 884 (3d Cir.1977).

***3** Finally, we also address whether, and to what extent, consideration of extrinsic evidence is permitted to resolve the jurisdictional issue.

A. The First Amendment Guarantee of Freedom of Speech.

The protections afforded by the First Amendment guarantee against laws "abridging the freedom of speech" are of fundamental importance to a democratic society. Justice Cardozo once characterized the First Amendment as "the matrix, the indispensible condition of nearly every other form of freedom." [4] The reach of the First Amendment extends to individuals as well as to corporations and other entities. First National Bank of Boston v. Bellotti, 435 U.S. 765 (1978).

The Constitution, however, accords different degrees of protection based upon the type of speech at issue. The core examples of speech entitled to the highest level of protection are political discourse and expressions about philosophical, religious, artistic, literary or ethical matters. In light of its high societal value, regulation of such "fully protected" speech generally is limited to reasonable time, place and manner restrictions.

Commercial speech, by contrast, is accorded less constitutional protection, but protection that is "nonetheless substantial." Bolger v. Youngs Drug Products Corp., 463 U.S. 60, 68 (1983). [5] Unlike fully protected speech, commercial speech can be regulated on the basis of its content.

The more limited protection accorded commercial speech permits the FTC to act when necessary to challenge false or deceptive advertising. [6] See, e.g., Thompson Medical Co. v. FTC, 791 F.2d 189 (D.C.Cir.1986), cert. denied, 107 S.Ct. 1289 (19 87); Sears, Roebuck & Co. v. FTC, 676 F.2d 385 (9th Ci r.1982); Warner-Lambert Co. v. FTC, 562 F.2d 749 (D. C.Cir.1977), cert. denied, 435 U.S. 950 (1978); Beneficial Corp. v. FTC, 542 F.2d 611 (3d Cir.1976), cert. denied, 430 U.S. 983 (1977). Commission action to prevent false or deceptive advertising, in turn, serves the important public interest in informed commercial decision-making.

B. Commercial Speech.

The Supreme Court has referred to the "core notion" of commercial speech as speech proposing a commercial transaction. Bolger v. Youngs Drug Products, 463 U.S. at 66 (citing Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 762 (1976) and Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations, 413 U.S. 376, 385 (1973)). See also Central Hudson Gas & Electric Corp. v. Public Service Comm'n, 447 U.S. 557, 562 (1980); Linmark Associates, Inc. v. Township of Willingboro, 431 U.S. 85 (1977). In Central Hudson, the Court also discussed commercial speech as speech solely related to the economic interests of both the speaker and the speaker's audience. 447 U.S. at 561.

The Court also has made it clear that commercial speech may include speech that links a product to important public issues or matters subject to current public debate. Central Hudson, 447 U.S. at 562 n. 5; Bolger v. Youngs

Drug Products Corp., 463 U.S. at 67-68; Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626, 637 n. 7 (1985). Indeed, in Central Hudson, the Court majority found that the New York State Public Service Commission order banning all advertising intended to promote the sale of utility services or electricity involved "only commercial speech." 447 U.S. at 561. The majority expressly rejected Justice Stevens' suggestion that the category "promotional advertising" would also include fully protected speech if, for example, the speech touted the environmental benefits of electricity, noting:

***4** [Justice Stevens' approach] would grant broad constitutional protection to any advertising that links a product to a current public debate. But many, if not most, products may be tied to public concerns with the environment, energy, economic policy, or individual health and safety.

Id. at 562 n. 5. The Court observed that companies have full constitutional protection for their direct comments on public issues and thus, there did not appear to be a need for similar protection "when such statements are made only in the context of commercial transactions. In that context, the State retains the power to 'ensur[e] that the stream of commercial information flow[s] cleanly as well as freely.' " Id. (citing Virginia State Board of Pharmacy, 425 U.S. at 772).

The Supreme Court has not established a bright line test for ascertaining the boundary between commercial speech that may also include information about matters of important public interest and speech that constitutes direct comments on public issues. Indeed, the Court has noted the complexities of delineating the boundary. See Zauderer v. Office of Disciplinary Counsel, 471 U.S. at 637 (the "precise bounds" of commercial speech are "subject to doubt"); In re Primus, 436 U.S. 412, 438 n. 32 (1978) (line between commercial and noncommercial speech "will not always be easy to draw"). Moreover, the Court has recognized that "the diverse motives, means, and messages of advertising may make speech 'commercial' in widely varying degrees." Bigelow v. Virginia, 421 U.S. 809, 826 (1975).

The Court, however, has offered guidance for determining what constitutes commercial speech by mentioning a number of characteristics of commercial speech. The Commission considers it premature, particularly in the absence of a full record, to say which characteristics will be determinative in deciding whether the Reynolds advertisement constitutes commercial speech. It is appropriate, however, to start with those characteristics that the Court has considered in its relatively few commercial speech decisions. [7]

We begin with the content of the speech in question. See Bates v. State Bar of Arizona, 433 U.S. 350, 363 (1977). The Court in Central Hudson identified speech containing a message promoting the demand for a product or service as speech that can be classified as commercial. See 447 U.S. at 559-62.

In addition, commercial speech typically refers to a specific product or service. Bolger v. Youngs Drug Products, 463 U.S. at 66. In many cases, the product reference includes the brand name of a product offered for sale. However, the Bolger Court stated that a generic reference to a product would not necessarily remove it from the category of commercial speech: "For example, a company with sufficient control of the market for a product may be able to promote the product without reference to its own brand name. Or, a trade association may make statements about a product, without reference to specific brand names." 463 U.S. at 66-67 n. 13 (citing with approval National Commission on Egg Nutrition v. FTC, 570 F.2d 157 (7th Cir .1977), cert. denied, 439 U.S. 821 (1978)). [8]

***5** In Friedman v. Rogers, 440 U.S. 1, 11 (1979), the Court noted that information about attributes of a product or service offered for sale, such as type, price, or quality, is also indicative of commercial speech. [9] Likewise, the Court has indicated that information about health effects associated with the use of a product can properly be classified as commercial speech. [10] See Bolger v. Youngs Drug Products, 463 U.S. at 66-67 (claims discussing

the benefits of condoms for the prevention of venereal disease). See also National Commission on Egg Nutrition, 570 F.2d at 163 (deceptive claims to the effect that no scientific evidence supported the claim that eating eggs increases the risk of heart disease).

In addition to content, the Court has found that the means used to publish speech is relevant to the classification issue. For example, the Court has recognized that commercial speech frequently takes the form of paid-for advertising. See Bolger v. Youngs Drug Products, 463 U.S. at 66 (citing New York Times Co. v. Sullivan, 376 U.S. 254, 265-66 (1964)). See also Bates v. State Bar of Arizona, 433 U.S. at 363-64; Virginia State Board of Pharmacy, 425 U.S. at 761.

The Court also has indicated that the speaker's economic or commercial motivation is germane to the issue of whether speech is commercial. In re Primus, 436 U.S. at 438 n. 32 (line between commercial and noncommercial speech is "based in part on the motive of the speaker"); Bolger v. Youngs Drug Products, 463 U.S. at 67. See also National Commission on Egg Nutrition, where the Seventh Circuit held that commercial speech should not "be narrowly limited to the mere proposal of a particular commercial transaction but [should] extend to false claims as to the harmlessness of the advertiser's product asserted for the purpose of persuading members of the reading public to buy the product." 570 F.2d at 163.

It would appear for purposes of this analysis that an important consideration will be whether the speech is promotional in nature. Does the speech benefit or seek to benefit the economic interests of the speaker by promoting sales of its products? And, does the speech affect or seek to affect purchasing decisions by the receivers of the information?

This type of speech can be contrasted with speech that does not benefit the economic interests of the speaker by influencing the reader or listener in the role of consumer, but instead provides, for example, information relevant to individual political decisions, or to artistic or cultural choices. Such speech may not further the informational function of commercial decision-making. See, e.g., Consolidated Edison Co. of N.Y., Inc . v. Public Service Comm'n, 447 U.S. 530 (1980) (billing insert was not addressed to informed decision-making about the purchase of a specific product, i.e., nuclear-generated electricity, but concerned the human and environmental risks that could result from a malfunction or accident at a nuclear power plant); First National Bank of Boston v. Bellotti, 435 U.S. 765 (1978) (speech in question was limited to expression directed to the reader or listener as a voter). [11]

***6** Although it may be difficult in some cases, the Commission thinks that it is possible to determine whether a specific advertisement that includes information connected to public issues nonetheless addresses the concerns of a purchaser of the advertiser's product or service. To conclude otherwise would allow sellers of certain products to avoid the proscription against false and misleading advertising merely by linking their product to a public issue. Indeed, in National Commission on Egg Nutrition, the product eggs was inextricably linked to the cholesterol-and-heart-disease issue. Despite the connection, the Seventh Circuit ruled that the advertisements, including "Cholesterol and the Egg: A Mystery," were commercial speech.

C. The ALJ's Decision to Grant Respondent's Motion.

The question remains, of course, whether the ALJ erred when he granted respondent's motion to dismiss. In reaching his decision, the ALJ was required to consider the various "messages, means, and motives" of the advertisement (see Bigelow, 421 U.S. at 826), including the presence or absence of the characteristics identified by the case law as relevant to whether speech is commercial.

Accepting the allegations of the complaint concerning jurisdiction as true for purposes of this appeal, [12] the content of the Reynolds advertisement includes words and messages that are characteristic of commercial speech. The

advertisement refers to a specific product, cigarettes. Complaint, ¶ ¶ 2, 4; Bolger v. Youngs Drug Products, 463 U.S. at 66. Moreover, the advertisement discusses an important product attribute the alleged connection between smoking and heart disease. Complaint, ¶ ¶ 4, 5; Friedman v. Rogers, 444 U.S. at 11; National Commission on Egg Nutrition, 570 F.2d at 1 63. A message that addresses health concerns that may be faced by purchasers or potential purchasers of the speaker's product may constitute commercial speech. See Bolger v. Youngs Drug Products, 463 U.S. at 66-67; National Commission on Egg Nutrition, 570 F.2d at 163.

Similarly, the complaint alleges that "Of Cigarettes and Science" is an advertisement (Complaint, ¶ 2), which we understand to mean a notice or announcement that is publicly published or broadcast and is paid-for. Thus, viewed in light of the allegations of the complaint, the "means" used to disseminate the Reynolds advertisement paid-for advertising is typical of commercial speech. Bolger v. Youngs Drug Products, 463 U.S. at 66; Virginia State Board of Pharmacy, 425 U.S. at 761.

Finally, the complaint alleges that respondent is in the business of selling cigarettes. Complaint, ¶ 4. It is reasonable to infer that Reynolds, as a seller of cigarettes, had a direct, sales-related motive for disseminating the "Of Cigarettes and Science" advertisement. As discussed above, economic motivation also may be indicative of commercial speech. In re Primus, 436 U.S. at 438 n. 32; Bolger v. Youngs Drug Products, 463 U.S. at 67; National Commission on Egg Nutrition, 570 F.2d at 163.

***7** Thus, viewed in light of the allegations contained in the complaint, we conclude that the ALJ erred when he granted respondent's motion to dismiss at this stage of the proceeding.

It should be clear, however, that the Commission makes no final determination of jurisdiction. As we noted above, supra at 4-5, any such conclusion requires proof that the complaint allegations concerning jurisdiction are true. Inasmuch as respondent has not answered the complaint, the record does not indicate what factual allegations concerning jurisdiction, if any, are controverted. Thus, final findings of fact with respect to jurisdiction at this stage of the proceeding would be premature.

Instead, we think it is appropriate to remand the matter to the ALJ for the purpose of determining whether application of the facts to the appropriate legal standards supports a finding of jurisdiction. Upon remand, the ALJ may weigh the evidence and resolve any factual disputes. If the ALJ determines that additional evidence is needed to make a final determination on jurisdiction, [13] he shall permit further opportunity to develop and present evidence on the issue. See Part II.D, infra at 1 7-22. We emphasize, however, that we have not concluded that presentation of extrinsic evidence is necessarily required for determining whether the Reynolds advertisement is commercial speech. The decision of what evidence to present in order to attempt to meet their burden of proving jurisdiction is a decision to be made properly by counsel supporting the complaint.

D. Consideration of Extrinsic Evidence.

Another issue that arose below is whether, and to what extent, consideration of extrinsic evidence is permitted to resolve the jurisdictional issue. As a general matter, a party may establish the existence of subject matter jurisdiction through the use of extrinsic evidence. [14] Respondent, however, contends that reliance upon extrinsic evidence is irrelevant and itself violative of the First Amendment.

We agree that consideration of extrinsic evidence is permitted only if the evidence is relevant to the issues presented and is not barred by any evidentiary privilege. [15] Nonetheless, we disagree with respondent's sweeping assertion that this standard prohibits any and all consideration of extrinsic evidence in determining whether the Reynolds advertisement is subject to the Commission's jurisdiction. We are aware of no decision holding

that consideration of extrinsic evidence is impermissible in determining whether an advertisement constitutes commercial speech.

Indeed, the Supreme Court in In re Primus, 436 U.S. 412 (1978), clearly relied upon extrinsic evidence for its finding that application by the Supreme Court of South Carolina of its Disciplinary Rules to appellant's solicitation by letter on the American Civil Liberties Union's ("ACLU") behalf violated the First Amendment. In addition to considering the solicitation letter, the Court looked to evidence relating to the circumstances that led to appellant's letter and the events that took place after the letter was sent, the aims and practices of the ACLU, and the appellant's lack of any economic motivation a characteristic which the Court noted distinguished the appellant's solicitation from the purely commercial solicitation present in Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447 (1978), decided the same day.

***8** Moreover, in Herbert v. Lando, 441 U.S. 153, 175 (1979), the Supreme Court held that the First Amendment did not bar a plaintiff in a defamation action from inquiring into the editorial processes of the respondent members of the press because the information sought to be discovered was directly relevant to proof of a critical element of the plaintiff's cause of action. [16] Instead, the Court found that the relevancy requirement of Rule 26(b)(1) was sufficient protection against improper forays into the respondents' thought processes. We find the reasoning in Herbert v. Lando applicable here. [17] Thus, we find no basis for concluding that discovery and presentation of relevant and non-privileged evidence concerning jurisdiction must be categorically barred.

Evidence that may be relevant to deciding whether the Reynolds advertisement is commercial speech includes facts concerning the publication or dissemination of the advertisement, such as whether it was paid-for, where and in which publications it was disseminated, whether it was placed in editorial space (such as an opened page) or advertising space in the publication, whether it was prepared as a letter to the editor, whether it was sent to representatives of the media for selection on merit by editorial boards, and to whom it was disseminated outside the media.

Evidence about the promotional nature of the advertisement also may be relevant. Therefore, it might be useful to consider the circumstances surrounding the development of the advertisement, such as whether it was targeted to consumers or legislators; whether it was intended to affect demand for Reynolds' cigarettes or brands or to affect particular legislative or regulatory proposals; whether the advertisement was subjected to copy testing or to review by focus groups and, if so, the nature of the questions used in the copy tests or focus group sessions; and the results of those procedures both in terms of what they showed and what changes, if any, Reynolds made in response to those showings. Evidence relating to the message(s) Reynolds itself intended to convey through the advertisement also may be relevant. In addition, Reynolds' share of the cigarette market may be relevant to deciding whether including a brand name reference is a prerequisite to a determination that the advertisement constitutes commercial speech. [18]

Of course, to the extent that any specific facts are protected by an evidentiary privilege, their use would not be permitted even if relevant. Determination of whether or not evidence is privileged, however, should be made on an individual basis. In this connection, we disagree with respondent's contention that use of all evidence other than the "Of Cigarettes and Science" advertisement would violate the First Amendment. See Herbert v. Lando, 441 U.S. at 175.

In sum, other than the relevancy and privilege requirements, we find no categorical evidentiary bar against discovery or presentation of extrinsic evidence that might assist in determining on the record whether the Reynolds advertisement constitutes commercial speech, and consequently, would be subject to the Commission's jurisdiction.

***9** III. Conclusion.

For the reasons discussed above, we reverse the Administrative Law Judge's order granting respondent's motion to dismiss for lack of subject matter jurisdiction, and remand for further proceedings consistent with this opinion.

***10** SEPARATE STATEMENT OF CHAIRMAN OLIVER, DISSENTING

I. INTRODUCTION

The First Amendment prohibits the federal government from acting as umpire in the contest of ideas. The government cannot select which issues are worth debating nor selectively exclude certain participants from that debate. Under the First Amendment, individuals and corporations alike have a fully protected right to engage in direct comment on public issues free from governmental regulation or censorship.

First Amendment protection of public debate generally coexists very peacefully with the Federal Trade Commission's exercise of its authority to ban deceptive commercial speech. While the First Amendment protects unfair and false statements in the public marketplace of ideas, it does not protect such statements in the commercial marketplace for goods and services. The Commission's jurisdictional authority extends to the hawking of wares, not the hawking of ideas.

The American marketplace for ideas is decentralized and occurs in numerous arenas: in Congress, in academia, in books and pamphlets, in newspapers, over the airways, over backyard fences, at the workplace, door-to-door. Seldom does the government step in to crown a victor or promulgate an official version of the truth. In the debate over public policies regarding smoking, however, the government has not only based its policies on an official version of the truth, it has compelled private citizens to propagandize in favor of that version of the truth.[1] In this case, the Federal Trade Commission is attempting to go one step further and regulate a challenge to the official orthodoxy.

At issue in this case is whether R.J. Reynolds Tobacco Co. (RJR) has a fully protected right under the First Amendment to question the officially accepted view regarding the link between cigarette smoking and heart disease. In March 1985, RJR paid various newspapers and magazines to publish a communication captioned “Of Cigarettes and Science,” in which RJR questioned the objectivity of the scientists who examine the issue of smoking and health.[2] Relying on data from a governmentally funded study, RJR argued that there is still a scientific question about the link between cigarettes and heart disease.

The Federal Trade Commission responded by issuing a complaint that alleges that the RJR communication is deceptive. RJR has in turn challenged the subject matter jurisdiction of the FTC, arguing that the publication at issue is fully protected under the First Amendment. The Administrative Law Judge ruled that RJR is correct, that the publication is an editorial rather than commercial speech, and dismissed the complaint for lack of subject matter jurisdiction.

In my opinion, RJR and the Administrative Law Judge are clearly correct. The RJR publication is, without doubt, a direct comment on a matter of public concern the link between cigarette smoking and heart disease. Any commercial effect of the RJR communication is inextricably intertwined with RJR's participation in the contest of ideas. Accordingly, the RJR publication is fully protected by the First Amendment, even if one of the consequences of the publication is to affect cigarette consumption. R.J. Reynolds cannot be disqualified from questioning scientific certitude merely because its potential success in persuading the general public that the question remains open could also have an effect on sales of its product.

***11** The Commission majority attempts to finesse the issue of whether the RJR communication is commercial speech (which the Commission has subject matter jurisdiction over) or fully protected speech (thus requiring dismissal). The Administrative Law Judge is reversed, and the case remanded, but the reasons for doing so are not immediately apparent. Although finding that the words and message of the RJR communication are characteristic of commercial speech, the Commission majority purportedly declines to decide whether the communication is commercial speech. Further, without ruling that additional extrinsic evidence is needed to decide the key jurisdictional issue,[3] the majority nonetheless sets forth the facts it believes may be relevant. On closer examination, it becomes apparent that the majority makes determinations that logically compel it to conclude that the piece is commercial speech, but seeks to duck the issue, sending the matter back to the ALJ for further discovery that might bolster a finding that the Commission has subject matter jurisdiction.

In my considered opinion there is no reason why the Commission cannot make an explicit determination today. The text and the context of RJR's communication are before the Commission. From the face of the document itself we can determine that the communication is a direct comment on a matter of public debate. The piece is not a solicitation for a commercial transaction with a gratuitous reference to a public debate thrown in to evade laws relevant to commercial advertising. RJR's direct comment on a matter of public debate is inextricably intertwined with any commercial effect that may result from RJR's participation in that debate. As Supreme Court precedent establishes, direct comment on a matter of public debate is fully protected under the First Amendment, even if it has a commercial effect, unless the comment on the public issue is merely gratuitously linked with a commercial message. No discovery is needed or justified prior to a ruling on the Commission's subject matter jurisdiction. The factual inquiry that the majority proposes would either produce unnecessary background information or engage the Commission in an irrelevant quest to establish RJR's "intent" in running this piece. The facts before the Administrative Law Judge and the Commission establish that we lack subject matter jurisdiction. Consistent with the First Amendment, we have no choice but to dismiss the complaint.

II. RELEVANT BACKGROUND FACTS

The RJR piece,[4] "Of Cigarettes and Science," was published in March 1985 in a number of newspapers and magazines. (Abrams Aff. ¶ 2) In that communication, RJR argues that one set of scientific principles is being used to judge most scientific matters but that a different set is being used for experiments involving cigarettes. In support of this thesis, RJR cites its version of the scientific treatment of a study called the Multiple Risk Factor Intervention Trial (MR FIT). The study, funded by the federal government, cost $115,000,000 and took ten years. RJR's communication describes the study as follows:

***12** The subjects were over 12,000 men who were thought to have a high risk of heart disease because of three risk factors that are statistically associated with this disease: smoking, high blood pressure and high cholesterol levels.

Half of the men received no special medical intervention. The other half received medical treatment that consistently reduced all three risk factors, compared with the first group.

It was assumed that the group with lower risk factors would, over time, suffer significantly fewer deaths from heart disease than the higher risk factor group.

But that is not the way it turned out.

After 10 years, there was no statistically significant difference between the two groups in the number of hear disease deaths.

The Commission does not allege that this description of the study is inaccurate. [5] Nor is it disputed that the results of the MR FIT were not as expected. [6]

After describing the study, RJR provides its view of the scientific reaction to that study:
We at R.J. Reynolds do not claim this study proves that smoking doesn't cause heart disease. But we do wish to make a point.

Despite the results of MR FIT and other experiments like it, many scientists have not abandoned or modified their original theory, or re-examined its assumptions.

They continue to believe these factors cause heart disease. But it is important to label their belief accurately. It is an opinion. A judgment. But not scientific fact.

We believe in science. That is why we continue to provide funding for independent research into smoking and health.

But we do not believe there should be one set of scientific principles for the whole world, and a different set for experiments involving cigarettes. Science is science. Proof is proof. That is why the controversy over smoking and health remains an open one. [7]

The Administrative Law Judge determined that the characterization of "Of Cigarettes and Science" as commercial speech or fully protected speech can be made from the face of the publication. [8] In summary, his conclusion was: "From a common sense approach, Reynolds' 'Of cigarettes and science' is clearly an editorial; it is not commercial speech by any stretch of the imagination." [9]

III. CONTROLLING SUPREME COURT PRECEDENT

The Supreme Court has recognized that corporations are free to engage in public debate and have a fully protected right to do so, noting that: "[t]he inherent worth of the speech in terms of its capacity for informing the public does not depend upon the identity of its source, whether corporation, association, union, or individual." First National Bank of Boston v. Belotti, 435 U.S. 765, 777 (1978), rehearing denied, 438 U.S. 907 (1978). Corporations, like others, do not lose the protection of the First Amendment by virtue of the fact that they pay to make their views known. In rejecting a claim that libelous statements received no protection because they had been paid for in an advertisement attempting to raise funds, the Supreme Court stated:
***13** That the Times was paid for publishing the advertisement is as immaterial in this connection as is the fact that newspapers and books are sold. Any other conclusion would discourage newspapers from carrying "editorial advertisements" of this type, and so might shut off an important outlet for the promulgation of information and ideas by persons who do not themselves have access to publishing facilities who wish to exercise their freedom of speech even though they are not members of the press. The effect would be to shackle the First Amendment in its attempt to secure the "widest possible dissemination of information from diverse and antagonistic sources."

New York Times v. Sullivan, 376 U.S. 254, 266 (1964) (citations omitted). [10]

Public debate is protected because, "above all else, the First Amendment means that government has no power to restrict expression because of its message, its ideas, its subject matter, or its content." [11] The government may not

"select which issues are worth discussing or debating" and "must afford all points of view an equal opportunity to be heard." [12] "Selective exclusions from a public forum may not be based on content alone, and may not be justified by reference to content alone." [13]

The First Amendment evidences a deliberate policy choice to limit the government's ability to control speech and to rely instead on the abilities of the citizenry to judge the facts and opinions offered by themselves. That choice is made with a clear view of the consequences, that "erroneous statement of fact is ... inevitable in free debate.... The First Amendment requires that we protect some falsehood in order to protect speech that matters." Gertz v. Robert Welch, Inc., 418 U.S. 323, 340-41 (1974). Such an accommodation is necessary to give freedom of speech the "breathing space" which is necessary for its "fruitful exercise" (Id. at 342) and "survival." NAACP v. Button, 371 U.S. 415, 433 (1963). Indeed, "[u]nder the First Amendment there is no such thing as a false idea ." Gertz, supra, 418 U.S. at 339. This does not imply that the truth is not preferred, but that the arbiters should be the public rather than the government. "If there be time to expose through discussion the falsehood and fallacies, to avert the evil by the processes of education, the remedy to be applied is more speech, not enforced silence." [14]

Commercial speech, like debate over ideas, is protected under the First Amendment, but it receives a lower level of protection. [15] The distinction is drawn to avoid "dilution, simply by a leveling process, of the force of the Amendment's guarantee with respect to [noncommercial speech]." [16]

Unlike noncommercial speech, commercial speech can be regulated to prohibit false and deceptive advertising. The Supreme Court has cited two aspects of commercial speech that justify regulation based on the content of the message:
First, commercial speakers have extensive knowledge of both the market and their products. Thus, they are well situated to evaluate the accuracy of their messages and the lawfulness of the underlying activity. Bates v. State Bar of Arizona, 433 U.S. 350, 381 (1977). In addition, commercial speech, the offspring of economic self-interest, is a hardy breed of expression that is not "particularly susceptible to being crushed by overbroad regulation."

***14** Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York, 447 U.S. at 564 n. 6.

The first basis for affording less protection to commercial speech, the relative costs of avoiding injury from untruthful speech, is discussed more fully in Bates:
the advertiser seeks to disseminate information about a product or service that he provides, and presumably he can determine more readily than others whether his speech is truthful and protected.

Bates v. State Bar of Arizona, 433 U.S. 350, 381 (1977).

The second basis for affording less protection to commercial speech, its hardiness because it is the offspring of economic self-interest, was discussed in Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, n. 24 at 771-72 (1976):
Also, commercial speech may be more durable than other kinds. Since advertising is the sine qua non of commercial profits, there is little likelihood of its being chilled by proper regulation and foregone entirely.

Since commercial speech is used to sell goods and services and is "related solely to the economic interests of the speaker and its audience," Central Hudson, supra, at 561, an advertiser expects to be able to capture a large percent of the value of his commercial speech. By contrast, speech dealing with matters of public concern is potentially of value to a much broader audience, i.e., to the public at large. Self-censorship is more likely to occur when

speech relates to matters of public concern. To provide the necessary breathing space for vigorous public debate involving matters of public controversy, potentially false statements in communications relating to such matters receive a greater degree of protection under the First Amendment. [17]

To aid in the process of distinguishing commercial speech from more traditional First Amendment expression, the Supreme Court has provided two definitions of commercial speech. First, there is a " 'common-sense' distinction between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech," [18] or, as restated, the "core notion of commercial speech" is "speech which does 'no more than propose a commercial transaction'." Bolger v . Youngs Drug Products Corp., 463 U.S. 60, 66 (1983). The other definition of commercial speech is "expression related solely to the economic interest of the speaker and its audience." Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557, 561 (1980).

These two definitions of commercial speech may not comprehend all commercial speech, as evidenced by Bolger v. Youngs Drug Products Corp., supra. Bolger involved a challenge to the application of a federal statute that prohibited the mailing of unsolicited advertisements for contraceptives. After the Postal Service had advised Youngs that certain proposed mailings would violate the statute, Youngs sought a ruling that the statute was unconstitutional as applied to the mailings in question. The district court held that the three types of mailings in question were all commercial solicitations but that the statutory prohibition was more extensive than necessary to protect the interests asserted by the Government. [19] Accordingly, the district court held that the statute was unconstitutional as applied.

***15** The Supreme Court affirmed the district court's ruling, but in the process addressed the question whether the mailings were commercial speech. The Supreme Court concluded that the mailings were commercial speech. Most of the mailings, it held, fell "within the core notion of commercial speech" since they did 'no more than propose a commercial transaction.' Id. at 66. But the informational pamphlets could not "be characterized merely as proposals to engage in commercial transactions." [20]

The Court concluded that the pamphlets could not be classified as commercial speech merely because they were "conceded to be advertisements" (id. at 66), merely because of a "reference to a specific product" (id. at 66), or merely because "Youngs has an economic motivation for mailing the pamphlets" (id. at 67). These three facts taken together, in this particular case, were, however, enough to satisfy the Court that the pamphlets were commercial speech: "The combination of all these characteristics, however, provides strong support for the District Court's conclusion that the informational pamphlets are properly characterized as commercial speech." (id. at 67).

The Bolger Court noted that the pamphlets at issue "contain[ed] discussions of important public issues," Id. at 67-68, but held that the informational pamphlets were commercial speech notwithstanding the discussion of important public issues:

The mailings constitute commercial speech notwithstanding the fact that they contain discussions of important public issues such as venereal disease and family planning. We have made clear that advertising which "links a product to a current public debate" is not thereby entitled to the constitutional protection afforded noncommercial speech. A company has the full panoply of protections available to its direct comments on public issues, so there is no reason for providing similar constitutional protection when such statements are made in the context of commercial transactions. Advertisers should not be permitted to immunize false or misleading product information from government regulation simply by including references to public issues.

Id. at 67-68 (emphasis provided) (quoting Central Hudson Gas & Electric Corp. v. Public Service Commission of New York, 447 U.S. 563, n. 5).

The Bolger Court's distinction between "direct comments on public issues" and "advertising which 'links a product to a current public debate' " is best understood by reference to two Supreme Court decisions cited in Bolger: Consolidated Edison Co. v. Public Service Commission, supra, and Central Hudson Gas & Electric Corp. v. Public Service Commission of New York, supra.

In Consolidated Edison, Con Ed challenged a rule forbidding it from mailing, along with its billing statements, leaflets discussing controversial issues of public policy. The rule had been promulgated in response to a Con Ed leaflet proclaiming the benefits of nuclear power. The Supreme Court held that the rule conflicted with the First Amendment, emphasizing that "[t]he First Amendment's hostility to content-based regulation extends not only to restrictions on particular viewpoints, but also to prohibition of public discussion of an entire topic." Consolidated Edison Co. v. Public Service Commission, 447 U.S. at 537. The Court discussed its Consolidated Edison holding in the companion Central Hudson case, stating: "[w]e rule today in Consolidated Edison Co. v. Public Service Commission ... that utilities enjoy the full panoply of First Amendment protections for their direct comments on public issues." Central Hudson Gas & Electric Corp. v. Public Service Commission of New York, 477 U.S. at 563 n. 5.

***16** In the Central Hudson case, the plaintiff utility company challenged a rule that banned an electric utility from advertising to promote the use of electricity. The rule was enacted in response to the perceived energy shortage. The Supreme Court struck down the rule, holding that the public utility commissions' rule was more extensive than necessary to further the state's interest in energy conservation.

In a concurring opinion, Justice Stevens criticized the regulation as banning all promotional advertising and thus being overly broad:

This ban encompasses a great deal more than mere proposals to engage in certain kinds of commercial transactions. It prohibits all advocacy of the immediate or future use of electricity. It curtails expression by an informed and interested group of persons of their point of view on questions relating to the production and consumption of electrical energy questions frequently discussed and debated by our political leaders.

Id. at 580-81 (Stevens, J., concurring in judgment).

In a footnote, the majority in Central Hudson discussed Justice Stevens' concerns. The majority concluded that the advertising ban "was restricted to all advertising 'clearly intended to promote sales'." Id. at 562 n. 5. Further, while the complaint and the lower court opinions viewed the litigation as involving only commercial speech, the majority addressed the issue whether full First Amendment protection should be afforded to "all promotional advertising that includes claims 'relating to ... questions frequently discussed and debated by our political leaders' ":

Although this approach responds to the serious issues surrounding our national energy policy as raised in this case, we think it would blur further the line the Court has sought to draw in commercial speech cases. It would grant broad constitutional protection to any advertising that links a product to a current public debate. But many, if not most, products may be tied to public concerns with the environment, energy, economic policy, or individual health and safety. We rule today in Consolidated Edison Co. v. Public Service Comm'n, ante, 530, that utilities enjoy the full panoply of First Amendment protection for their direct comments on public issues. There is no reason for providing similar constitutional protection when such statements are made only in the context of commercial transactions.

Id. at 563 n. 5.

A simple message flows from these cases. In Consolidated Edison the Court held that the First Amendment did not allow the government to foreclose discussion of an entire topic the benefits of nuclear power. In dealing with broad categories of messages, the Court has gone no further than deciding that those 'clearly intended to promote sales' could be treated as commercial speech. Central Hudson, supra, at 565 n. 5. Moreover, if companies attempt to evade regulation of commercial speech by including gratuitous references to public issues the court will not countenance it. Bolger, supra, at 68. There is no need to allow that sort of subterfuge because companies have full First Amendment rights to make their views known in other ways. Id.

***17** The dividing line is thus clear if, by a common sense view, the advertisement is clearly intended to promote sales it is commercial speech. If, in addition, there is a public message incorporated, the advertisement can be regulated if inclusion of that public message is simply a gratuitous linkage. If, however, the message is direct comment on a public issue, the full protection of the First Amendment applies. If direct comment on public issues cannot be severed from speech that otherwise might be characterized as commercial speech because it may affect sales, i.e., if the two parts are inextricably intertwined, the full protection of the First Amendment must be afforded to direct comment on public issues. Otherwise, the speaker would be selectively excluded from participating in a public discussion of an entire topic, an outcome precluded by the First Amendment.

I point out, however, that my reading of the controlling Supreme Court precedent is not shared by the Commission majority. The Commission majority (pp. 13-14) reasons as follows:
Although it may be difficult in some cases, the Commission thinks that it is possible to determine whether a specific advertisement that includes information connected to public issues nonetheless addresses the concerns of a purchaser of the advertiser's product or service. To conclude otherwise would allow sellers of certain products to avoid the proscription against false and misleading advertising merely by linking their product to a public issue.

Note that the Commission majority uses the words "whether" and "nonetheless." In the view of the Commission majority, a communication that "addresses the concerns of a purchaser of the advertiser's product or service" can never be fully protected speech, no matter how close the link between the public issue addressed and the potential commercial effect that may arise because the communication deals in part with a characteristic of the speaker's product or service of interest to consumers. Under the Commission majority's analysis, a product manufacturer loses its fully protected right to engage in debate over a matter of public concern whenever the public issue is the manufacturer's product.

On this critical issue, the Commission majority and I part company. On my reading of the controlling Supreme Court precedent, a product manufacturer cannot be selectively excluded from participating in a public discussion of an entire topic. I conclude that product manufacturers, like everyone else, "enjoy the full panoply of First Amendment protection for their direct comments on public issues," Central Hudson, supra, at 563 n. 5; that they cannot be singled out for "[s]elective exclusions from a public forum ... based on content alone ... [or] justified by reference to content alone," Police Department of Chicago v. Mosely, supra, at 96; that they cannot be barred from "public discussion of an entire topic," Consolidated Edison Co. v. Public Service Commission, supra, at 537; and that this full First Amendment protection is not lost unless the consequence would be to allow a product manufacturer "to immunize false or misleading product information from government regulation simply by including references to public issues." Bolger, supra, at 68 (emphasis supplied).

III. CHARACTERIZATION OF THE RJR COMMUNICATION

***18** RJR's "Of Cigarettes and Science" does not come within either of the two Supreme Court definitions of commercial advertising. It does more far more than propose a commercial transaction. It does not relate solely to the economic interest of the speaker and its audience.

Nor would regulation of the RJR piece come within the rationales provided for the commercial speech distinction. The verifiability rationale does not apply because the claims made in "Of Cigarettes and Science" do not address an aspect of cigarettes uniquely within the knowledge of RJR. Since the MR FIT study was not conducted by RJR, others can determine as readily as RJR whether the statements in "Of Cigarettes and Science" are truthful. [21] Nor does the hardiness rationale apply. Since the subject matter discussed by RJR is a matter of public concern, this type of speech by RJR is particularly susceptible to being crushed by regulation. Noncommercial speech by a firm such as RJR about public issues related to its products may well be chilled by discriminatory governmental regulation or by the threat of expensive investigations or litigation. Indeed, RJR terminated its entire series of editorial-like communications once the FTC began this proceeding.

In addition to not fitting within the definitions or the rationales of commercial speech, the RJR communication does not fit within the three Bolger criteria. Although RJR undoubtedly had an economic motivation in paying for its publication, "Of Cigarettes and Science" is hardly an advertisement in the ordinary sense of that word; [22] indeed, it refers only to a generic rather than a particular product. [23]

Even if "Of Cigarettes and Science" affects the sales of cigarettes, there is no question that it is also a direct comment on a matter of public concern. [24] The question thus arises whether "Of Cigarettes and Science" gratuitously invokes a matter of public concern. The answer is clear. There is no gratuitous link. The effect of cigarettes on health is itself the issue of public concern. RJR cannot possibly make its argument about the correct conclusions to be drawn from MR FIT without at the same time discussing an attribute of cigarette smoking of concern to purchasers of its product.

If RJR is not permitted to publish a piece such as "Of Cigarettes and Science" without the fear of government censorship, then there is simply no way for RJR to engage effectively in the debate over cigarette smoking and health free from governmental oversight determining the truth or falsity of RJR's arguments. [25] RJR cannot argue about the lack of conclusiveness of scientific evidence without at the same time potentially influencing consumers' purchase decisions.

Virtually every other person and corporation in America is free to participate in the debate about cigarette smoking and health, without government evaluation whether their claims are true or false. Whether or not RJR's participation in the debate is "unfair or deceptive," its speech challenged by this proceeding is undoubtedly a part of the contest of ideas. Under the First Amendment, RJR cannot be selectively excluded from participating in that debate merely because it produces cigarettes.

***19** Since "Of Cigarettes and Science" is a direct comment on a public issue, RJR cannot, consistent with the First Amendment, be precluded from publishing that comment. Can anyone doubt that a Congressional ban on all cigarette advertising [26] could not constitutionally be applied to the type of statement at issue in this case? And if Congress cannot ban such a communication, how can the Federal Trade Commission regulate its content?

Consider the ironic result if "Of Cigarettes and Science" were held to be commercial speech. In that event, the RJR communication would be deemed to be a cigarette advertisement. As such, it would have to carry one of the four Surgeon General rotational health warnings. [27] Thus, an RJR editorial arguing that there is lack of definitive evidence on smoking and heart disease would have to be accompanied by a governmentally mandated warning that "Smoking Causes ... Heart Disease ..."

Quite simply, this case involves attempted federal regulation of the content of a communication that engages in a debate over ideas. RJR is forced to undergo this proceeding in part because it has the temerity to argue, in the words of the Commission's complaint, that "[a] major government study about smoking and coronary heart disease

(the MR FIT study) provides credible scientific evidence that smoking is not as hazardous as the public or the reader has been led to believe ..." [28] RJR is in a distinct minority. It has challenged the official position taken by the Surgeon General and the United States Congress. RJR may be wrong. But on my reading of the Constitution, that determination is to be made by each individual, not by the government.

IV. THE MAJORITY'S BASES FOR NOT DISMISSING THE COMPLAINT

A. Propriety of Postponing a Ruling on Jurisdiction

Although this case in on appeal from an Administrative Law Judge's determination that the Commission lacks subject matter jurisdiction because the communication is fully protected speech, the majority has declined to determine whether the RJR communication is commercial speech or noncommercial speech. Postponing a ruling on the determinative First Amendment question might be understandable (even if wrong) if the majority had determined that further discovery were necessary before the Commission could make such a ruling. The Commission majority has not, however, made any such determination. Absent a holding that the Commission needs more evidence to decide whether the communication is commercial speech, the majority has no justifiable basis for not ruling on that issue.

The apparent explanation for the majority's action (or inaction) is their assertion: "Accepting the allegations of the complaint concerning jurisdiction as true for purposes of this appeal, the content of the Reynolds advertisement includes words and messages that are characteristic of commercial speech." (p. 15, citation omitted) This explanation, however, provides no basis for not ruling on the commercial speech question. The complaint's allegations referred to by the majority discuss facts that are apparent from the face of the RJR communication itself. Since the RJR communication is itself attached to and incorporated within the complaint, the complaint by itself, under the majority's own reasoning, provides a full basis for ruling on the question of commercial versus noncommercial speech.

***20** Consider the complaint allegations cited by the majority. First, the majority cites the complaint for the proposition that RJR's communication "refers to a specific product, cigarettes" and "discusses an important product attribute the alleged connection between smoking and heart disease." (p. 15) These facts are apparent from the face of the communication. Second, the majority states: "the Complaint alleges that 'Of Cigarettes and Science' is an advertisement (Complaint ¶ 2), which we understand to mean a notice or announcement that is publicly published or broadcast and is paid-for." (pp. 15-16) The communication evidences on its face that it was publicly published. RJR's name at the bottom of the communication indicates that the communication was paid for by RJR. Finally, the majority states: "the Complaint alleges that Respondent is in the business of selling cigarettes." The communication itself reveals that it was presented by R.J. Reynolds Tobacco Company; the name and the content of the communication indicate that RJR is in the business of selling cigarettes.

On the basis of the complaint allegations cited above, the majority asserts, "the content of the Reynolds advertisement includes words and messages that are characteristic of commercial speech." Having made this determination, the Commission majority must logically conclude that the communication is commercial speech unless (1) there is some step between having the characteristics of commercial speech and being commercial speech or (2) there is a possible characteristic of a communication that will cause it be fully protected even though it also has the characteristics of commercial speech. Since the Commission majority has already excluded the second possibility, [29] only the first possibility could possibly remain. As to that possibility, I can only ask: what step could there be between having the characteristics of commercial speech and being commercial speech? As I read the complaint and the majority opinion, the Commission majority has, whether it realizes it or not, already concluded that the communication is commercial speech.

B. Propriety of Further Discovery

As a means of possibly garnering additional support for a finding that the Commission has subject matter jurisdiction, the majority has instructed the Administrative Law Judge to permit further discovery. The further discovery suggested by the majority is irrelevant. Accordingly, such discovery itself would be an unjustifiable burden on RJR's exercise of the First Amendment rights.

The Commission majority suggests two lines of discovery. The first line relates to the publication itself (p. 20):
Evidence that may be relevant to deciding whether the Reynolds advertisement is commercial speech includes facts concerning the publication or dissemination of the advertisement, such as whether it was paid-for, where and in which publications it was disseminated, whether it was placed in editorial space (such as an op-ed page) or advertising space in the publication, whether it was prepared as a letter to the editor, whether it was sent to representatives of the media for selection on merit by editorial boards, and to whom it was disseminated outside the media.

***21** No discovery is necessary or relevant regarding background information of this type.[30] From the face of the publication, it is self-evident where it was published. The communication was not on an opened page nor a “letter to the editor.” Since RJR's name appears at the bottom of the communication, the indication is that RJR paid for the publication. Whether the communication “was disseminated outside the media” is irrelevant. If the communication as published is commercial speech, it does not become any less so by virtue of having been disseminated outside the media. If the communication as published is not commercial speech, dissemination outside the media would not provide a basis for Commission action because such dissemination is not alleged in the complaint.

The second line of discovery suggested by the majority relates to RJR's intent in publishing the communication. (p. 20-21):
Evidence about the promotional nature of the advertisement also may be relevant. Therefore, it might be useful to consider the circumstances surrounding the development of the advertisement, such as whether it was targeted to consumers or legislators; whether it was intended to affect demand for Reynolds' cigarettes or brands or to affect particular legislative or regulatory proposals; whether the advertisement was subjected to copy testing or to review by focus groups and, if so, the nature of the questions used in the copy tests or focus group sessions; and the results of those procedures both in terms of what they showed and what changes, if any, Reynolds made in response to those showings. Evidence relating to the message(s) Reynolds itself intended to convey through the advertisement also may be relevant. In addition, Reynolds' share of the cigarette market may be relevant to deciding whether including a brand name reference is a prerequisite to a determination that the advertisement constitutes commercial speech.

In deciding whether a publication is commercial speech, the Supreme Court has never looked to the subjective intent of the speaker.[31] Objective standards are essential. Otherwise, there will be a chilling of fully protected speech. If the Commission cannot determine from the face of a publication that it is commercial speech, it has no basis for challenging such a publication. A fishing expedition to determine the subjective intent of particular RJR employees would impose an unjustifiable burden on RJR and chill its right to engage in free speech.

V. CONCLUSION

R.J. Reynolds has full First Amendment rights for its direct comments on public issues. “Of Cigarettes and Science” is patently direct comment on a public issue. In this case, it is precisely the product that is the public issue. Discussion of the health consequences of smoking can hardly be labeled a mere gratuitous linking of a

product with a current public debate.[32] If corporations have full First Amendment rights they must be allowed to participate in the public debate about issues involving their products, at least in an editorial format. Effectively removing a company from a debate by contending that its message about its product is deceptive would infringe on its basic constitutional rights. In such a public debate the decision regarding truth and falsity must be made by the public, not the government. This is particularly true when the government itself has taken a public position and established its own orthodoxy. Having done so, it cannot then prohibit challenges to the governmentally approved version of the truth.

***22** Publication of RJR's communication may or may not have an effect on cigarettes sales and such an effect may or may not have been intended. In my view, that is irrelevant. Extrinsic evidence of RJR's intentions is not needed to decide whether this communication is fully protected. It is, on its face, direct comment on a public issue and not commercial speech. To conclude otherwise would turn a common-sense distinction into an intrusive inquiry into facts about the motives of the speaker. If the editorial is deceptive, or not believable, or runs counter to other information on the health question that the public is aware of, consumers are free to reject the message in the editorial. But it is critical for First Amendment purposes that the public, and not the government, decide the answer to this question. To conclude otherwise would erode First Amendment protection by extending the commercial speech doctrine into areas traditionally thought to be fully protected. Governmental inquiry into the motives of the speaker to determine if his views are to be constitutionally protected seems to me completely antithetical to the goals the First Amendment as intended to further. I would affirm the Administrative Law Judge and dismiss the complaint.

EXHIBIT 1

***23** Of cigarettes and science.

This is the way science is supposed to work.

A scientist observes a certain set of facts. To explain these facts, the scientist comes up with a theory.

Then, to check the validity of the theory, the scientist performs an experiment. If the experiment yields positive results, and is duplicated by other scientists, then the theory is supported. If the experiment produces negative results, the theory is re-examined, modified or discarded.

But, to a scientist, both positive and negative results should be important. Because both produce valuable learning.

Now let's talk about cigarettes.

You probably know about research that links smoking to certain diseases. Coronary heart disease is one of them.

Much of this evidence consists of studies that show a statistical association between smoking and the disease.

But statistics themselves cannot explain why smoking and heart disease are associated. Thus, scientists have developed a theory: that heart disease is caused by smoking. Then they performed various experiments to check this theory.

We would like to tell you about one of the most important of these experiments.

A little-known study

It was called the Multiple Risk Factor Intervention Trial (MRFIT).

In the words of the Wall Street Journal, it was “one of the largest medical experiments ever attempted.” Funded by the Federal government, it cost $115,000,000 and took 10 years, ending in 1982.

The subjects were over 12,000 men who were thought to have a high risk of heart disease because of three risk factors that are statistically associated with this disease: smoking, high blood pressure and high cholesterol levels.

Half of the men received no special medical intervention. The other half received medical treatment that consistently reduced all three risk factors, compared with the first group.

It was assumed that the group with lower risk factors would, over time, suffer significantly fewer deaths from heart disease than the higher risk factor group.

But that is not the way it turned out.

After 10 years, there was no statistically significant difference between the two groups in the number of heart disease deaths.

The theory persists

We at R.J. Reynolds do not claim this study proves that smoking doesn't cause heart disease. But we do wish to make a point.

Despite the results of MR FIT and other experiments like it, many scientists have not abandoned or modified their original theory, or re-examined its assumptions.

They continue to believe these factors cause heart disease. But it is important to label their belief accurately. It is an opinion. A judgment. But not scientific fact.

We believe in science. That is why we continue to provide funding for independent research into smoking and health.

But we do not believe there should be one set of scientific principles for the whole world, and a different set for experiments involving cigarettes. Science is science. Proof is proof. That is why the controversy over smoking and health remains an open one.

***24** R.J. Reynolds Tobacco Company

EXHIBIT 2-A

Can we have an open debate about smoking?

The issues that surround smoking are so complex, and so emotional, it's hard to debate them objectively.

In fact, many of you probably believe there is nothing to debate.

Over the years, you've heard so many negative reports about smoking and health and so little to challenge these reports that you may assume the case against smoking is closed.

But this is far from the truth.

Studies which conclude that smoking causes disease have regularly ignored significant evidence to the contrary. These scientific findings come from research completely independent of the tobacco industry.

We at R.J. Reynolds think you will find such evidence very interesting. Because we think reasonable people who analyze it may come to see this issue not as a closed case, but as an open controversy.

We know some of you may be suspicious of what we'll say, simply because we're a cigarette company.

We know some of you may question our motives.

But we also know that by keeping silent, we've contributed to this climate of doubt and distrust. We may also have created the mistaken impression that we have nothing to say on these issues.

That is why we've decided to speak out now, and why we intend to continue speaking out in the future.

During the coming months we will discuss a number of key questions relating to smoking and health. We will also explore other important issues including relations between smokers and non-smokers, smoking among our youth, and “passive smoking.”

Some of the things we say may surprise you. Even the fact that we say them may prove controversial.

But we won't shy away from the controversy because, quite frankly, that's our whole point.

We don't say there are no questions about smoking. Just the opposite. We say there are lots of questions but, as yet, no simple answers.

Like any controversy, this one has more than one side. We hope the debate will be an open one.

R.J. Reynolds Tobacco Company

EXHIBIT-2B

What not to do in bed.

You can read.

You can rest.

You can sleep.

You can make phone calls.

You can eat breakfast.

You can watch television.

You can listen to music.

You can exercise.

You can snore.

You can even eat crackers provided you're alone.

And yes, you can snuggle.

But don't ever light up a cigarette when you're in bed.

Because if you doze off just once, all your dreams can go up in smoke.

R.J. Reynolds Tobacco Company

EXHIBIT 2-C

A message from those who don't to those who do.

We're uncomfortable.

To us, the smoke from your cigarettes can be anything from a minor nuisance to a real annoyance.

We're frustrated.

Even though we've chosen not to smoke, we're exposed to second-hand smoke anyway.

We feel a little powerless.

Because you can invade our privacy without even trying. Often without noticing.

***25** And sometimes when we speak up and let you know how we feel, you react as though we were the bad guys.

We're not fanatics. We're not out to deprive you of something you enjoy. We don't want to be your enemies.

We just wish you'd be more considerate and responsible about how, when, and where you smoke.

We know you've got rights and feelings. We just want you to respect our rights and feelings, as well.

A message from those who do to those who don't.

We're on the spot.

Smoking is something we consider to be a very personal choice, yet it's become a very public issue.

We're confused.

Smoking is something that gives us enjoyment, but it gives you offense.

We feel singled out.

We're doing something perfectly legal, yet we're often segregated, discriminated against, even legislated against.

Total strangers feel free to abuse us verbally in public without warning.

We're not criminals. We don't mean to bother or offend you. And we don't like confrontations with you.

We're just doing something we enjoy, and trying to understand your concerns.

We know you've got rights and feelings. We just want you to respect our rights and feelings, as well.

Brought to you in the interest of common courtesy by

R.J. Reynolds Tobacco Company

EXHIBIT 2-D

Smoking in public:

Let's separate fact

from friction.

There has always been some friction between smokers and non-smokers. But lately this friction has grown more heated.

The controversy has been fueled by questionable reports which claim that “second-hand smoke” is a cause of serious diseases among non-smokers.

But, in fact, there is little evidence and certainly nothing which proves scientifically that cigarette smoke causes disease in non-smokers.

Skeptics might call this the wishful thinking of a tobacco company. But consider the scientific judgment of some of the leading authorities in the field including outspoken critics of smoking.

For example, in 1983 the organizer of an international conference on environmental tobacco smoke (ETS) summarized the evidence on lung cancer as follows: “An overall evaluation based upon available scientific data leads to the conclusion that an increased risk for non-smokers from ETS exposure has not been established.”

Even the chief statistician of the American Cancer Society, Lawrence Garfinkel, has gone on record as saying, “passive smoking may be a political matter, but it is not a main issue in terms of health policy.”

Which brings us back to our original point: cigarette smoke can be very annoying to non-smokers.

But how shall we as a society deal with this problem?

Confrontation? Segregation? Legislation?

No. We think annoyance is neither a governmental problem nor a medical problem. It's a people problem.

Smokers and non-smokers have to talk to one another. Not yell, preach, threaten, badger or bully. Talk.

Smokers can help by being more considerate and responsible. Non-smokers can help by being more tolerant. And both groups can help by showing more respect for each other's rights and feelings.

***26** But eliminating rumor and rhetoric will help most of all.

Because when you stick to the facts, it's a lot easier to deal with the friction.

R.J. Reynolds Tobacco Company

EXHIBIT 2-E

We don't advertise to children.

Who are you kidding?

The newspapers and magazines and billboards are filled with cigarette ads. Kids can't help but see them.

How can you expect us to believe you're not trying to reach and influence our children?

We're not surprised if many people feel this way especially when years of negative publicity have made them totally cynical about our industry.

Nevertheless, we'd like to set the record straight.

First of all, we don't want young people to smoke. And we're running ads aimed specifically at young people advising them that we think smoking is strictly for adults.

Second, research shows that among all the factors that can influence a young person to start smoking, advertising is insignificant. Kids just don't pay attention to cigarette ads, and that's exactly as it should be.

Finally and this is sometimes hard for people outside the marketing field to understand all of our cigarette ads are what we call “brand advertising.” Its purpose is to get smokers of competitive products to switch to one of our brands, and to build the loyalty of those who already smoke one of our brands.

At the present there are some 200 different cigarette brands for sale in the U.S. Many of them have only a very small fraction of the total cigarette market. Getting smokers to switch is virtually the only way a cigarette brand can meaningfully increase its business.

That's why we don't advertise to young people.

Of course, if you'd like to share this ad with your children, that would be just fine with us.

R.J. Reynolds Tobacco Company

EXHIBIT 2-F

Second-Hand Smoke:

The Myth

and The Reality.

Many non-smokers are annoyed by cigarette smoke. This is a reality that's been with us for a long time.

Lately, however, many non-smokers have come to believe that cigarette smoke in the air can actually cause disease.

But, in fact, there is little evidence and certainly nothing which proves scientifically that cigarette smoke causes disease in non-smokers.

We know this statement may seem biased. But it is supported by findings and views of independent scientists including some of the tobacco industry's biggest critics.

Lawrence Garfinkel of the American Cancer Society, for example. Mr. Garfinkel, who is the Society's chief statistician, published a study in 1981 covering over 175,000 people, and reported that “passive smoking” had “very little, if any” effect on lung cancer rates among non-smokers.

You may have seen reports stating that in the course of an evening, a non-smoker could breathe in an amount of smoke equivalent to several cigarettes or more.

But a scientific study by the Harvard School of Public Health, conducted in various public places, found that non-smokers might inhale anywhere from 1/1000th to 1/100th of one filter cigarette per hour. At that rate, it would take you at least 4 days to inhale the equivalent of a single cigarette.

***27** Often our own concerns about our health can take an unproven claim and magnify it out of all proportion; so, what begins as a misconception turns into a frightening myth.

Is “second-hand smoke” one of these myths? We hope the information we've offered will help you sort out some of the realities.

R.J. Reynolds Tobacco Company

EXHIBIT 2-G

Second-hand smoke:

Let's clear the air.

Can cigarette smoke in the air cause disease in non-smokers?

That's an emotional question for smokers and non-smokers alike. So we'll try to set the record straight in the most direct way we know.

There is little evidence and certainly nothing which proves scientifically that cigarette smoke causes disease among non-smokers.

You don't have to take our word for it.

U.S. Surgeon General Julius B. Richmond who was no friend of smoking said in his 1979 Report: “Healthy non-smokers exposed to cigarette smoke have little or no physiologic response to the smoke, and what response does occur may be due to psychological factors.”

And in the 1982 Report, Surgeon General C. Everett Koop could not conclude that passive smoking is a cause of cancer in non-smokers.

The director of the National Heart, Lung and Blood Institute, Dr. Claude Lenfant, has been one of the tobacco industry's sharpest critics. Yet Dr. Lenfant stated in 1980 (and we believe it remains true today) that “the evidence that passive smoking in a general environment has health effects remains sparse, incomplete and sometimes unconvincing.”

We've decided to speak out on passive smoking because there is so much rumor and rhetoric on this subject today. And we intend to continue, from time to time, to speak out on other topics of concern to you and to us.

Our critics may try to discredit these messages as self-serving. In a sense, they will be right. We will challenge allegations that are unproven and attacks we think are unfounded. If that is self-serving, so be it.

The questions that surround smoking raise many important issues. We believe that you're entitled to hear all sides of these controversies.

R.J. Reynolds Tobacco Company

EXHIBIT 2-H

How to handle

peer pressure.

If some of your friends smoke, and they make you feel like you should smoke, too, that's “peer pressure.”

But even though we're a cigarette company, we think young people shouldn't smoke. Even the decision to smoke or not to smoke should wait until you're an adult.

So we put together these ideas to help you recognize peer pressure and resist it.
Tactic # 1: Go ahead and take a puff what's the matter, are you chicken?

Answer: You must think I'm pretty dumb to fall for that one. It takes a lot more guts to do your own thing than to just go along with the crowd.

Tactic # 2: Come on, all the cool kids smoke.

Answer: Maybe the kids who smoke are trying to look cool. But if they really were cool, maybe they wouldn't have to try so hard.

***28** Tactic # 3: Hey, I'm your friend would I steer you wrong?

Answer: Friends are people who like you for who you are, not for what they want you to be. If you're really my friend, back off.

Tactic # 4: Do you want everybody to think you're a nerd?

Answer: Sure I care what other kids think of me. But if they base their opinions on stuff like smoking, their opinions aren't worth much.

Tactic # 5: I bet you're just scared your parents will find out.

Answer: I wouldn't blame my parents for getting teed off. How can I expect them to treat me like an adult if I sneak around and act like a kid?

It's natural for you to want to be just like your friends.

But if you don't smoke, maybe your friends will want to be just like you.

R.J. Reynolds Tobacco Company

EXHIBIT 2-I

Some surprising advice to young people from R.J. Reynolds Tobacco.

Don't smoke.

For one thing, smoking has always been an adult custom. And even for adults, smoking has become very controversial.

So even though we're a tobacco company, we don't think it's a good idea for young people to smoke.

Now, we know that giving this kind of advice to young people can sometimes backfire.

But if you take up smoking just to prove you're an adult, you're really proving just the opposite.

Because deciding to smoke or not to smoke is something you should do when you don't have anything to prove.

Think it over.

After all, you may not be old enough to smoke. But you're old enough to think.

R.J. Reynolds Tobacco Company

EXHIBIT 2-J

Passive smoking:

An active controversy.

Periodically the public hears about an individual scientific study which claims to show that “environmental tobacco smoke” (ETS) may be harmful to non-smokers. These reports usually receive sensational media coverage.

Yet, three times within two years, groups of distinguished experts have gathered to review not just one study but the whole body of evidence on this subject. In all three cases, the scientists came to similar and far less sensational conclusions.

Yet the media have remained almost silent.

In March 1983 there was the “Second Workshop on Environmental Tobacco Smoke” in Geneva, Switzerland. In May 1983 there was the “Workshop on Respiratory Effects of Involuntary Smoke Exposure” in Bethesda, Maryland.

And, most recently, in April 1984, leading experts from around the world gathered in Vienna for a symposium, “Passive Smoking from a Medical Point of View.”

After this symposium was over, the presidents of the two organizing groups issued a press release summarizing their findings.

The summary said, “the connection between [ETS] and lung cancer has not been scientifically established to date.” It also said “there is a high probability that cardiovascular damage due to [ETS] can be ruled out in healthy people.”

And it went on to say, “Should law-makers wish to take legislative measures with regard to [ETS], they will, for the present, not be able to base their efforts on a demonstrated health hazard from [ETS].”

***29** Perhaps the media would say they cannot be blamed for devoting little attention to what some would consider “non-news.” But we at R.J. Reynolds are concerned about the effects such one-sided coverage may be having on the public.

For today, many non-smokers who once saw cigarette smoke merely as an annoyance now view it as a threat to their health. Their growing alarm is being translated into heightened social strife and unfair anti-smoker legislation.

We believe these actions are unwarranted by the scientific facts and that it is rhetoric, more than research, which makes passive smoking an active controversy.

R.J. Reynolds Tobacco Company

EXHIBIT 2-K

Of cigarettes and science.

This is the way science is supposed to work.

A scientist observes a certain set of facts. To explain these facts, the scientist comes up with a theory.

Then, to check the validity of the theory, the scientist performs an experiment. If the experiment yields positive results, and is duplicated by other scientists, then the theory is supported. If the experiment produces negative results, the theory is re-examined, modified or discarded.

But, to a scientist, both positive and negative results should be important. Because both produce valuable learning.

Now let's talk about cigarettes.

You probably know about research that links smoking to certain diseases. Coronary heart disease is one of them.

Much of this evidence consists of studies that show a statistical association between smoking and the disease.

But statistics themselves cannot explain why smoking and heart disease are associated. Thus, scientists have developed a theory: that heart disease is caused by smoking. Then they performed various experiments to check this theory.

We would like to tell you about one of the most important of these experiments.

A little-known study

It was called the Multiple Risk Factor Intervention Trial (MRFIT).

In the words of the Wall Street Journal, it was “one of the largest medical experiments ever attempted.” Funded by the Federal government, it cost $115,000,000 and took 10 years, ending in 1982.

The subjects were over 12,000 men who were thought to have a high risk of heart disease because of three risk factors that are statistically associated with this disease: smoking, high blood pressure and high cholesterol levels.

Half of the men received no special medical intervention. The other half received medical treatment that consistently reduced all three risk factors, compared with the first group.

It was assumed that the group with lower risk factors would, over time, suffer significantly fewer deaths from heart disease than the higher risk factor group.

But that is not the way it turned out.

After 10 years, there was no statistically significant difference between the two groups in the number of heart disease deaths.

The theory persists

We at R.J. Reynolds do not claim this study proves that smoking doesn't cause heart disease. But we do wish to make a point.

***30** Despite the results of MRFIT and other experiments like it, many scientists have not abandoned or modified their original theory, or re-examined its assumptions.

They continue to believe these factors cause heart disease. But it is important to label their belief accurately. It is an opinion. A judgment. But not scientific fact.

We believe in science. That is why we continue to provide funding for independent research into smoking and health.

But we do not believe there should be one set of scientific principles for the whole world, and a different set for experiments involving cigarettes. Science is science. Proof is proof. That is why the controversy over smoking and health remains an open one.

R.J. Reynolds Tobacco Company

EXHIBIT 2-L

Smoking in public:

A radical proposal.

These days the level of social discourse between smokers and non-smokers is approaching that of a tag-team wrestling match.

While some people try to solve this problem through segregation or confrontation, we at R.J. Reynolds have been proposing a more daring solution: greater courtesy.

For these outlandish views we might be called dreamers and cockeyed optimists. But we continue to believe in the power of politeness to change the world.

We can almost imagine how it might begin.

A smoker is about to light a cigarette in public. He pauses in mid-match, suddenly conscious of the non-smoker next to him. Bracing himself for a hostile response, he asks, “Excuse me, do you mind if I smoke?”

The non-smoker is momentarily stunned by this unexpected act of courtesy. She stifles several witty replies that leap to mind; she cannot let his politeness go unchallenged. “I don't mind,” she answers, “as long as you don't let your smoke blow in my face.”

Her flagrant tolerance puts the smoker on the defensive. But he tries to regain the upper hand. “I'll do my best,” he responds. “Let me know if the smoke bothers you.”

A deft comeback. But the non-smoker presses her attack: “I will and thanks for asking.” Not to be outdone, the smoker brazenly replies, “Thanks for being so understanding.”

An unlikely dialogue? Perhaps. But, who knows? If this sort of thing ever caught on, it might lead to a sudden outbreak of civil decency. Or even escalate into full-scale friendliness.

Common courtesy. It's just crazy enough, it might work.

Brought to you in the interest of common courtesy by

R.J. Reynolds Tobacco Company

EXHIBIT 2-M

The most inflammatory question of our time.

“Hey, would you put out that cigarette?”

Just seven little words. But in today's over-heated climate of opinion, they can make sparks fly.

For with all the rhetoric about “second-hand smoke,” many non-smokers are beginning to feel not just bothered but threatened by cigarettes.

And with all the talk about anti-smoking legislation, many smokers are beginning to feel threatened by non-smokers.

***31** This is not exactly a recipe for social harmony. In fact, it's practically a guarantee of further discord.

Since we have discussed scientific aspects of the “passive smoking” controversy in previous messages, we'd like to focus here on the social questions.

Will more confrontation or more segregation produce less abrasion? Do we solve anything by creating yet another way to divide our society? Shouldn't all of us be wary of inviting government to involve itself further in our private lives?

At R.J. Reynolds, we see an alternative.

We think we should start not by raising barriers, but by lowering our voices. We think smokers and non-smokers can work out their differences together, in a spirit of tolerance and fairness and respect for each other's rights and feelings. We think common courtesy can succeed where coercion is bound to fail.

And maybe, after we have learned peaceful coexistence by talking to each other civilly and sensibly, we can apply the same approach to our many other problems.

Because, after all, this is hardly the most inflammatory question of our time.

Brought to you in the interest of common courtesy by

R.J. Reynolds Tobacco Company

EXHIBIT 2-N

Does smoking really make you look more grown up?

It's a crazy world.

Most adults we know would love to look younger than they really are. While most young people are busy trying to look more adult.

This is one reason why many young people take up smoking.

Well, we wish they wouldn't.

For one thing, it doesn't work. A fifteen-year-old smoking a cigarette looks like nothing more or less than a fifteen-year-old smoking a cigarette.

Even though we're a tobacco company, we don't think young people should smoke. There is plenty of time later on to think about whether or not smoking is right for you.

Besides, when you think about it, being grown up is highly overrated. You have to go to work, pay taxes, wear normal clothes and raise kids who grow up to be teenagers.

Why be in such a hurry?

R.J. Reynolds Tobacco Company

EXHIBIT 2-O

The second-hand smokescreen.

For decades, public and private organizations have waged a massive campaign to discourage cigarette smoking. For most of that time, the target of this effort has been the smoker.

Recently, however, the emphasis has undergone a major shift. Today there are scientists who claim that cigarette smoke in the air can actually cause disease in non-smokers. We hear a great deal about “second-hand smoke” and “passive smoking.”

But is this new approach wholly motivated by concern for the non-smoker, or is it the same old war on smoking in a new guise?

These doubts are raised when we recall statements like the following, by a spokesperson for the American Lung Association:
Probably the only way we can win a substantial reduction [in smoking] is if we can somehow make it nonacceptable socially.... We thought the scare of medical statistics and opinions would produce a major reduction. It really didn't.

***32** Obviously, one way to make smoking “nonacceptable socially” would be to suggest that second-hand smoke could cause disease. So it is not surprising that we are now seeing a flurry of research seeking scientific support for these suggestions.

Many independent experts believe the scientific evidence on passive smoking is questionable. But a zealous group of anti-smokers are using this issue in their campaign against tobacco as if the claims were established scientific fact.

We deplore the actions of those who try to manipulate public opinion through scare tactics. As the late, respected pathologist, Dr. H. Russell Fisher, stated in testimony submitted to a Congressional hearing on passive smoking:
... [I]n the absence of any scientific proof of harm from atmospheric tobacco smoke, we are dealing with a social question and not a medical one. In this regard it should be noted that, since fears and phobias can lead to ill health,

those who urge policies based on fear and not scientific facts could be making a medical problem out of a social one. This is indeed a strange prospect to see coming from the efforts of members of the medical profession.

We are not ignoring the fact that cigarette smoke can be bothersome to many non-smokers. But we believe this problem is best solved not by governments but by individuals, and not with more rhetoric but more common sense and courtesy.

Of course, if anti-smoking advocates want to work for the abolition of smoking, that is their right. We only wish they would come out from behind their second-hand smokescreen.

R.J. Reynolds Tobacco Company

EXHIBIT 2-P

Some straight talk about smoking for young people.

We're R.J. Reynolds Tobacco, and we're urging you not to smoke.

We're saying this because, throughout the world, smoking has always been an adult custom. And because today, even among adults, smoking is controversial.

Your first reaction might be to ignore this advice. Maybe you feel we're talking to you as if you were a child. And you probably don't think of yourself that way.

But just because you're no longer a child doesn't mean you're already an adult. And if you take up smoking just to prove you're not a kid, you're kidding yourself.

So please don't smoke. You'll have plenty of time as an adult to decide whether smoking is right for you.

That's about as straight as we can put it.

R.J. Reynolds Tobacco Company

EXHIBIT 2-Q

Workplace smoking restrictions:

A trend that never was.

Reports in the news media may have given you the impression that restrictive corporate smoking policies are the wave of the future.

But, when the facts are analyzed, the wave shrinks to just a ripple.

Today, most of corporate America continues to rely on the common sense and common courtesy of employees not on formal policy to resolve differences arising out of smoking in the workplace.

This is the key finding of a major new survey of America's leading companies. The survey, commissioned by the Tobacco Institute and completed early in 1985, was conducted by the Human Resources Policy Corporation of Los Angeles among the Fortune 1000 service and industrial companies and Inc. magazine's 100 fastest-growing companies.

***33** Only about one-third of the responding companies said they had any official smoking guidelines in effect. Furthermore, the reasons most frequently given centered around common-sense situations where workers dealt with hazardous substances, sensitive equipment or food. And almost half of these policies had been in effect for over five years.

Two-thirds of the companies reported they prefer to encourage individual workers to settle smoking issues with mutual respect for each other's legitimate rights and feelings.

We at R.J. Reynolds think this is not just common sense, but good business. Because it also gives managers the flexibility they need to make decisions in the best interest of the company as a whole.

That's the way it's worked in the past. And we think it's the best blueprint for the future.

R.J. Reynolds Tobacco Company

EXHIBIT 2-R

Workplace smoking restrictions:

A trend that never was.

Reports in the news media may have given you the impression that restrictive corporate smoking policies are the wave of the future.

But, when the facts are analyzed, the wave shrinks to just a ripple.

Today, most of corporate America continues to rely on the common sense and common courtesy of employees not on formal policy to resolve differences arising out of smoking in the workplace.

This is the key finding of a major new survey of America's leading companies. The survey, commissioned by the Tobacco Institute and completed early in 1985, was conducted by the Human Resources Policy Corporation of Los Angeles among the top 1000 service and industrial companies ranked by Fortune magazine and Inc. magazine's 100 fastest-growing companies.

Only about one-third of the responding companies said they had any official smoking guidelines in effect. Furthermore, the reasons most frequently given centered around common-sense situations where workers dealt with hazardous substances, sensitive equipment or food. And almost half of these policies had been in effect for over five years.

Two-thirds of the companies reported they prefer to encourage individual workers to settle smoking issues with mutual respect for each other's legitimate rights and feelings.

We at R.J. Reynolds think this is not just common sense, but good business. Because it also gives managers the flexibility they need to make decisions in the best interest of the company as a whole.

That's the way it's worked in the past. And we think it's the best blueprint for the future.

R.J. Reynolds Tobacco Company

FTC

Footnotes

1 The motion also sought to stay further proceedings until after the motion was decided and to dismiss on the ground that Section 5 of the FTC Act violated the constitutional requirements of separation of powers. Motion to Dismiss, ¶ ¶ 2, 3. The ALJ denied respondent's motion on the separation of powers ground (Order, dated August 4, 1986), and the issue was not appealed. In light of the ALJ's order, which the Commission has found to be sufficient to constitute an initial decision, an order staying the proceeding was unnecessary and beyond the authority of the ALJ to grant or deny. Commission Order, dated August 8, 1986.

2 Reply Memorandum of Law of R.J. Reynolds Tobacco Co. in Support of its Motion to Dismiss Complaint and to Stay Proceedings Pending Dismissal at 2-10, 22-25 (July 21, 1986).

3 Memorandum of Law in Opposition to Respondent's Motion to Dismiss Complaint and to Stay Proceedings at 5-13 (July 17, 1986).

4 Palko v. Connecticut, 302 U.S. 319, 327 (1937) .

5 Until fairly recently, commercial speech was thought to be unprotected by the First Amendment. See Valentine v. Chrestensen, 316 U.S. 52 (1942). Beginning in the mid-1970's, the Court indicated that commercial speech was entitled to some constitutional protection. See Bigelow v. Virginia, 421 U.S. 809 (1975); Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations, 413 U.S. 376 (1973). In Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976), the Court expressly held that commercial speech was entitled to First Amendment protection.

6 One permitted category of content-based restriction consists of regulations that prohibit false or misleading commercial advertising. Because of its hardier nature, requiring truthfulness and accuracy for commercial speech runs less risk of self-censorship and, thus, there is "little need to sanction some falsehood in order to protect speech that matters." Virginia State Board of Pharmacy, 425 U.S. at 777-78 (Stewart, J., concurring) (citing Gertz v. Robert Welch, Inc., 418 U.S. 323 (1974)).

7 Bolger v. Youngs Drug Products illustrates how the Supreme Court has relied upon the factors discussed infra when the speech at issue does more than merely propose a commercial transaction, and in fact, discusses matters of important public interest. 463 U.S. at 66- 67. In analyzing the "Plain Facts About Venereal Disease" pamphlet, the Court indicated that the combined presence of three characteristics led it to characterize the pamphlet as commercial: (1) the speech was a paid-for advertisement; (2) it referred to a specific product; and (3) the advertisement was motivated by economic gain. Id. The Court stated, however, that it was not holding that each characteristic must be present in order to classify speech as commercial. Id. at 67 n. 14.

8 The Bolger Court expressed "no opinion as to whether reference to any particular product or service is a necessary element of commercial speech." 463 U.S. at 67 n. 14.

9 The Supreme Court found in Friedman that a trade name is a form of advertising because after the name has been used for some period of time, it conveys information about a certain quality of goods and services. 440 U.S. at 11.

10 Respondent contends that commercial speech includes only information about positive product characteristics and, thus, does not encompass speech that, for example, claims that a product is less dangerous than another product or is useful for the prevention of disease. See, e.g., Respondent's Answering Brief on Appeal at 25-26, 28-29; Abrams Tr. at 83-85. We disagree. Claims that a product or service is less dangerous than consumers perceive it to be are likely to be potent selling messages. Under respondent's standard, for example, any comparative cigarette tar and nicotine claim would constitute fully protected speech because it does not relate to any positive attribute of the advertised cigarette, but only to its (comparative) lack of harm. Compare FTC v. Brown & Williamson Tobacco Corp., 778 F.2d 35 (D.C.Cir.1985) (regulating deceptive tar claims as commercial speech).

11 The insurance industry advertisements at issue in Rutledge v. Liability Insurance Industry, 487 F.Supp. 5 (W.D .La.1979) and Quinn v. Aetna Life & Casualty Co., 616 F.2d 38 (2d Cir.1980) similarly can be distinguished.

Those advertisements urged the public to support limits on jury awards in tort liability actions. The advertisements did have a commercial aspect because insurance companies would benefit economically from reduced jury awards. However, the advertisements did not attempt to sell insurance nor did they contain factual information addressed to informed decision-making concerning consumers' purchases of insurance.

12 As noted above (supra at 4-5), under the standards applicable to motions to dismiss, the allegations of the complaint are presumed to be true. The factual allegations concerning jurisdiction include ¶ ¶ 2 and 4 of the complaint and the Reynolds advertisement, which is incorporated by reference as Attachment A. Similarly, whether an advertisement makes a claim is an issue of fact. See FTC v. Colgate-Palmolive Co., 380 U.S. 374, 386 (1965); Thompson Medical Co. v. FTC, 791 F.2d at 197. As a result, complaint ¶ ¶ 5 and 7 also contain factual allegations relating to jurisdiction.

13 The ALJ granted complaint counsel's motion for an additional 10 days in which to file a response to the motion to dismiss. We find that 10 days is not a reasonable opportunity for discovery. Nonetheless, complaint counsel did obtain and present an affidavit from Dr. Dennis L. McNeill. Attachment A to Complaint Counsel's Memorandum of Law in Opposition to Respondent's Motion to Dismiss and to Stay Proceedings. Respondent has not filed a response to the affidavit. We note simply at this stage of the proceeding that the unrebutted affidavit of Dr. McNeill is consistent with our finding that the ALJ erred when he granted respondent's motion to dismiss.

14 Land v. Dollar, 330 U.S. 731, 735 n. 4 (1947). See also 2A J. Moore, J. Lucas & G. Grotheer, Moore's Federal Practice, ¶ 12.07[2.-1] at 12-47 (2d ed. 1987); 4 J. Moore, J. Lucas & G. Grotheer, Moore's Federal Practice ¶ 26.56[6] at 26-154 (2d ed. 1987); 5 C. Wright & A. Miller, Federal Practice and Procedure § 1350 at 549 (1969); 8 C. Wright & A. Miller, Federal Practice and Procedure § 2009 (1970).

15 See Fed.R.Civ.P. 26(b)(1); Fed.R.Evid. 402. Although the Commission is an administrative agency which is not bound by the Federal Rules, the Commission has held that the Rules "can provide an analytical framework for the disposition of related issues." Crush International, Ltd., 80 F.T.C. 1023, 1028 (1972).

16 Like respondent, the defendants in Herbert v. Lando contended that permitting such discovery would chill their First Amendment rights. The Court disagreed, noting:

But if the claimed inhibition flows from the fear of damages liability for publishing knowing or reckless falsehoods, those effects are precisely what New York Times and other cases have held to be consistent with the First Amendment. Spreading false information in and of itself carries no First Amendment credentials.

441 U.S. at 171.

17 We recognize that Herbert v. Lando involved discovery of evidence relevant to proving the plaintiff's case in chief, while the issue presented here concerns discovery of evidence relevant to proving the preliminary issue of jurisdiction. Nonetheless, Rule 26(b)(1) clearly does not distinguish between information relevant to proving jurisdiction and evidence relevant to proving a party's cause of action. Further, in both situations, the plaintiff bears the burden of proof, and in both situations, failure to meet that burden requires dismissal of the proceeding.

18 The examples of relevant evidence discussed above are illustrative only and are not intended as an exclusive list of facts that may be relevant to the jurisdictional issue raised in this proceeding.

1 The Comprehensive Smoking Education Act, 15 U.S.C. §§ 1331 et seq., requires four health warnings to be affixed on a rotational basis to each pack of cigarettes and contained on a rotational basis in all cigarette advertising. The four warnings are:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

SURGEON GENERAL'S WARNING: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

2 This piece was one of a series introduced by RJR to discuss various smoking issues. RJR ceased the entire campaign when the complaint was issued. Abrams Aff. ¶ ¶ 6-8. The other communications are attached.

3 The majority states at page 9: "The Commission considers it premature, particularly in the absence of a full record, to say which characteristics will be determinative in deciding whether the Reynolds advertisement constitutes commercial speech." Later, at page 17, the opinion says: "We emphasize, however, that we have not concluded that presentation of extrinsic evidence is necessarily required for determining whether the Reynolds advertisement is commercial speech." Nonetheless, the majority finds that the ALJ did not allow a "reasonable opportunity for discovery" page 19, n. 14, and provides a list of the evidence that "may be relevant." Pages 20-21. The majority does not, however, suggest that resolution of the jurisdictional question must await resolution of the deception issues.

4 The Commission majority continually refers to the RJR communication as an "advertisement," a characterization that may, by itself, cause the majority to conclude that the RJR communication is commercial speech.

5 The Commission has alleged, however, that RJR misrepresented the purpose of the study.

6 Multiple Risk Factor Intervention Trial, 248 J.A.M.A. 1465 (1982).

7 The Commission has alleged that this analysis falsely or misleadingly represents that "[a] major government study about smoking and coronary heart disease (the MR FIT study) provides credible scientific evidence that smoking is not as hazardous as the public or the reader has been led to believe" and "[t]he MR FIT study, a major government study, tends to refute the theory that smoking causes coronary heart disease."

8 Initial Decision at 14. The Administrative Law Judge also allowed the parties to introduce evidence (affidavits were, in fact, submitted and received) and heard oral argument on the jurisdictional issue. Id. at 1, 15 n. 18, 16. In addition, at oral argument before the Administrative Law Judge complaint counsel agreed that Judge Hyun could decide the jurisdictional question on the basis of the record before him.

9 Initial Decision at 7. Order of Administrative Law Judge Montgomery K. Hyun.

10 See also Pittsburgh Press Co. v. Pittsburgh Commission on Human Relations, 413 U.S. 376, 391 (1973), rehearing denied, 414 U.S. 881 (1973) ("[N]othing in our holding allows government at any level to forbid Pittsburgh Press to publish and distribute advertisements commenting on the Ordinance, the enforcement practices of the Commission, or the propriety of sex preferences in employment."); Buckley v. Valeo, 424 U.S. 1, 16 (1976) ("Yet this Court has never suggested that the dependence of a communication on the expenditure of money operates itself to introduce a nonspeech element or to reduce the exacting scrutiny required by the First Amendment.")

11 Police Department of Chicago v. Mosely, 408 U.S. 92, 95 (1972). See also Consolidated Edison Co. v. Public Service Comm'n, 477 U.S. 530, 536 (1980) ("But when regulation is based on the content of speech, governmental action must be scrutinized more carefully to ensure that communication has not been prohibited 'merely because public officials disapprove the speaker's view's'." quoting Niemotko v. Maryland, 340 U.S. 268, 282 (1951) (Frankfurther, J., concurring in result).

12 Police Dept. of Chicago v. Mosely, supra, at 96.

13 Id.

14 Central Hudson Gas & Electric Corp. v. Public Service Comm'n, 477 U.S. 557, 582 (Stevens, J., concurring) (quoting Mr. Justice Brandeis in Whitney v. California, 272 U.S. 357, 376-77).

15 Central Hudson Gas & Electric Corp. v. Public Service Comm'n, 447 U.S. 557 (1980).

16 Ohralok v. Ohio State Bar Ass'n, 436 U.S. 447, 456 (1978), rehearing denied, 439 U.S. 883 (1978).

17 Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc., 472 U.S. 749, 757-61 (1985). The Court's determination that greater breathing space is required for speech that deals with a matter of public concern is seen most clearly in libel cases. When speech does not involve matters of public concern, injured parties can recover presumed and punitive damages for false statements made negligently and without malice. Id. at 755. By contrast, when speech involves a matter of public concern, only actual damages are recoverable by public figures or officials and only if the plaintiff shows "actual malice," that is, "knowledge of falsity or reckless disregard for the truth." Id.

18 Ohralok v. Ohio State Bar Ass'n, 436 U.S. 447, 455-56 (1978), rehearing denied, 439 U.S. 883 (1978).

19 Young Drug Products Corp. v. Bolger, 526 F.Supp. 823 (1981) ("In this case all three types of proposed mailings are commercial solicitations. Accordingly, this Court must consider this case ... within the framework set forth by the Supreme Court for commercial speech cases.") Id. at 826.

20 Id. at 66. The informational pamphlets were described as follows: "The first, entitled 'Condoms and Human Sexuality,' is a 12-page pamphlet describing the use, manufacture, desirability, and availability of condoms, and providing detailed descriptions of various Trojan-brand condoms manufactured by Youngs. The second, entitled 'Plain Talk about Venereal Disease,' is an eight-page pamphlet discussing at length the problem of venereal disease and the use and advantages of condoms in aiding the prevention of venereal disease. The only identification of Youngs or its products is at the bottom of the last page of the pamphlet, which states that the pamphlet has been contributed as a public service by Youngs, the distributor of Trojan-brand prophylactics." Id. at 62-63, n. 4.

21 Product characteristics such as price, weight, and composition can generally be easily verified by a manufacturer. In this case RJR does not provide that type of product information; it discusses evidence developed by a governmentally funded study and implicitly questions the categorical statements contained in the government's health warnings.

22 Only in a highly cerebral sense of the word could it be said that the RJR publication promotes the sale of RJR products. RJR products are not shown in an attractive light, and consumers are not assured that smoking will not lead to heart

disease. The piece tells consumers explicitly that there are "studies that show a statistical association between smoking and [heart disease]." At best consumers are told that the case against cigarettes is not conclusive.

23 Although reference to a generic product obviously is not dispositive, it is an added factor corroborating the conclusion that the publication is not, in the ordinary sense of the term, an advertisement. In Bolger, the commercial speech referred to a specific brand and, nota bene, the brochures were "conceded [by Youngs] to be advertisements." Bolger, supra, at 66.

24 The majority opinion does not question that the publication in issue is direct comment on a public issue.

25 Complaint Counsel have suggested that RJR could frame the communication as a letter to the editor, testify before legislative bodies, or have representatives appear on talk shows. Even if these were equally effective means for RJR to engage in the debate of ideas, they could not constitutionally be limited to these means. As the Supreme Court stated in Consolidated Edison, supra, at 541 n. 10, "we have consistently rejected the suggestion that a government may justify a content-based prohibition by showing that speakers have alternative means of expression."

26 Such a ban has been proposed. See, H.R. 1272, 100th Cong., 1st Sess. (1987) (a bill that would prohibit any "tobacco sales promotion.").

27 See note 1, infra.

28 Complaint, ¶ 5b.

29 As pointed out above, the Commission majority has concluded that a product manufacturer does not enjoy full First Amendment protection for direct comment on a matter of public concern if that comment also "addresses the concerns of a purchaser of the advertiser's product or service." In addition, there is no hint in the Commission opinion of any other ground under which a communication that is "characteristic of commercial speech" can receive full First Amendment protection.

30 If this information were needed, RJR would undoubtedly stipulate to the facts. In addition, if the Commission majority truly believes that this evidence is necessary to its decision it could simply receive it without remanding. See Chrysler Corp. v. FTC, 561 F.2d 357, 362 (D.C.Cir .1977).

31 As the Court has noted: "Normally the purpose or motive of the speaker is not central to First Amendment protection, but it does bear on the distinction between conduct that is 'an associational aspect of "expression",' and other activity subject to plenary regulation by government." In re Primus, 436 U.S. 412, 438 n. 32 (citation omitted). In Primus the conduct at issue (client solicitation by an ACLU attorney) was association for the advancement of ideas or beliefs. Id. Thus the Court concluded that the "motive of the speaker" was relevant only because that factor determined whether or not the expression was associational. Id. First Amendment rights of association are not present in the case before us. Thus the majority's conclusion (at p. 12) that Primus holds that the "motive of the speaker" is relevant to determining whether speech is commercial or fully protected is simply incorrect.

32 That might be the case if a cigarette company talked about the need for clean air and incorporated false information about discount prices.

1988 WL 490114 (F.T.C.)

End of Document

2014 WL 4211193
Only the Westlaw citation is currently available.
United States Court of Appeals,
Sixth Circuit.

Russell KISER, Plaintiff–Appellant,
v.
Lili REITZ et al., Defendants–Appellees.

No. 13–3956. | Argued: May 8, 2014. | Decided and Filed: Aug. 27, 2014.

Synopsis

Background: Dentist brought § 1983 action seeking declaratory and injunctive relief against members of Ohio State Dental Board, alleging that Board's regulations chilled his exercise of First Amendment commercial speech rights by restricting his ability to advertise as specialist in endodontics while also practicing as general dentist. The United States District Court for the Southern District of Ohio, Algenon L. Marbley, J., 2013 WL 4080734, dismissed for lack of subject matter jurisdiction. Dentist appealed.

[Holding:] The Court of Appeals, Karen Nelson Moore, Circuit Judge, held that allegations of future threat of enforcement supported injury in fact element for Article III standing.

Reversed and remanded.

Attorneys and Law Firms

ARGUED: Todd W. Newkirk, Frank R. Recker & Associates, Columbus, Ohio, for Appellant. Katherine J. Bockbrader, Office of the Ohio Attorney General, Columbus, Ohio, for Appellees. **ON BRIEF:**Todd W. Newkirk, Frank R. Recker & Associates, Columbus, Ohio, for Appellant. Katherine J. Bockbrader, Office of the Ohio Attorney General, Columbus, Ohio, for Appellees.

Before: MOORE and ROGERS, Circuit Judges; NIXON, District Judge. *

OPINION

KAREN NELSON MOORE, Circuit Judge.

***1** Dr. Russell Kiser is trained as a general dentist and as an endodontist specializing in root canal procedures. The Ohio State Dental Board (the "Board"), of which the Defendants are members, promulgated regulations that restrict his ability to advertise as a specialist in endodontics while also practicing as a general dentist. Kiser asserts that the regulations are unconstitutional because they chill his exercise of his First Amendment commercial speech rights. On this appeal, we must determine whether Kiser has adequately demonstrated that he has standing to bring his claim under the Supreme Court's recent opinion in *Susan B. Anthony List v. Driehaus*, ––U.S. ––––, 134 S.Ct. 2334, 189 L.Ed.2d 246 (2014). Because Kiser has alleged facts demonstrating that he faces a credible threat that the Board's advertising regulations will be enforced against him in the future, we conclude that he has standing to assert his pre-enforcement challenge to the regulations. Accordingly, we **REVERSE** the district court's dismissal of Kiser's complaint for lack of subject-matter jurisdiction and **REMAND** for further proceedings.

I. BACKGROUND

Dr. Russell Kiser is a licensed dentist practicing in Mansfield, Ohio. R. 2 (Compl. ¶ 19) (Page ID # 9). He is thus subject to the regulation of the Ohio State Dental Board, which is authorized by statute to regulate the dental profession in Ohio by promulgating rules, investigating violations of the rules, and administering discipline. Ohio Rev.Code §§ 4715.02 and 4715.03. One regulation promulgated by the Board relates to dentists' advertising: it provides that if a dentist chooses to advertise as a "specialist" in a recognized field, he may not practice or advertise services outside the scope of that specialty. Ohio Admin. Code §§ 4715–5–04, 4715–13–05. Kiser completed an accredited post-doctoral program in endodontics and he is a Diplomate of the American Board of Endodontics. He accordingly may be recognized as a "specialist" in endodontics pursuant to Ohio Administrative Code § 4715–5–04(B)(3) and (4). R. 2 (Compl. ¶ 20) (Page ID # 10).

Kiser opted to advertise himself as a specialist in endodontics, but he also continued to perform general dentistry services. On August 17, 2009, the Board issued a written warning to Kiser for practicing "outside the scope" of his declared specialty in endodontics, in violation of Ohio Administrative Code § 4715–5–04(B)(2). *Id.* ¶ 22 (Page ID # 10–11); R. 8–1 (Warning Ltr.) (Page ID # 88–89). In relevant part, the letter stated as follows:

> The Ohio State Dental Board (Board) recently concluded an investigation regarding the treatment rendered by you to a particular patient. Based on information received during the course of the investigation, and information that the Board had received previous thereto, concerns have arisen regarding the scope of your practice as an endodontist.
>
> ...
>
> [A]s a specialist, one can only advertise services associated with the specialty declared.
>
> ***2** ...
>
> You have limited your license to the specialty of endodontics. Although you are qualified to perform procedures outside the scope of endodontics, you are NOT permitted to perform procedures that are not part of the specialty training of an ADA [American Dental Association] accredited program in endodontics.
>
> Therefore, if you wish to continue to declare yourself as a specialist in endodontics, you must advertise accordingly, and limit your practice per the ADA's definition. If you would prefer to practice in areas outside the scope of endodontics, you may do so by no longer holding yourself out as a specialist in endodontics. You can be a general dentist, and then advertise and perform specialty services you are qualified to perform, so long as you also state you are a general dentist.

R. 8–1 (Warning Ltr.) (Page ID # 88–89). The Board did not take any further action at that time.

In May 2012, Kiser requested that the Board approve proposed signage for his office, which included the terms "endodontist" and "general dentist." R. 2 (Compl. ¶ 23) (Page ID # 11). The Board neither approved nor rejected Kiser's proposed signage. Instead, on May 24, 2012, the Board sent Kiser a second letter recommending that he consult legal counsel. *Id.* Enclosed with the letter were a copy of the regulations at issue and a copy of the first warning letter. *Id.*

Kiser filed a complaint in the United States District Court for the Southern District of Ohio pursuant to 42 U.S.C. § 1983 alleging that the provisions of the Ohio Administrative Code regulating dentists' advertising unconstitutionally restrict his First Amendment rights by limiting his truthful advertisement of the full range of

services for which he is licensed.[1] He sought injunctive and declaratory relief. On the Board's motion, the district court dismissed Kiser's complaint for lack of subject matter jurisdiction because "the Board has not yet enforced the regulations at issue against Dr. Kiser, [and] his claim is not ripe for adjudication." *Kiser v. Reitz*, No. 2:12–cv–574, 2013 WL 4080734, at *3 (S.D.Ohio Aug. 13, 2013). The district court explained that Kiser's challenge to the regulations was not ripe because "[i]t is uncertain whether the Dental Board will ever initiate any formal charges against Dr. Kiser, and if it does, there are mechanisms in place at the administrative level for Dr. Kiser to challenge the Board's disciplinary action." *Id.* at *4. Kiser timely appealed the district court's dismissal of his complaint.

II. STANDARD OF REVIEW

[1] [2] [3] [4] We review de novo a district court's grant of a motion to dismiss for lack of subject matter jurisdiction. *McCormick v. Miami Univ.*, 693 F.3d 654, 658 (6th Cir.2012). When considering a challenge to a complaint based on lack of subject-matter jurisdiction, we "must take the material allegations of the [complaint] as true and construe[ ] [them] in the light most favorable to the nonmoving party." *United States v. Ritchie*, 15 F.3d 592, 598 (6th Cir.1994). It is the plaintiff's burden, however, to prove that this court has jurisdiction over his claim, *Rogers v. Stratton Indus., Inc.*, 798 F.2d 913, 915 (6th Cir.1986), and that the complaint contains sufficient factual matter to state a claim for relief that is plausible on its face, *see Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–57, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007).

III. STANDING

***3 [5] [6] [7] [8] [9]** The jurisdiction of federal courts is limited by Article III of the Constitution to "Cases" and "Controversies." U.S. Const. art. III, § 2. The standing doctrine delineates the boundary between justiciable cases and controversies and those disputes that are not appropriately resolved through judicial process. Although "the core component of standing is an essential and unchanging part of the case-or-controversy requirement of Article III," the Supreme Court has recognized that "some of [the standing doctrine's] elements express merely prudential considerations that are part of judicial self-government." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). The ripeness doctrine is one of several justiciability doctrines "drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." *Reno v. Catholic Soc. Servs., Inc.*, 509 U.S. 43, 57 n. 18, 113 S.Ct. 2485, 125 L.Ed.2d 38 (1993). The "basic rationale" of ripeness doctrine "is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements ... and also to protect ... from judicial interference until a[ ] ... decision has been formalized and its effects felt in a concrete way by the challenging parties." *Abbott Labs. v. Gardner*, 387 U.S. 136, 148–49, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967). In addition, "[a] claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300, 118 S.Ct. 1257, 140 L.Ed.2d 406 (1998) (internal quotation marks omitted).

[10] Although the ripeness doctrine traditionally incorporates both constitutional and prudential elements, the Supreme Court has recently suggested that prudential justiciability doctrines are "in some tension with ... the principle that a federal court's obligation to hear and decide cases within its jurisdiction is virtually unflagging." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, —— U.S. ——, 134 S.Ct. 1377, 1386, 188 L.Ed.2d 392 (2014) (internal quotation marks omitted). Thus, the Supreme Court has cast into some doubt "the continuing vitality" of the long-established prudential aspects of the ripeness doctrine, specifically the aspects that concern hardship to the parties and fitness of the dispute for resolution. *Susan B. Anthony List v. Driehaus*, —— U.S. ——, 134 S.Ct. 2334, 2346–47, 189 L.Ed.2d 246 (2014). Instead, the Court addressed the constitutional component of

ripeness in terms of standing. *Id.* at 2341 n. 5. Accordingly, we will address Kiser's claim, which was dismissed as unripe by the district court, using the constitutional standing framework. [2]

[11] **[12]** A plaintiff must demonstrate that he has standing to pursue his claim in federal court by showing three elements: (1) that he has suffered an "injury in fact," (2) that there is a "causal connection between the injury and the conduct complained of," and (3) that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan*, 504 U.S. at 560–61, 112 S.Ct. 2130 (internal citations and quotation marks omitted). In a pre-enforcement challenge, whether the plaintiff has standing to sue often turns upon whether he can demonstrate an "injury in fact" before the state has actually commenced an enforcement proceeding against him. "In the context of a free-speech overbreadth challenge like this one, [however,] a relaxed ripeness standard applies to steer clear of the risk that the law 'may cause others not before the court to refrain from constitutionally protected speech or protection.' " *Carey v. Wolnitzek*, 614 F.3d 189, 196 (6th Cir.2010) (quoting *Broadrick v. Oklahoma*, 413 U.S. 601, 612, 93 S.Ct. 2908, 37 L.Ed.2d 830 (1973)); *see also Laird v. Tatum*, 408 U.S. 1, 11, 92 S.Ct. 2318, 33 L.Ed.2d 154 (1972) ("[C]onstitutional violations may arise from the deterrent, or 'chilling,' effect of governmental regulations that fall short of a direct prohibition against the exercise of First Amendment rights.").

***4** **[13]** **[14]** **[15]** **[16]** A plaintiff suffers an "injury in fact" when his legally protected interest has been invaded and the injury is both "concrete and particularized" and "actual or imminent, not 'conjectural' or 'hypothetical.' " *Lujan*, 504 U.S. at 560, 112 S.Ct. 2130 (citations omitted). Although most federal claims assert allegations that the plaintiff has suffered a past injury, "[a]n allegation of future injury may suffice if the threatened injury is certainly impending, or there is a substantial risk that the harm will occur." *SBA List*, 134 S.Ct. at 2341 (internal quotation marks omitted). A plaintiff satisfies this requirement when he alleges "an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder." *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298, 99 S.Ct. 2301, 60 L.Ed.2d 895 (1979). When a plaintiff has engaged in a course of conduct and the state has instructed him to stop or face disciplinary action, we may infer a threat of prosecution that is neither "chimerical," *Steffel v. Thompson*, 415 U.S. 452, 459, 94 S.Ct. 1209, 39 L.Ed.2d 505 (1974) (internal quotation marks omitted), nor "imaginary or wholly speculative," *Babbitt*, 442 U.S. at 302, 99 S.Ct. 2301. Under such circumstances, a plaintiff has adequately alleged a concrete and imminent harm sufficient to meet the "injury in fact" requirement.

[17] In the instant case, Kiser alleges that he has been harmed by the Board's "unlawful[ ] restrict[ion] [of his] First Amendment commercial free speech rights." R. 2 (Compl. ¶ 34) (Page ID # 14). He asserts that the Board's threatened enforcement of its regulations has "exert[ed] a chilling effect on his attempt to advertise" because he "would ... like to advertise that he performs [general dentistry] services, but is prohibited from doing so by the [Board's] regulation[s]." *Id.* ¶¶ 23, 26 (Page ID # 11–12). Because the Board has not yet enforced its regulations in a disciplinary action against Kiser, he cannot demonstrate past injury. However, Kiser has alleged a credible threat of future prosecution sufficient to demonstrate that he is suffering an injury in fact.

[18] **[19]** First, Kiser has alleged "an intention to engage in a course of conduct arguably affected with a constitutional interest." *Babbitt*, 442 U.S. at 298, 99 S.Ct. 2301. Kiser alleged that he has advertised both general dentistry and endodontic services in the past and that he intends to do so in the future. Although advertisements and other commercial speech enjoy less rigorous First Amendment protection than other forms of expression, *see United States v. Edge Broadcasting Co.*, 509 U.S. 418, 426, 113 S.Ct. 2696, 125 L.Ed.2d 345 (1993), commercial speech is nonetheless constitutionally protected so long as it "concerns lawful activity and is not misleading," *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367, 122 S.Ct. 1497, 152 L.Ed.2d 563 (2002). Therefore, Kiser's intended advertisement of his general dentistry and endodontic services—both of which he is licensed and qualified to perform—implicates a constitutional interest. *See Elrod v. Burns*, 427 U.S. 347, 373, 96 S.Ct. 2673, 49 L.Ed.2d 547 (1976) (concluding that First Amendment freedoms are affected when speech is "either threatened or in fact being impaired at the time relief [is] sought").

***5** Second, Kiser's intended conduct is "arguably ... proscribed by" the regulations issued by the Board. *Babbitt*, 442 U.S. at 298, 99 S.Ct. 2301. The Board's regulations provide that a dentist may practice and advertise either as a generalist or as a specialist; however, if the dentist chooses to "seek[ ] specialty recognition," his practice and advertising "must be limited exclusively to the indicated specialty area(s)." Ohio Admin. Code § 4715–5–04(B)(2). Kiser wishes to advertise himself as a specialist in endodontics while also advertising and performing general dentistry procedures. This is the same speech that the Board has in the past warned Kiser that it considers a violation, "[a]nd, there is [thus] every reason to think that similar speech in the future will result in similar proceedings." *SBA List*, 134 S.Ct. at 2345. Accordingly, Kiser's intended conduct arguably violates the Board's regulations.

[20] **[21]** Finally, Kiser has alleged that a credible threat of prosecution under the regulations exists. A plaintiff asserting standing to challenge a law before it has been enforced against him must show a "credible fear" that the state or its agents will in fact enforce the law in his case. *Norton v. Ashcroft*, 298 F.3d 547, 554 (6th Cir.2002). A threat of future enforcement may be "credible" when the same conduct has drawn enforcement actions or threats of enforcement in the past. *See Steffel*, 415 U.S. at 459, 94 S.Ct. 1209. Such a threat is considered especially substantial when the administrative agency "ha[s] not disavowed enforcement if [the plaintiffs] make similar statements in the future." *SBA List*, 134 S.Ct. at 2345; *see also Holder v. Humanitarian Law Project*, 561 U.S. 1, 16, 130 S.Ct. 2705, 177 L.Ed.2d 355 (2010). Moreover, the threat need not stem from a criminal action: "[A]dministrative action, like arrest or prosecution, may give rise to harm sufficient to justify pre-enforcement review." *SBA List*, 134 S.Ct. at 2345 (noting that the threat of administrative proceedings was "a substantial one" but declining to "decide whether that threat standing alone gives rise to an Article III injury"); *see also Ohio Civil Rights Comm'n v. Dayton Christian Schs., Inc.*, 477 U.S. 619, 625–26 n. 1, 106 S.Ct. 2718, 91 L.Ed.2d 512 (1986) ("If a reasonable threat of prosecution creates a ripe controversy, we fail to see how the actual filing of the administrative action threatening sanctions in this case does not.").

Here, Kiser has alleged that the Board has in the past threatened to enforce the regulations against him when he advertised or practiced general dentistry services in addition to endodontic specialty services. On one occasion, the Board sent a letter to Kiser explaining that it had investigated his practice and determined that his advertising or services were "outside the scope" of his specialty, and thus in violation of the regulations. R. 2 (Compl. ¶¶ 22–23) (Page ID # 10–11); R. 8–1 (Warning Ltr.) (Page ID # 88–89). On a second occasion, after Kiser sought approval of proposed signage for his office, the Board reiterated its warning that Kiser was advertising beyond the scope of his specialty, and recommended that Kiser seek the advice of counsel. R. 2 (Compl. ¶ 23) (Page ID # 11). Although these letters did not commence an official enforcement action, they may fairly be read to threaten implicitly enforcement of the regulations if Kiser persisted in practicing or advertising outside the scope of his specialty. Moreover, the Board has not represented that it will decline to enforce the regulations against Kiser should he continue to advertise as both an endodontist and a general dentist. Thus, the Board's warning regarding Kiser's past advertisements and its response to the signage that he wishes to display in the future together constitute a credible threat that Kiser will be subject to an enforcement action.

***6** Furthermore, the injury Kiser would suffer from an enforcement action is not insubstantial merely because it is not accompanied by a threat of criminal sanctions. An administrative action carries significant consequences for Kiser: the Board is empowered to suspend or revoke Kiser's license to practice dentistry in the State of Ohio, *see* Ohio Rev.Code § 4715.03(B)(1), and thus Kiser faces a threat to his livelihood should he persist in flouting the Board's regulations. The potential administrative sanctions are therefore serious enough on their own, absent any potential criminal penalties, to create a constitutional injury in fact.

[22] **[23]** We conclude that Kiser has alleged facts demonstrating that he has suffered an injury in fact because he faces a credible threat that the regulations will be enforced against him in violation of his First Amendment

right to engage in commercial speech. He has also alleged a causal connection between his injury and the allegedly unconstitutional regulations—it is the threatened enforcement of the regulations that chills his truthful advertisement of his services. Finally, Kiser has alleged that it is likely that his "injury will be redressed by a favorable decision." *Lujan*, 504 U.S. at 561, 112 S.Ct. 2130 (internal quotation marks omitted). If warranted, the court may issue a declaratory judgment that the regulations are unconstitutional or it may enjoin enforcement of the regulations against Kiser. Accordingly, Kiser's claim is ripe for adjudication, and he has standing to assert his claim in federal court.

IV. CONCLUSION

For the foregoing reasons, we **REVERSE** the district court's dismissal of Kiser's complaint and **REMAND** for further proceedings consistent with this opinion.

* The Honorable John T. Nixon, Senior United States District Judge for the Middle District of Tennessee, sitting by designation.

1 Kiser made additional constitutional claims in his complaint, but he has not raised those issues on appeal. Accordingly, we will not consider whether those claims are ripe for adjudication. *Robinson v. Jones*, 142 F.3d 905, 906 (6th Cir.1998).

2 The "prudential" ripeness factors—hardship to the parties and fitness of the record for review—are also satisfied in the instant case. Kiser will suffer continuing injury every day that he is unable to engage in constitutionally protected commercial speech. *See Elrod v. Burns*, 427 U.S. 347, 373, 96 S.Ct. 2673, 49 L.Ed.2d 547 (1976) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury."). Moreover, we would not benefit from allowing the factual record to develop further because this case presents a purely legal question. The regulations are not subject to refinement on a case-by-case basis: either a dentist's advertisement conforms to the regulations or it does not. *Compare Abbott Labs.*, 387 U.S. at 152, 87 S.Ct. 1507 (concluding that a challenge to regulations relating to the labeling of pharmaceuticals did not need further factual development because the regulations were "clear-cut" and not subject to further agency discretion or refinement), *with Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 735, 118 S.Ct. 1665, 140 L.Ed.2d 921 (1998) (concluding that immediate judicial review would interfere with administrative efforts to refine logging policies because the agency's regulations called for administrative approval of site-specific proposals). Accordingly, the prudential ripeness factors do not pose a barrier to judicial review of Kiser's claim.

2011 WL 5360899
Only the Westlaw citation is currently available.
United States District Court,
S.D. California.

MARKETQUEST GROUP, INC., Plaintiff,
v.
BIC CORPORATION; BIC USA, Inc.; Norwood Promotional Products, LLC; et al., Defendants.

No. 11–CV–618 JLS (WMC). | Nov. 7, 2011.

ORDER: (1) DENYING PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION; (2) DENYING DEFENDANTS' MOTION TO STRIKE

JANIS L. SAMMARTINO, District Judge.

***1** Presently before the Court is Plaintiff Marketquest Group, Inc.'s (Marketquest) motion for a preliminary injunction. (ECF No. 27.) Also before the Court are Defendants BIC Corp., BIC USA, and Norwood Promotional Products' (BIC) opposition (ECF No. 33), Marketquest's reply (ECF No. 35), and BIC's motion to strike (ECF No. 40). The motion hearing set for November 10, 2011, is **HEREBY VACATED,** and the matter is taken under submission without oral argument pursuant to Civil Local Rule 7.1(d)(1). Having considered the parties' arguments and the law, the Court **DENIES** Marketquest's motion for a preliminary injunction and **DENIES** BIC's motion to strike.

BACKGROUND

Plaintiff Marketquest is a California corporation engaged in the production, advertising, and sale of customizable promotional products, including writing instruments such as pens, using the registered trademarks "ALL–IN–ONE" and "THE WRITE CHOICE." (FAC ¶ 10–12.)[1] According to Marketquest, in late 2010 Defendant BIC, comprised of Connecticut and Delaware corporations, began advertising and selling products, including pens and related products and services, using marks similar to Marketquest's. (FAC ¶ 21–25.) Specifically, BIC began using the phrase "The Write Pen Choice" in an online advertising campaign for writing instruments, including pens, in or around October, 2010. (FAC ¶ 23.) BIC also began advertising customizable promotional products, including pens, in 2011 Catalogues using the phrase "All in ONE." (FAC ¶ 24.)

[1] Marketquest lists five separate registered trademarks (four for the "ALL–IN–ONE" mark, and one for "THE WRITE CHOICE" mark; collectively, "the Infringing Marks"):

1. The mark "ALL–IN–ONE," registered in connection with its sale of products including "writing instruments, namely pens, pencils, markers, highlighting markers." Registration No. 2,422,967 (registered Jan. 23, 2001). (FAC ¶ 13, Ex. A.)
2. The mark "ALL–IN–ONE–LINE," registered in connection with its sale of products including "writing instruments, namely pens, pencils, markers." Registration No. 2,426,417 (registered Feb. 6, 2001). (FAC ¶ 14, Ex. B.)
3. The mark "ALL–IN–ONE stylized design," registered in connection with its sale of products and services including "writing instruments, namely pens, pencils, markers, highlighting markers" and "dissemination of advertising matter." Registration No. 3,153,089 (registered Oct. 10, 2006). (FAC ¶ 15, Ex. C.)

4. The mark "THE WRITE CHOICE," registered in connection with its sale of products including "writing instruments, namely pens, pencils, markers, highlighting markers." Registration No. 3,164,707 (registered Oct. 31, 2006). (FAC ¶ 16, Ex. D.)
5. The mark "ALL–IN–ONE stylized design," registered in connection with its sale of services including "customized imprinting of equipment, merchandise and accessories for business promotion." Registration No. 3,718,333 (registered Dec. 1, 2009). (FAC ¶ 17, Ex. E.)

By way of relevant background, in 2009 Defendant BIC USA acquired what became Defendant Norwood Promotional Products, LLC, a competitor in the promotional products business. (Def.'s Opp'n 2.) Norwood has its own trademark registrations for the NORWOOD mark and logo/design.[2] (*Id.*) In late 2010, BIC printed a number of NORWOOD catalogues for 2011, one of which was the "NORWOOD All in ONE" catalogue, which "consolidated all of Norwood's available hard goods products in one catalogue." (Def.'s Opp'n 3.) As of the date of BIC's opposition to this motion, on October 3, 2011, BIC claims that this "NORWOOD All in ONE" catalogue is no longer in print and is no longer being distributed. (*Id.*) "Norwood will be changing the name of its NORWOOD Catalogue for 2012 and will no longer use the phrase 'All in ONE.' " (*Id.* at 4.)

[2] BIC lists two relevant registered trademarks:
1. The mark "NORWOOD," registered in connection with "preparation of custom advertisements and custom promotional products for others," Registration No. 2,894,578 (registered Oct. 14, 2004). (Def.'s Opp'n 2.)
2. The mark "NORWOOD logo/design," registered in connection with "custom imprinting for others of company name, trade name, logo or other copy, namely, words, phrases, and decorative designs on promotional products, namely, promotional merchandise, apparel, and corporate gifts; custom printing for others of company name, trade name, logo or other copy, namely, words, phrases, decorative designs on advertising matter," Registration No. 3,575,173 (registered Feb. 17, 2009). (Def.'s Opp'n 2–3.)

On March 28, 2011, Marketquest filed this action for trademark infringement and unfair competition against BIC. (ECF No. 1.) On May 5, 2011, Marketquest filed the operative First Amended Complaint. (ECF No. 14.) Marketquest alleges what are essentially three causes of action: (1) trademark infringement under 15 U.S.C. § 1114(1) of its ALL–IN–ONE mark (Count I) and its THE WRITE CHOICE mark (Count III); (2) unfair competition under 15 U.S.C. § 1125(a) for its ALL–IN–ONE mark (Count II) and its THE WRITE CHOICE mark (Count IV); and (3) unfair competition in violation of Cal. Bus. & Prof.Code § 17200 (Count V). Marketquest requests a preliminary and permanent injunction to enjoin BIC from using the Infringing Marks in any manner, to order BIC to remove any products bearing the Infringing Marks from sale or display, and to order BIC to deliver any such goods to the Court for destruction. (FAC 8–10.) Marketquest claims BIC's use of the Infringing Marks is likely to confuse consumers, causing irreparable injury. (FAC ¶ 28–34.) On August 26, 2011, Marketquest moved for a preliminary injunction. (ECF No. 27.)

LEGAL STANDARD

***2** A preliminary injunction is an equitable remedy aimed at preserving the status quo and at preventing the occurrence of irreparable harm during the course of litigation. *See* Fed.R.Civ.P. 65. The Ninth Circuit has recently modified its preliminary injunction analysis in response to the Supreme Court's rejection of its previous standard. Now, it is clear that "[a] plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Natural Res. Def. Council, Inc. (NRDC),* 555 U.S. 7, 20 (2008) (citing *Munaf v. Geren*, 553 U.S. 674, 689–90 (2008)); *see also Am. Trucking Ass'ns, Inc. v. City of L.A.*, 559 F.3d 1046, 1052 (9th Cir.2009). A preliminary injunction is an "extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *NRDC*, 555 U.S. at 22. This "clear showing" requires the plaintiff to show more than a mere "possibility" of irreparable harm; instead, he

must "demonstrate that irreparable injury is *likely* in the absence of an injunction." *Id.* at 22 (emphasis in original); *American Trucking*, 559 F.3d at 1052.

Federal Rule of Civil Procedure 65(d) requires that every order granting an injunction must "state the reasons why it issued; state its terms specifically; and describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained or required." This mandate for specificity ensures that those against whom an injunction is issued receive fair and precise notice of what conduct is prohibited. *See Halo Mgmt., LLC v. Interland, Inc.*, 308 F.Supp.2d 1019, 1027 (N.D.Cal.2003) (citing *Union Pac. R.R. v. Mower*, 219 F.3d 1069, 1077 (9th Cir.2000)). [3]

[3] Rule 65 also requires the movant to give security in an amount that the Court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained. Fed.R.Civ.P. 65(c). Marketquest has requested the Court dispense with the security requirement or provide for a nominal bond. (Pl.'s Mem. ISO Mot. 16–17.) BIC has not requested Marketquest give security, nor has it submitted any evidence regarding its likely damages if the Court grants Marketquest's motion for a preliminary injunction. Thus, the Court will not address the security question here. *Cf. Halo Mgmt.*, 308 F.Supp.2d at 1027 n. 11 (declining to consider the question of bond where the defendant did not request it); *see also Connecticut General Life Ins. Co. v. New Images of Beverly Hills*, 321 F.3d 878, 882 (9th Cir.2003) (refusing to address a bond-related question on appeal where the district court was not presented with the bond issue).

ANALYSIS

The Ninth Circuit, as noted, has elaborated a four-part test for determining whether a moving party is entitled to a preliminary injunction. *See, e.g., American Trucking*, 559 F.3d at 1052. To succeed on a motion for a preliminary injunction, the movant must show: (1) likelihood of success on the merits; (2) likelihood of irreparable harm in the absence of a preliminary injunction; (3) that the balance of equities tips in his favor; and (4) that an injunction is in the public interest. *Id.* (citing *NRDC*, 555 U.S. at 20.) The Court will address each aspect of this test below.

1. Likelihood of Success on the Merits

In order to establish a claim for trademark infringement and unfair competition, Marketquest must show: (1) that it has a protectable ownership interest in the mark; and (2) that BIC's use of the mark is likely to cause consumer confusion. [4] *Network Automation, Inc. v. Advanced Sys. Concepts, Inc.*, 638 F.3d 1137, 1144 (9th Cir.2011) (citing *Dep't of Parks & Recreation v. Bazaar Del Mundo Inc.*, 448, F.3d 1118, 1124 (9th Cir.2006). "The core element of trademark infringement is the likelihood of confusion, *i.e.*, whether the similarity of the marks is likely to confuse consumers about the source of the products." *E. & J. Gallo Winery v. Gallo Cattle Co.*, 967 F.2d 1280, 1290 (9th Cir.1992). Likelihood of confusion is determined by a fact-intensive, non-exclusive, eight-factor test. *AMF Inc. v. Sleekcraft Boats*, 599 F.2d 341, 348–49 (9th Cir.1979); *Surfvivor Media, Inc. v. Survivor Prods.*, 406 F.3d 625, 631 (9th Cir.2005).

[4] Trademark infringement under Section 32 of the Lanham Act and unfair competition under both Section 43 of the Lanham Act and California Bus. & Prof.Code § 17200 are in this sense coextensive. *Cleary v. News Corp.*, 30 F.3d 1255, 1262–63 (9th Cir.1994) ("This Circuit has consistently held that state common law claims of unfair competition and actions pursuant to California Business and Professions Code § 17200 are 'substantially congruent' to claims made under the Lanham Act."); *Enesco Corp. v. Price/Costco Inc.*, 146 F.3d 1083, n. 1 (9th Cir.1998); *Mattel, Inc. v. MCA Records, Inc.*, 296 F.3d 894 (9th Cir.2002), *cert. denied*, 537 U.S. 1171 (2003) ("The likelihood of confusion test also governs [plaintiff's] [California] state law claims of unfair competition.") Section 32(1) of the Lanham Act applies to federally registered marks and provides:

> Any person who shall, without the consent of the registrant—

> (a) use in commerce any reproduction, counterfeit, copy, or colorable imitation of a registered mark in connection with the sale, offering for sale, distribution, or advertising of any goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive; ... shall be liable in a civil action by the registrant for the remedies hereinafter provided.

15 U.S.C. § 1114(1). Essentially the same standard is embodied in Section 43(a)(1) of the Lanham Act, which applies to both registered and unregistered trademarks. 15 U.S.C. § 1125(a)(1).

***3** Marketquest argues that it is likely to succeed on the merits of its federal claims because BIC's use of "All in ONE" is "likely to cause, and has, in fact, caused consumer confusion" because of its similarity to Marketquest's ALL–IN–ONE mark.[5] (Pl.'s Mem. ISO Mot. 6.) BIC counters that Marketquest's ALL–IN–ONE marks were obtained fraudulently or have been abandoned and are thus invalid, and also that no likelihood of confusion exists. (Def.'s Opp'n 7–8.) Finally, BIC argues that even if a likelihood of confusion exists, its use of the phrase "All in One" is a protected fair use. (Def.'s Opp'n 14.) The Court addresses each of these arguments in turn.

5 Marketquest's motion for a preliminary injunction focuses almost entirely on its ALL–INONE mark, referencing only cursorily its THE WRITE CHOICE mark. (*see* Pl.'s Mem. ISO Mot. 5–7.) None of its arguments or evidence in support of the instant motion pertain to BIC's use of THE WRITE CHOICE mark. Thus, the Court deems Marketquest's request for a preliminary injunction as to THE WRITE CHOICE mark waived, and focuses entirely on the use of the ALL–IN–ONE mark.

(A) Validity of the ALL–IN–ONE Marks

To determine whether BIC's use of "All in ONE" constitutes trademark infringement or unfair competition, the Court must first resolve whether Marketquest has a valid, protectable trademark interest in the ALL–IN–ONE mark.[6]

6 Before entering into its analysis, the Court notes that it has "discretion to consider otherwise inadmissible evidence in ruling on an application for temporary restraining order or preliminary injunction." *Glow Indus. v. Lopez*, 252 F.Supp.2d. 962, 966 n. 1 (C.D.Cal.2002) (citing *Sierra Club v. F.D.I.C.*, 992 F.2d 545, 551 (5th Cir.1993) ("At the preliminary injunction stage, the procedures in the district court are less formal, and the district court may rely on otherwise inadmissible evidence, including hearsay evidence. Thus, the district court can accept evidence in the form of deposition transcripts and affidavits" (citations omitted)); *see also Flynt Distrib. Co., Inc. v. Harvey*, 734 F.2d 1389, 1394 (9th Cir.1984) ("The Harveys argue that Flynt's evidence is hearsay. The urgency of obtaining a preliminary injunction necessitates a prompt determination and makes it difficult to obtain affidavits from persons who would be competent to testify at trial. The trial court may give even inadmissible evidence some weight, when to do so serves the purpose of preventing irreparable harm before trial"); *see also Mattel, Inc. v. MCA Records, Inc.*, 1998 WL 422641, * 1 (C.D.Cal. Feb. 18, 1998) (denying both parties' motions to strike declarations because "strict evidentiary rules" do not apply at the preliminary injunction phase (citations omitted)). For these reasons, BIC's motion to strike Marketquest's evidence in support of its motion for preliminary injunction (ECF No. 40) **IS DENIED.**

Marketquest's registration of the four ALL–IN–ONE marks on the Principal Register in the Patent and Trademark Office (PTO) constitutes prima facie evidence of the validity of each registered mark and of Marketquest's exclusive right to use the marks on the goods and services specified in the registration. *See* 15 U.S.C. §§ 1057(b); 1115(a). Further, both parties agree that two of the four ALLIN–ONE registrations have achieved "incontestable" status, having been in continuous use for five consecutive years subsequent to the date of registration. 15 U.S.C. § 1065; (*see also* Pl.'s Mem. ISO Mot. 8; Def.'s Opp'n 5.) To the extent that the right to use a registered mark has become incontestable under Section 1065, "the registration serves as conclusive evidence of the validity of the registered mark and of the registration of the mark, of the registrant's ownership of the mark, and of the registrant's exclusive right to use the registered mark in commerce." 15 U.S.C. § 1115(a). However, even marks with incontestable status remain subject to the defenses set forth in Section 1115(b).

BIC claims all four of Marketquest's ALL–IN–ONE registrations were procured fraudulently or have been abandoned, and are thus invalid under Section 1115(b). (Def.'s Opp'n 7.) Specifically, Section 1115(b)(1) provides the defense "[t]hat the registration or the incontestable right to use the mark was obtained fraudulently," and Section 1115(b)(2) provides the defense "[t]hat the mark has been abandoned by the registrant." The Court examines both of these asserted defenses.

(i) Fraudulent Procurement of Mark

A trademark registration, even if incontestable, is invalid if it was fraudulently obtained. *See* 15 U.S.C. § 1115(b)(1). "Fraud in procuring a trademark registration or renewal occurs when an applicant knowingly makes false, material representations of fact in connection with his application." *In re Bose Corp.*, 91 U.S.P.Q.2d 1938, 1939 (Fed.Cir.2009). A party seeking cancellation of a mark due to fraud bears a heavy burden. The party must identify a deliberate attempt by the registrant to mislead the PTO, and must show that misstatements were made with respect to material fact. *Halo Mgmt.*, 308 F.Supp.2d at 1031 (citing *Woodstock's Enter., Inc. v. Woodstocks' Enter., Inc.*, 43 U.S.P.Q .2d 1440 (T.T.A.B.1997) ("Fraud in a trademark cancellation is something that must be 'proved to the hilt' ....").

***4** Here, BIC provides very little evidence to support its theory that Marketquest's ALL–IN–ONE marks were fraudulently procured, especially in the face of such a heavy burden. BIC merely states that there is "a serious question" as to whether the registrations were obtained fraudulently. (Def.'s Opp'n 7.) As its one example, BIC points to Marketquest's submission to the PTO of specimens of use that BIC states, "on information and belief, appear to be computer renderings of products that Plaintiff never intended to sell in commerce." (Def.'s Opp'n 7–8.) In other words, BIC objects that Marketquest provided the PTO with mock-ups of its products bearing the ALL–IN–ONE design/logo, when in fact Marketquest never intended to sell its products bearing its own logo; rather, it intended to sell and in fact did sell versions of these products customized with the marks of clients. (*Id.* at 8; Ex. 14.) However, BIC does not explain how these catalogues fail to constitute use in commerce of the logo in conjunction with the sale of goods.

The Lanham Act defines "use in commerce" as "the bona fide use of a mark in the ordinary course of trade." 15 U.S.C. § 1127. BIC has not shown that failure to actually sell pens and other items with the ALL–IN–ONE logo imprinted exactly as depicted in its advertisements necessarily means Marketquest did not use the mark in the ordinary course of trade. A trademark need not "appear in any particular position on the goods." *In re Morganroth*, 208 U.S.P .Q. 284, 288 (T.T.A.B.1980). Instead, the key to the use in commerce inquiry is whether Marketquest used the mark *as a* trademark, to identify the source of its goods or services. *Id.*

Through its extensive use of the mark on its internet website and catalogues to identify its customizable product lines, Marketquest is likely to succeed in establishing it has used the mark in commerce sufficiently extensively to merit some manner of trademark protection. Further, Marketquest has provided evidence that at least some of its customizable products, such as pens and luggage tags, were in fact sold with the ALL–IN–ONE mark embossed on them, in addition to the customer's imprinted mark. (Pl.'s Reply 2; Pl.'s Mem. ISO Mot, Ex. 5.) Thus, BIC has failed to provide the Court with a sufficient basis to find Marketquest did not use its ALL–IN–ONE mark in commerce as a designation of source. As a result, the Court finds BIC has not satisfied its heavy burden to identify a deliberate attempt by Marketquest to mislead the PTO, nor has it identified a material misstatement required for a finding of fraudulent procurement.

(ii) Abandonment

Under the Lanham Act, a mark may be deemed "abandoned" in one of two situations: (1) "[w]hen its use has been discontinued with intent not to resume such use," and (2) "[w]hen any course of conduct of the owner, including

acts of omission as well as commission, causes the mark to become the generic name for the goods or services on or in connection with which it is used or otherwise to lose its significance as a mark." 15 U.S.C. § 1127.

***5** BIC's argument that the ALL–IN–ONE marks were abandoned relies upon the same unsupported reasoning as its argument that the marks were fraudulently procured. BIC asserts that Marketquest "may very well use the ALL IN ONE marks as its trade name or service mark, but no longer in association with its physical products." (Def.'s Opp'n 8.) However, BIC provides no proof of this contention. Further, even if the Court takes as true BIC's statement that Marketquest no longer imprints its mark on its customized goods, BIC still does not provide support for the proposition that Marketquest's extensive use of the mark in advertising its customizable products fails to constitute use in commerce for the purposes of the Lanham Act.

For these reasons, the Court concludes Marketquest is likely to succeed in showing it has valid, protectable rights in the ALL–IN–ONE marks.

(B) Likelihood of Confusion

Next, the Court turns to the issue of customer confusion. As previously noted, the Ninth Circuit has used an eight-factor test to analyze the likelihood of confusion in trademark cases, building on the rubric first elaborated in *Sleekcraft*, 599 F.2d 341 (9th Cir.1979). The eight factors are: (1) strength of the mark, (2) proximity of the goods, (3) similarity of the marks, (4) evidence of actual confusion, (5) marketing channels used, (6) type of goods and degree of care likely to be exercised by the purchaser, (7) defendant's intent in selecting the mark, and (8) likelihood of expansion of the product lines. *Id.* at 348–49. To determine likelihood of confusion, the Court must apply the *Sleekcraft* factors in "a flexible manner, keeping in mind that the eight factors it recited are not exhaustive, and that only some of them are relevant to determining whether confusion is likely" in any given case. *Network Automation*, 638 F.3d at 1145; *Sleekcraft*, 599 F.2d at 348 n. 11. The Lanham Act places the burden of proving likelihood of confusion on the party charging infringement even when relying on an incontestable registration. *KP Permanent Make–Up, Inc. v. Lasting Impression I, Inc.*, 543 U .S. 111, 118 (2004).

(i) Strength of the Mark

The strength of the mark, in terms of its ability to link products to their source, determines the amount of protection from infringement that mark should be afforded. *See Sleekcraft*, 559 F.2d at 349; *Brookfield Commc'ns, Inc. v. West Coast Entm't Corp.*, 174 F.3d 1036, 1058 (9th Cir.1999) ("The stronger a mark—meaning the more likely it is to be remembered and associated in the public mind with the mark's owner—the greater the protection it is accorded by the trademark laws.")

In determining the strength of the mark, courts may look to two relevant measurements: conceptual strength and commercial strength. *Network Automation*, 638 F.3d at 1149. A mark's conceptual strength depends largely on the obviousness of the connection between the mark and the goods or services to which it refers. *Fortune Dynamic, Inc. v. Victoria's Secret Stores Brand*, 618 F.3d 1025, 1032 (9th Cir.2010). Marks may be classified according to a spectrum of five categories originally formulated by Judge Friendly, ranging from weakest to strongest: generic, descriptive, suggestive, arbitrary, or fanciful. *Id.* The other relevant measurement, commercial strength, is based on "actual marketplace recognition, and thus advertising expenditures can transform a suggestive mark into a strong mark." *Network Automation*, 638 F .3d at 1149 (quotations omitted).

***6** Conceptual strength attempts to quantify the inherent distinctiveness of the mark. At one end of the spectrum, "generic marks refer to the genus of which the particular product is a species, such as 'bread' or 'door,' and are not registerable as trademarks." *Fortune Dynamic*, 618 F.3d at 1033 (quotations omitted). At the other end of the spectrum are arbitrary marks, "actual words with no connection to the product—such as Apple computers and Camel cigarettes," and fanciful marks, "made-up words with no discernable meaning—such as Kodak film and

Sony electronics that are inherently distinctive and therefore receive maximum trademark protection." *Id.* In the middle are descriptive and suggestive marks. Descriptive marks "tell [ ] something about the product; [they] will be protected only when secondary meaning is shown." *Sleekcraft*, 599 F.2d at 349. Suggestive marks, one step further along the spectrum of conceptual strength, "subtly connote something about the products. Although less distinctive than an arbitrary or fanciful mark and therefore a comparatively weak mark, a suggestive mark will be protected without proof of secondary meaning." *Id.* In the conceptual strength inquiry, registration of the mark "adds something on the scales," but is not determinative. *Zobmondo Entertainment, LLC v. Falls Media, LLC*, 602 F.3d 1108, 1115 (9th Cir.2010).

In terms of conceptual strength, BIC correctly points out that the incontestable status of two of the ALL–IN–ONE marks does not, alone, establish a strong mark. *Miss World (UK), Ltd. v. Mrs. America Pageants, Inc.*, 856 F.2d 1445, 1449 (9th Cir.1988); (*see also* Def.'s Opp'n 9.) BIC argues that the ALL–IN–ONE mark is a descriptive term that is weak and should merit only limited trademark protection. (Def.'s Opp'n 9–10.) BIC frames the ALL–IN–ONE mark as a description of Marketquest's services "as a one-stop source for a variety of customizable products." (Def.'s Opp'n 10.)

Although it is true that incontestable status does not determine whether a mark is strong or weak, incontestable marks are conclusively presumed to have secondary meaning. *Miss World*, 856 F.2d at 1448 n. 4; 15 U.S.C. § 1115(b). Further, Marketquest persuasively argues that the ALL–IN–ONE mark is at least suggestive, rather than descriptive, and as such is inherently distinctive. (Pl .'s Reply 4.) Marketquest contends that "[n]othing in the phrase ALL IN ONE immediately conveys knowledge to a consumer that [Marketquest] offers customized imprinting services on the business promotion merchandise it supplies to wholesale distributors." (*Id.*) Instead, Marketquest argues that "ALL IN ONE suggests or connotes, rather than describes, a characteristic of its services and requires consumer imagination to determine what those services are." (*Id.*)

In determining the conceptual strength of a mark, the Court may be aided by the "imagination test" and the "need test." *Miss World*, 856 F.2d at 1449. The imagination test asks "how much imagination a consumer must use to associate a given mark with the goods or services it identifies." *Id.* Essentially, the more imagination required to make the association, the stronger the mark. The need test approaches the question "from the opposite end." *Id.* It asks "to what extent a mark is actually needed by competitors to identify their goods or services." *Id.* If "the message conveyed by the mark about the goods or services is so direct and clear that competing sellers would be likely to [need to] use the term in describing or advertising their goods [or services], then this indicates the mark is descriptive." *Id.* There is an inverse relationship between the imagination test and the need test; as the amount of imagination required increases, the need decreases. *Id.*

***7** Here, the Court agrees with Marketquest that ALL–IN–ONE is at least a suggestive mark because it "requires a mental leap from the mark to the product," and as a registered trademark it is inherently distinctive. *Brookfield*, 174 F.3d at 1058; *see also Network Automation*, 638 F.3d at 1150. Categorizing trademarks is "necessarily an imperfect science. Far from being neatly distinct and discrete, trademark categories often blur at the edges and merge together." *Fortune Dynamic*, 618 F.3d at 1033. However, here the mark's need aspect is plainly quite low. In describing a company that sells customizable business promotion merchandise, the phrase "all in one" is not needed. Correspondingly, the mark's imagination aspect is high. The Court could imagine a connection between the phrase "all in one" and a service, like Marketquest's, that offers merchandise and advertising combined—a useful item and an advertisement, *all in one* product, perhaps—but this connection is far from obvious, nor was it supplied by either party. While BIC is correct that the phrase "all in one" comes closest to describing the "one-stop source" aspect of Marketquest's service, it does not explain how the phrase in any way describes customizable business promotion merchandise, which is in essence the heart of Marketquest's service.

The Court's determination that the ALL–IN–ONE mark is inherently distinctive when applied to customizable promotional merchandise may not end the inquiry into the strength of the mark. *Network Automation*, 638 F.3d at 1150. As stated above, commercial strength and the sophistication of the consumer may also play a role. *See id.* However, the Court cannot discern from the proffered evidence a basis to adequately determine commercial strength here. Further, as an evidence-intensive inquiry, consideration of commercial strength is unnecessary at the preliminary injunction stage. *Id.* Therefore, the Court finds that this factor weighs in favor of Marketquest.

(ii) Proximity of the Goods

The more closely related the goods, the higher the danger that the consumer public will "mistakenly assume there is an association between the producers of the related goods, though no such association exists." *Sleekcraft*, 599 F.2d at 350. In determining the relatedness of goods, courts consider: (1) whether the goods are complementary; (2) whether the products are sold to the same class of purchasers; and (3) whether the goods are similar in use and function. *Id.*

Here, BIC acknowledges that the goods and services at issue are similar. (Def.'s Opp'n 10.) Both parties sell customizable promotional merchandise such as pens, USB flash drives, computer peripherals, and other office-related products. (Pl.'s Mem. ISO Mot. 10.) Because the products at issue here are virtually interchangeable, this factor "may be helpful, but it must be considered in conjunction with the labeling and appearance of the advertisements and the degree of care exercised by the consumers." *Network Automation*, 638 F.3d at 1150; *see also Playboy Enters., Inc. v. Netscape Commc'ns Corp.*, 354 F.3d 1020, 1035 (9th Cir.2004) (Berzon, J., concurring) (emphasizing that the proximity of the goods becomes less important if advertisements are clearly labeled or consumers exercise a high degree of care, because rather than being confused, the consumer would merely be confronted with choices among similar products.)

***8** Thus, although the Court finds that this factor decidedly weighs in favor of Marketquest, the Court should not view this factor in isolation, and must consider whether the parties' status as direct competitors would actually lead to a likelihood of confusion in light of the following factors.

(iii) Similarity of the Marks

This is an important factor in the current analysis because, "[w]here two marks are entirely dissimilar, there is no likelihood of confusion." *Perfumebay.com Inc. v. eBay, Inc.*, 506 F.3d 1165, 1174 (9th Cir.2007). The similarity of the marks used by both parties is measured in terms of appearance, sound, and meaning. *Sleekcraft*, 559 F.2d at 351. Each of these aspects should be considered as they are encountered by consumers in the market for that good or service. *Id.*

Standing alone the words used are identical in all respects. Marketquest uses the phrase and logo "ALL–IN–ONE" or "All in One" to mark its catalogues and products, while BIC uses the phrase "All in ONE" on its 2011 NORWOOD Catalogue. (*See* Pl.'s Reply Appx. A.) Aside from slight variations in capitalization and punctuation, the words are the same.

BIC emphasizes that the words appear differently on the two companies' catalogues. (Def.'s Opp'n 11.) The Court agrees that the font and graphical appearance of the phrase as used by the two parties is distinguishable. The ALL–IN–ONE logo/design used by Marketquest contains distinctive colors and graphics, consisting of a red slanted box with white outlined lettering, with the word "IN" backed by a yellow box, all encircled by a curling white line. (*See* Pl.'s Mem. ISO Mot., Ex. 5.) BIC's use, on the other hand, is not graphically distinctive, consisting of the words "All in ONE" in plain yellow or black type. (*See* Pl.'s Mem. ISO Mot ., Ex. 6.)

However, Marketquest's use of its ALL–IN–ONE marks is not confined to the logo/design. For example, it also uses the phrase as its web domain name, and apparently imprints some of its products with the words “All–In–One” in plain type. (*See* Pl.'s Mem. ISO Mot., Ex. 5.) Thus, even the appearance of the mark is often similar. In the similarity analysis, “similarities weigh more heavily than differences.” *Sleekcraft*, 599 F.2d at 351.

Lastly, BIC argues that its use of the NORWOOD mark wherever the phrase “All in ONE” appears on its catalogues should weigh in its favor in the similarity analysis, as it identifies its products in the marketplace as clearly originating from BIC, and differentiates the products in the consumer's eye. (Def.'s Opp'n 11.)

In *Sleekcraft*, the Ninth Circuit noted that the use of a housemark can reduce the likelihood of confusion, but concluded that the effect was negligible where the housemark was inconspicuous and the logo often absent. *Sleekcraft*, 599 F.2d at 351. Here, BIC's use of its housemark, NORWOOD, is not inconspicuous, nor is the logo often absent. To the contrary, the NORWOOD logo appears as the largest words on the cover of the Catalogue, with the phrase “All in ONE” appearing in slightly smaller type, below and to the side. Even on the first page of the Catalogue, where “All in ONE” is larger than the NORWOOD mark, the NORWOOD mark appears at least five times on the page. (Pl.'s Mem. ISO Mot. Ex. 6.)

***9** However, Courts have found that “the addition of a celebrity ‘housemark’ to an allegedly infringing mark may heighten confusion rather than reduce it,” especially in cases where reverse confusion is alleged. *Glow Indus. v. Lopez*, 252 F.Supp.2d 962, 995 (C.D.Cal.2002) (citing *Americana Trading, Inc. v. Russ Berrie & Co.*, 966 F.2d 1284, 1288 (9th Cir.1992) (“[T]he prominence of Russ's housemark may serve to create reverse confusion that Russ, and not Amtra, is the source of Amtra's ‘Wedding Bears.’ Russ's housemark therefore does not, as a matter of law, render its use of ‘Wedding Bear’ non-similar to Amtra's trademark.... Indeed, use by Russ of its housemark along with Amtra's trademark may be an aggravation and not a justification, for it is openly trading in the name of another.”))

Marketquest argues that, as in *Americana Trading*, BIC's usage of the ALL–IN–ONE mark in conjunction with its own well-known mark actually heightens the likelihood of confusion in the similarity analysis. (Pl.'s Reply 6–7.) Marketquest further asserts that, viewing all of the 2011 NORWOOD Catalogues in context, the placement of the phrase “All in ONE” below the NORWOOD mark, compared to the similar placement of other phrases (trademarked brands such as Atchison, RCC Koozie, Triumph Calendars, Good Value Calendars, etc.) below the NORWOOD mark on the cover of other catalogues, could imply the use of “All in ONE” as a mark to designate source. (*See* Pl.'s Reply 6–7, Ex. 13.) Marketquest also notes that the phrase “All in ONE” appears again on the first page of the NORWOOD Catalogue, this time at the top of the page, as the largest words on the page. (*See* Pl.'s Mem. ISO Mot. Ex. 6.)

The Court agrees that such reverse confusion is possible here. However, the context Marketquest depicts for BIC's use of the phrase does not tell the whole story. The phrase “All in ONE” appears in a different position on the cover of that Catalogue than the other marks on the catalogues Marketquest points to, such that the covers are not directly analagous. (*See* Pl.'s Reply Ex. 13.) Instead of directly below the NORWOOD mark, the phrase “All in ONE” appears smaller, lower, and to the side. (*Id.*) In addition, on the first page of the NORWOOD Catalogue, in which “All in ONE” appears in large font at the top of the page, a blurb on the side of that same page explains that this is the “NEW! Norwood All in ONE Catalog. Our primary product resource, featuring all product lines in ONE catalog.” (Pl.'s Mem. ISO Mot., Ex. 6.) On page 14 of what is presumably the same 2011 NORWOOD Catalogue, text further explains the use of the phrase: “2011 Catalog: Your all-in-one product resource! The new All in ONE Norwood Catalog includes 14 different product categories and the brands you trust, including Atchison—now exclusive to Norwood.... All categories in ONE Flyer ...” (*Id.*) These descriptions may do some work in clarifying potential consumer confusion as to whether or not NORWOOD was using the phrase “All in ONE” as a mark to designate the source of the goods in the catalogue.

***10** In the context of these facts, BIC's use of the NORWOOD mark may mitigate against a finding of similarity as consumers encounter the phrase in the marketplace. BIC's marketing materials clearly explain its use of the phrase as the title of its Catalogue, such that consumers could deduce BIC intended to use the phrase in its descriptive sense, referring to the Catalogue's omnibus contents, not as a mark indicating the source of the products contained therein. However, given the reverse confusion context that Marketquest alleges (*see* Pl.'s Reply 5 n. 13), and the extreme similarity in proximity of goods and marketing channels of both parties (*see infra.*), the Court cannot conclude that BIC's addition of the NORWOOD housemark renders the parties' uses of the phrase "All in One" completely dissimilar. *See, e.g.*, *Glow*, 252 F.Supp.2d at 995 ("[I]n the absence of survey or other evidence of consumer reaction to the products as encountered in the marketplace, [the Court declines to find that] the addition of the 'J.Lo' housemark mitigates the likelihood of consumer confusion.")

For these reasons, balancing the extreme similarity of the marks in many respects with the mitigating facts tending to belie this similarity, the Court concludes that this factor weighs slightly in favor of Marketquest.

(iv) Evidence of Actual Confusion

"Evidence that use of the two marks has already led to confusion is persuasive proof that confusion is likely." *Sleekcraft*, 559 F.2d at 352. However, such evidence is difficult to provide, and courts often discount it as unclear or insubstantial. *Id.* As a result, providing evidence of actual confusion is not necessary to a finding of likelihood of confusion. *Network Automation*, 638 F.3d at 1151. At the preliminary injunction stage of litigation, such evidence is more likely to be sparse or nonexistent. *See id.* Some courts have found that, because reliable evidence of actual confusion is difficult to obtain in trademark infringement cases, any such evidence is "substantial evidence that confusion is likely ." *See, e.g.*, *Jockey Int'l, Inc. v. Burkard*, 185 U.S.P.Q. 201, 207 (S.D.Cal.1975).

Here, Marketquest has provided what is akin to anecdotal evidence of several instances of actual confusion. (Pl.'s Mem. ISO Mot. 11; Pl.'s Reply 6.) Marketquest provides declarations from three agents who were confused by the NORWOOD Catalogue and thought the two companies were either the same or affiliated. (*Id.;* Strong Decl. ¶ 4; Smidt Decl. ¶ 4; Moreno Decl. ¶ 3.) In addition, Marketquest provides the declaration of Harris Cohen, founder and President of Marketquest, who states that on August 11, 2011, the company received an e-mail from a distributor who found BIC's "use of All–In–One's Mark there to be 'odd and confusing,' and thought that a 'majority' of industry distributors who were not as experienced as him could be confused by the advertising." (Pl.'s Mem. ISO Mot. 11–12; Cohen Decl. ¶ 30; Ex. 9.) Marketquest also points to two instances in which BIC representatives referred to the NORWOOD Catalogue intentionally as its "All in ONE" Catalogue at trade shows when talking to other industry representatives. (Pl.'s Mem. ISO Mot. 12; Land Decl. ¶ 4; Cohen Decl. ¶ 29.)

***11** Although five or six instances of actual customer confusion might be enough to find substantial evidence that confusion is likely in some circumstances, the facts here do not support such a finding. All of Marketquest's anecdotes involve experienced industry distributors or agents, who are likely to be sophisticated consumers and investigate any potential confusion. *See, e.g.*, *Glow*, 252 F .Supp.2d at 1000 ("Here, at most, Glow, Inc. present (*sic*) de minimis evidence of actual confusion; some of it, moreover, involves 'sophisticated' wholesalers who might be expected to inquire about the affiliation, if any, between the companies.") Although it is well established that initial interest confusion may be actionable, these few instances of alleged initial confusion are nonetheless weak evidence of actual confusion. *Brookfield*, 174 F.3d at 1062–64; *see also Moose Creek, Inc. v. Abercrombie & Fitch Co.*, 331 F.Supp.2d 1214, 1230 n. 9 (C.D.Cal.2004), *aff'd* 114 Fed. Appx. 921 (9th Cir.2004). Furthermore, the importance of this factor is diminished at the preliminary injunction stage. *Network Automation*, 638 F.3d at 1151. Accordingly, the Court finds this factor weighs only very slightly in Marketquest's favor.

(v) Marketing Channels Used

"Convergent marketing channels increase the likelihood of confusion." *Network Automation*, 638 F.3d at 1151. In *Sleekcraft*, the two products were sold in niche marketplaces, including boat shows, specialty retail outlets, and local and national trade magazines, using similar sales methods and price ranges. *Sleekcraft*, 599 F.2d at 353. This factor becomes less important "when the marketing channel is less obscure." *Network Automation*, 638 F.3d at 1151 (finding the Internet to be too broad a shared marketing channel to merit any weight in this factor.)

Here, BIC concedes that the parties occupy similar marketing channels, but instead attempts to blur the issue by emphasizing that the marketing channels consist of sophisticated customers. (Def.'s Opp'n 13.) The Court considers the sophistication of customers next. However sophisticated, the pool of potential customers is virtually identical for both parties. The two companies are direct competitors, as both supply customizable promotional merchandise. Both companies advertise their products and services via the Internet, through printed catalogues, and at trade shows. (Pl.'s Mem. ISO Mot. 12.) Accordingly, the Court finds this factor favors Marketquest.

(vi) Type of Goods and Degree of Care Likely to be Exercised by the Purchaser

Courts look at the likelihood of confusion through the lense of the reasonably discriminating purchaser. *See, e.g.*, *Network Automation*, 638 F.3d at 1152. "When the buyer has expertise in the field, a higher standard is proper though it will not preclude a finding that confusion is likely." *Sleekcraft*, 599 F.2d at 353. When goods are expensive, the buyer might be expected to exercise greater care, though confusion may still be likely. *Id.* Thus, the Court must examine how discriminating the average buyer of customizable promotional merchandise is likely to be.

***12** BIC argues the targeted consumers of both parties' products are sophisticated. (Def.'s Opp'n 14.) BIC cites the fact that the minimum order of each customized item listed in Marketquest's catalogue is 250 or 300, and that consumers seeking branded merchandise are likely to be institutions and companies rather than individuals. (*Id.*) Marketquest failed to address this factor in its motion, stating that it had yet to "fully investigate this factor." (Pl.'s Mem. ISO Mot. 13.) Instead, Marketquest points to the previously referenced instances of actual confusion to counter BIC's allegations of sophistication. (Pl.'s Reply 8.)

The degree of consumer care and sophistication can be proven by survey evidence, expert testimony, or inference. *See, e.g.*, *Star Indus., Inc. v. Bacardi & Co. Ltd.*, 412 F.3d 373 (2d Cir.2005), *cert. denied*, 126 S.Ct. 1570 (2006). Here, the parties have provided no survey evidence or expert testimony. Thus, the Court must rely on its own inference to determine whether the reasonably discriminating purchaser of customizable promotional merchandise should be held to a heightened standard.

The evidence currently before the Court indicates that buyers are likely to be sophisticated, institutional buyers placing bulk orders for corporate promotional purposes. The marketing materials of both parties appear to be aimed at institutional purchasers. However, the parties have barely addressed the factor, presenting the Court with very little evidence from which to form a solid conclusion.

It is possible, for example, that the average customer, although institutional, is not likely to exercise a heightened standard of care when making a purchase of 300 branded pens which will cost its company 50 cents each. (*See, e.g.*, Pl.'s Mem. ISO Mot. Ex. 5.) Further, customers, although institutional, may be likely to be companies whose main business has no relation to the purchase of customized promotional products, differentiating this situation from others in which courts have found professional consumers are likely to exercise a high degree of care. *See, e.g.*, *Moose Creek*, 331 F.Supp.2d at 1231 ("Plaintiff's customers are professional commercial clothing buyers and they are therefore likely to be familiar with the retail clothing market, likely to exercise a high degree of care in selecting wholesale clothing to purchase and thus unlikely to be easily confused by both parties' use of a moose on their marks.") In the alternative, it is possible that customers are more likely to be marketing representatives or agents who may have a lot of specific knowledge about customizable promotional products.

Given Marketquest's failure to contest BIC's assertion that the average customer is highly sophisticated and the lack of evidence pertaining to this issue, the Court finds this factor weighs slightly in favor of BIC but should be accorded little weight in the present analysis.

(vii) Defendant's Intent in Selecting the Mark

***13** "When the alleged infringer knowingly adopts a mark similar to another's, reviewing courts presume that the defendant can accomplish his purpose: that is, that the public will be deceived." *Sleekcraft*, 599 F.2d at 354. Thus, if Marketquest can show that BIC deliberately adopted the ALLIN–ONE mark in order to obtain advantage from Marketquest's goodwill, this may weigh heavily in favor of finding a likelihood of confusion.

Marketquest argues that bad faith is "the only reasonable explanation for Defendants' choice" of the phrase "All in ONE" for its NORWOOD Catalogue. (Pl.'s Mem. ISO Mot. 13.) Marketquest alleges that BIC was "well aware of All–In–One in advance" of choosing the phrase for its catalogue, and that the choice was an "attention getting symbol." (Pl.'s Reply 9.) To show bad faith, Marketquest alludes to several other marks it claims BIC "raided," including its THE WRITE CHOICE mark, which it originally claimed was infringed in the present action but has not pursued in the instant motion. (*Id.; see also* FAC ¶ 16.) BIC counters that it used the phrase "in good faith in an effort to streamline the number of catalogues Norwood would have to distribute, and to describe what the catalogue contains." (Def.'s Opp'n 14; Bauer Decl. ¶ 7.) In addition, BIC emphasizes that it displays the phrase next to its NORWOOD trademark, which indicates it did not intend to deceive consumers. (*Id.*)

The Ninth Circuit has recently emphasized that intent should not be considered in isolation, and that, "much like the proximity of the goods, the defendant's intent may be relevant here, but only insofar as it bolsters a finding that the use of the trademark serves to mislead consumers rather than truthfully inform them of their choice of products." *Network Automation*, 638 F.3d at 1153. In *Network Automation*, the district court failed to consider whether the defendant's intentional choice to use the plaintiff's mark was based on a bad faith intent to deceive, or a permissible intent to compare the two products. *Id.* Here, BIC has not alleged its use was based on an intent to compare. Instead, BIC asserts its use was unintentional and that it did not mean to conjure up Marketquest's products or services in any way in the minds of consumers. (Def.'s Opp'n 14–15.)

In the absence of any evidence that BIC acted with a bad faith intent when it used the phrase "All in ONE" on its 2011 NORWOOD Catalogue, the Court does not impute such intent based on Marketquest's circumstantial allegations. Accordingly, this factor weighs in favor of BIC.

(viii) Likelihood of Expansion of the Product Lines

The parties agree the Court need not consider this factor here, where the product lines already entirely overlap. (Pl.'s Mem. ISO Mot. 14; Def.'s Opp'n 14.) "Where two companies are direct competitors, this factor is unimportant." *Network Automation*, 638 F.3d at 1153; *cf. Brookfield*, 174 F.3d at 1060. Accordingly, the Court finds this factor should be accorded no weight.

(ix) Sleekcraft Factors Weigh in Favor of Finding a Likelihood of Confusion

***14** The Court notes that this likelihood of confusion test is fact-intensive, and many of the factors considered above are dependent upon factual conclusions that ultimately should be sent to trial for resolution. However, the Court must make a preliminary decision here for the purposes of this motion. Upon weighing the *Sleekcraft* factors, the Court concludes that the majority weigh in favor of finding a likelihood of confusion. Each of the first through fifth factors weighs at least slightly in favor of Marketquest, and only the sixth and seventh factors weigh

against. Having found some likelihood of confusion, the Court now turns to BIC's argument that the affirmative defense of fair use should bar liability here.

(C) Fair Use

BIC argues that even if the Court finds the likelihood of confusion factors weigh in favor of Marketquest, the "fair use" defense should shield BIC from infringement liability. (Def.'s Opp'n 15.) An affirmative defense of fair use is available to a party who uses a descriptive word "otherwise than as a mark ... [and] fairly and in good faith only to describe the goods or services of such party, or their geographic origin." 15 U.S.C. § 1115(b)(4). This Section of the Lanham Act codifies a longstanding common law principle that "[t]he use of a similar name by another to truthfully describe his own product does not constitute a legal or moral wrong, even if its effect be to cause the public to mistake the origin ... of the product." *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526, 529 (1924); *Fortune Dynamic*, 618 F.3d at 1039. Subjective good faith is relevant to the inquiry, but the main focus of the analysis is on whether the use of the mark was "objectively fair." *Fortune Dynamic*, 618 F.3d at 1039.

The Supreme Court recently clarified that the affirmative defense of fair use may be validly asserted even in cases where some degree of likelihood of confusion exists. *KP Permanent Make–Up*, 543 U.S. at 120 ("If a plaintiff succeeds in making out a prima facie case of trademark infringement, including the element of likelihood of consumer confusion, the defendant may ... raise an affirmative defense to bar relief ... [including fair use]."). However, the Ninth Circuit has explained that the degree of customer confusion remains a factor in evaluating fair use. *KP Permanent Make–Up Inc. v. Lasting Impression I*, 408 F.3d 596, 609 (9th Cir.2005). Among the relevant factors for consideration in determining the fairness of the use are "the degree of likely confusion, the strength of the trademark, the descriptive nature of the term for the product or service being offered by [the plaintiff] and the availability of alternate descriptive terms, the extent of the use of the term prior to the registration of the trademark, and any differences among the times and contexts in which [the plaintiff] has used the term." *Id.*

Here, although the Court has found that the phrase ALL–IN–ONE is an inherently distinctive mark that is not merely descriptive of Marketquest's service providing customizable promotional products, it is nonetheless a phrase commonly used by companies in general to describe the comprehensive nature of their services. The Supreme Court has explained that the Lanham Act exhibits a certain leniency where a descriptive phrase was selected to be a mark. *Id.* at 122. "If any confusion results, that is a risk the plaintiff accepted when it decided to identify its product with a mark that uses a well known descriptive phrase." *Id.* (citing *Park 'N Fly, Inc. v. Dollar Park and Fly, Inc.*, 469 U.S. 189 (1985) (noting safeguards in Lanham Act to prevent commercial monopolization of language); *Car–Freshener Corp. v. S.C. Johnson & Son, Inc.*, 70 F.3d. 267, 269 (2d Cir.1995) (noting importance of "protect[ing] the right of society at large to use words or images in their primary descriptive sense")).

***15** The question remains whether BIC's use of the phrase "All in ONE" on its 2011 NORWOOD Catalogue was otherwise than as a mark and only to describe its goods and services. To determine whether a term is being used as a mark, courts may look for indications that the term is being used to associate goods with a certain manufacturer. *Fortune Dynamic*, 618 F.3d at 1040 (citing *Sierra On–Line, Inc. v. Phoenix Software, Inc.*, 739 F.2d 1415, 1423 (9th Cir.1984)). Other indications of trademark use include "whether the term is used as a symbol to attract public attention, which can be demonstrated by the lettering, type style, size and visual placement and prominence of the challenged words, ... [and] whether the allegedly infringing user undertook precautionary measures such as labeling or other devices designed to minimize the risk that the term will be understood in its trademark sense." *Fortune Dynamic*, 618 F.3d at 1040 (citations omitted).

Here, the Court finds BIC likely used the phrase "All in One" otherwise than as a mark and solely in its descriptive sense, to distinguish one particular catalogue as a catch-all catalogue containing all of BIC's customizable promotional products. The NORWOOD mark was prominently displayed wherever the words "All in One"

appeared, and BIC also explained its use of the phrase in several places in the catalogue, such as: “Our primary product resource, featuring all product lines in ONE catalog.” (Pl.'s Mem. ISO Mot., Ex. 6.) Although Marketquest has offered evidence that BIC's use could be confused for an indication of source by comparison to NORWOOD's other catalogues tailored to the sale of other trademarked items or through a few instances of documented actual confusion, the Court finds this evidence unpersuasive.

The last factor in the fair use analysis asks whether BIC has exercised “good faith.” This inquiry is similar to the intent factor in the likelihood of confusion analysis, focusing on whether BIC intended to capitalize on Marketquest's good will in adopting its mark *Fortune Dynamic*, 618 F.3d at 1043. Marketquest offers no evidence of malicious intent on the part of BIC, other than assertions that BIC must have known about the ALL–IN–ONE mark and thus must have had bad faith. (Pl.'s Reply 9.) However, as above, this is not sufficient indication of bad faith to impute malicious intent. Further, using an objective fairness standard, the explanations BIC included in its catalogue of its use of the phrase “All in One” persuade the Court that use was likely fair. Thus, the Court finds BIC is likely to succeed on its affirmative defense of fair use.

2. The Other Preliminary Injunction Factors

Because the Court finds BIC is likely to succeed in asserting a fair use defense, it concludes Marketquest is unlikely to succeed on the merits of its trademark infringement case. Thus, the Court need not examine the other preliminary injunction factors: the likelihood of irreparable harm in the absence of a preliminary injunction; the balance of equities; and the public interest. *See Network Automation*, 638 F.3d at 1154 (finding that there is no need to reach the three remaining preliminary injunction elements where there is no likelihood of confusion.) Marketquest has fallen short of making the required showing that it is likely to succeed on the merits of its trademark infringement action. As a result, the Court finds the relief Marketquest seeks is better left to a trial on the merits and, if successful, an appropriately tailored permanent injunction.

CONCLUSION

***16** For the foregoing reasons, the Court **DENIES** Marketquest's motion for a preliminary injunction.

IT IS SO ORDERED.

Footnotes

2014 WL 347040
Only the Westlaw citation is currently available.
United States District Court,
S.D. Florida.

PRIDE FAMILY BRANDS, INC., Plaintiff,
v.
CARL'S PATIO, INC., Carl's Patio West, Inc., Woodard–Cm, Inc., and Scott Coogan, Defendants.

No. 12–21783–CIV. | Jan. 30, 2014.

Attorneys and Law Firms

Yale Lance Galanter, Galanter Law, P.A., Aventura, FL, for Plaintiff.

Andrew J. Daire, Boca Raton, FL, Oliver Alan Ruiz, Benjamin Michael Hanrahan, Malloy & Malloy, P.L. Miami, FL, for Defendants.

ORDER GRANTING DEFENDANTS' SECOND AND FINAL MOTION FOR SUMMARY JUDGMENT

PATRICIA A. SEITZ, District Judge.

***1** THIS CAUSE comes before the Court on Defendants Woodard–CM, LLC. ("Woodard") and Scott Coogan's Second and Final Motion for Summary Judgment [DE 111] wherein Defendants seek summary judgment on the remaining claims in this case.[1] Pride and Woodard are competing patio furniture manufacturers. Pride alleges Woodard infringed its unregistered trade dress by copying the design of Pride's Coco Isles and Cabana Bay furniture collections in a confusingly similar product line Woodard calls Jumby Bay. Pride claims that Woodard's copying violated § 43(a) of the Lanham Act (Claim II). Pride has also asserted common law claims for Unfair Competition (Claim III) and Unjust Enrichment (Claim IV), and a Florida statutory claim of Deceptive Acts and Practices (Claim V).[2]

1 The Court previously granted summary judgment for Defendants on Plaintiff's claim of design patent infringement (Claim I). [DE 132].

2 Though Defendants also seek the entry of summary judgment as to Defendant Coogan on legal grounds of individual non-liability, the merits of that argument are not reached because summary judgment is granted for both Defendants on other grounds. Defendants also seek a finding under 15 U.S.C. § 1117 that the action qualifies as an "exceptional case" which if granted would entitle Defendants to its attorney's fees. That issue is not reached here because an Order to Show Cause on the imposition of sanctions is forthcoming.

Having considered the motion, Pride's opposition [DE 121], and the reply [DE 130], summary judgment must be granted for Defendants. When the record evidence is viewed in the light most favorable to Pride, it cannot prevail on its trade dress infringement claim for three, separately dispositive reasons. First, the record evidence overwhelmingly shows that Pride's trade dress is functional and therefore not protectable. Second, the record evidence fails to demonstrate that either Pride collection achieved secondary meaning. Finally, there is no evidence that the relevant customers were likely to confuse Pride's and Woodard's collections. Because Claims III, IV, and V are predicated on Pride alleging a viable trade dress infringement claim, summary judgment must also be granted on those claims.

BACKGROUND [3]

[3] Unless otherwise noted the facts are taken from the undisputed record evidence.

a. Business Backdrop of the Dispute

Coco Isles, Cabana Bay, and Jumby Bay are each patio furniture collections in a tropical motif. [4] Defendant Scott Coogan designed all three collections. Coogan worked for Pride between 2004 and 2006 and joined Woodard in 2010. Pride contends that the Jumby Bay designs "are substantially identical and confusingly similar to the designs of the corresponding pieces of the [Coco Isles and Cabana Bay] collection[s]." [DE 6, ¶ 23]. [5]

[4] The collections include chairs, bar stools, sofas and love seats, dining tables, occasional tables, and ottomans. According to Plaintiff's CEO Steven Lowsky, Cabana Bay differs from Coco Isles in that the tubing used in Cabana Bay's frames is larger, Cabana Bay has a more nautical feel, and that Cabana Bay was intended for a different audience. (Deposition of Steven Lowsky, DE 111–4, 196:4–8).

[5] It is undisputed that Woodard brought certain pieces of Coco Isles furniture to its factory in Michigan when it fabricated its Jumby Bay prototypes. Woodard's chief engineer Reed Stauffer testified in his deposition that Woodard brought the Coco Isles pieces to its factory to ensure that the products Woodard was making surpassed Pride's comfort level. (Deposition of Reed Stauffer, 130–2, 71:8–18).

For several years Pride sold the Coco Isles and Cabana Bay collections to an outdoor furniture retailer called Carl's Patio ("Carl's"). In October or November 2011, Carl's decided to carry Woodard's Jumby Bay line and stopped buying Coco Isles or Cabana Bay. The patio furniture business is competitive. It is commonplace for manufacturers to involve large retailers in the design phase to ensure that new collections will sell. (Deposition of Greg Ecoff, DE 111–12, 74:5–17). Sometime after November 2010, when Coogan joined Woodard, Woodard approached Carl's with the prototype for its Jumby Bay collection. Carl's directed Woodard to change its designs to add lashing and flare the chairs' armrests. Woodard made the changes. Carl's bought Jumby Bay and abandoned Coco Isles and Cabana Bay. Pride now alleges that Defendant Coogan and Woodard conspired with Carl's to produce a cheaper "knock off' of Coco Isles and Cabana Bay. [6]

[6] Plaintiff named Carl's Patio and Carl's Patio West as Defendants. The Carl's entities filed a suggestion of bankruptcy on February 27, 2013. [DE 40, 41]. The Court stayed the case against Carl's [DE 43] and required status reports on the bankruptcy to be filed every sixty days. Carl's filed its last report on July 1, 2013 wherein it advised the bankruptcy case would be resolved by a global settlement which the Bankruptcy Court would review later that month. Carl's has not filed an additional report since the one in July and no party has moved to lift the stay against Carl's.

b. The Claimed Trade Dress

***2** Trade dress is the "the total image of a product and may include features such as size, shape, color or color combinations, textures, graphics, or even particular sales techniques." *Hyman v. Nationwide Mut. Fire Ins. Co.*, 304 F.3d 1179 (11th Cir.2002). Pride claims trade dress rights in an expansive, yet vague list of elements from the Coco Isles and Cabana Bay collections. [7] Pride marketed Coco Isles and Cabana Bay under three different brand names-Prestige, Castelle, and Expressions. [8] However, when Carl's displayed the collections in its stores, it displayed the pieces only with Carl's Patio hangtags and not with tags that had any brand identifier. With respect to the color or color combinations, Pride's offerings are highly customizable. Depending on collection and piece, retailers could choose up to seventeen different frame finishes and nineteen different fabrics. [DE 111–11].

[7] In its complaint Pride alleges that its "chair design," "leg ornamentation," "table and chair design," "arm wrapping," "paint finish," and "fabric" are protected trade dress. [DE 6, ¶ 19]. In a response to an interrogatory Plaintiff answered that its protected trade dress consists of "[f]abrication and design of the aluminum, including the curvature and the

aluminum lashings as [sic] various points on the products as well as the frame finish and cushion design and color and the overall unique product design of the collection." [DE 111–2, ¶ 17]. Moreover, when asked in depositions what features of the Coco Isles collection were distinctive Plaintiff's CEO Steven Lowsky responded "[i]t's got a very tropical feeling. It's got hand lashings in nine different areas. It's got a very plush, thick cushion. It's got great comfort. It's got a wonderful tortoise shell paint job." [DE 111–4, 192:12–15].

8 Carl's co-founder Gary Eckoff stated in his deposition that for a few years Carl's Patio put its own brand name on Pride's collections. [DE 111–12, pp. 89–90]. The record does not contain evidence of a consumer survey regarding consumer's association of any Pride brand to the Pride Family Brands company. [DE 111–19, ¶ 7]. However, in his deposition, Gary Ecoff stated that a study Carl's Patio commissioned regarding brand recognition in the patio furniture industry generally found very little brand recognition in industry. Only one manufacturer, Brown Jordan, had achieved recognition of over 3%, the statistical relevance threshold, and even then, Brown Jordan's recognition was only 3.5%. [DE 111–12, pp. 88–89].

Certain design elements are common to the tropical genre. [DE 111–12, pp. 83–84]. These include the use of brown and beige finishes, natural fabric colors, cast embellishments that resemble bamboo nodes, and lashings. Such elements intended to evoke bamboo and rattan, materials that furniture in the tropics is traditionally made from. (*See* Deposition of Paul Otowchits, DE 111–16, 82:10–22). The record evidence includes photographs of outdoor furniture collections by Tommy Bahama [DE 111–8], Lane Venture [DE 111–3], and Lloyd Flanders [111–10]. Many of these design elements are present in the collections of those manufacturers.

c. Relevant Market Factors

Pride's customers are furniture retailers. (Deposition of Steven Lowsky, DE 111–4, 218:4–8). Pride markets its collections at industry-wide trade shows in Chicago in July and September. (Deposition of Gary Ecoff, DE 111–12, 125:7–10). Like other players in the casual furniture industry, Pride displays its collection in large showrooms it leases at the Chicago Merchandise Mart. Buyers for retailers walk through the showrooms to view a particular manufacturer's collection and are presented with the manufacturer's marketing materials and, on request, its price lists. Pride also markets its furniture by using sales representatives to call on retailers at their stores. Retailers are aware that a manufacturer's representative only sells the manufacturer's products. [DE 111–4, 218:4–9].

II. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Anderson v. Liberty Lobby, Inc.*, *All* U.S. 242, 247 (1986). Once the moving party demonstrates the absence of a genuine issue of material fact, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial.' " *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986) (quoting Fed.R.Civ.P. 56(e)). The Court must view the record and all factual inferences therefrom in the light most favorable to the non-moving party and decide whether " 'the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.' " *Allen v. Tyson Foods, Inc.*, 121 F.3d 642, 646 (11th Cir.1997) (quoting *Anderson*, 477 U.S. at 251–52)).

***3** Summary Judgment must be granted for Defendants on Plaintiff's trade dress infringement claim (Claim II) because when the record evidence is viewed in the light most favorable to Plaintiff, it does not support that there is a disputed material issue of fact as to whether (i) Plaintiff's trade dress is non-functional and therefore protectable; or whether (ii) Plaintiff's trade dress had acquired secondary meaning; or whether (iii) Defendant's products were likely to cause confusion in the market as to their designation of origin. Because the remaining claims-Unfair Competition (Claim III), Unjust Enrichment (Claim IV), and Deceptive Acts and Practices (Claim V)—are each factually predicated on the viability of its trade dress infringement claim, summary judgment must also be granted as to those claims.

III. TRADE DRESS INFRINGEMENT

Plaintiff alleges that the design elements of its products constitute protected trade dress. Where a plaintiff alleges a defendant infringed its trade dress by copying designs rather than packaging, the claim can only go forward if the plaintiff shows the claimed design elements are nonfunctional and have secondary meaning such that they identify the producer. *Wal–Mart Stores, Inc. v. Samara Bros.*, 529 U.S. 205, 120 S.Ct. 1339, 146 L.Ed.2d 182 (2000). Once the plaintiff has established that its design constitutes protectable trade dress, it still must show that customers are likely to confuse the defendant's products for their own to prevail. *Dippin' Dots, Inc. v. Frosty Bites Dist., LLC*, 369 F.3d 1197, 1202 (11th Cir.2004). Each of these is a "threshold" element. *Id.* Therefore, Plaintiff's inability here to show a genuine factual dispute in record evidence as to non-functionality, secondary meaning, or market confusion means its trade dress claim fails thrice over.

a. The Claimed Elements are Functional

Because Pride does not own a registered trademark for the Coco Isles of Cabana Bay designs, pursuant to 15 U.S.C. § 1125(a)(3), it has the "burden of proving that the matter sought to be protected is not functional." There are two categories of functionality. *Dippin' Dots, Inc.*, 369 F.3d at 1203. First, an element is functional if "it is essential to the use or purpose of the article ... or affects the cost or quality of the article[.]" *Qualitex Co. v. Jacobson Prods. Co., Inc.*, 514 U.S. 159, 165, 115 S.Ct. 1300, 131 L.Ed.2d 248 (1995). Second, under the doctrine of aesthetic functionality, an element is functional if its "exclusive use ... would put competitors at a significant non-reputation-related disadvantage." *Id.* As such, courts look to the whether a competitor necessarily needs to use the claimed dress to compete in the field. *See Dippin' Dots, Inc.*, 369 F.3d at 1204, n. 7 ("Likewise, the color, shape, and size of dippin' dots are 'aesthetic functions' that easily satisfy the competitive necessity test because precluding competitors like FBD from copying any of these aspects of dippin' dots would eliminate all competitors in the flash-frozen ice cream market, which would be the ultimate non-reputation-related disadvantage."). The record evidence overwhelmingly supports that Plaintiff's trade dress is functional under the doctrine of aesthetic functionality. [9] [10]

9 One of the claimed elements, a lashing that connects the leaf to the arm of the Coco Isle chair is essential to the construction of the chair as Plaintiff's CEO even conceded and it is therefore functional under the first category. [DE 111–4, 185:11–21.]

10 Despite carrying the burden to prove its trade dress is non-functional, Plaintiff's opposition brief inexplicably ignores that requirement. In lieu of addressing Defendant's argument that Plaintiff's trade dress is functional, Plaintiff, at considerable length, argues that Defendants copied its designs. In so doing, Plaintiff has put the cart before the horse. Until Plaintiff shows its trade dress is protectable, Woodard, or anyone else, would be free to copy Plaintiff's claimed trade dress. *See TraFix Devices, Inc. v. Mkt'g Displays, Inc.*, 532 U.S. 23, 29, 121 S.Ct. 1255, 149 L.Ed.2d 164 (2001) ("Trade dress protection must subsist with the recognition that in many instances there is no prohibition against copying goods and products. In general, unless an intellectual property right such as a patent or copyright protects an item, it will be subject to copying.").

***4** The design elements Plaintiff seeks to claim as protected trade dress are common to the tropical motif. Plaintiff claims, *inter alia*, that its "chair design," "leg ornamentation," "table and chair design," "arm wrapping," "paint finish," "fabric," and "lashings" are protected trade dress. The tropical motif is referential of rattan and bamboo furniture of the tropics and, among other features, includes curving, naturalistic frame forms, fabrics in natural colors like brown and beige, and cast ornament applications meant to resemble natural features in bamboo. It is well-documented in the record that Plaintiff is simply one of many producers of tropical furniture that currently uses these techniques. For example, Tommy Bahama's Hibiscus Grove Collection uses natural, undulating frame forms and cast bamboo knots. Lane Venture's Summer Porch and Transitions Collection each incorporate lashings. Lloyd Flanders's "cane" and "penshell" finishes are brown and mahogany respectively.

If Plaintiff were granted the sweeping trade dress protection it seeks, all other manufacturers would be foreclosed from utilizing curving, naturalistic frame forms, natural color fabrics, cast ornamental applications that simulate natural features in bamboo, simulated lashings, or finishes evocative of tropical materials. Granting Plaintiff a monopoly on these features would put competitors in the tropical patio furniture industry at a significant non-reputation-related disadvantage. Therefore, applying the comparative necessity test, these elements are functional. Consequently, summary judgment must be granted for Defendants.

b. There is No Record Evidence of Secondary Meaning

Assuming that Plaintiff could have shown its claimed trade dress was non-functional, it would also have to show its trade dress has achieved secondary meaning.[11] Secondary meaning is acquired when "in the minds of the public, the primary significance of a product feature ... is to identify the source of the product rather than the product itself." *See* *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 851, n. 11, 102 S.Ct. 2182, 72 L.Ed.2d 606 (1982). Whether a product has established secondary meaning is a question of fact. Here, the record does not contain direct evidence that the claimed design elements of Coco Isles or Cabana Bay had achieved secondary meaning, nor can such a finding be made by simple inference.

11 A producer seeking trade dress protection must prove its product is distinctive. *Miller's Ale House, Inc. v. Boynton Carolina Ale House, LLC*, 702 F.3d 1312, 1322 (11th Cir.2012). Previously, a producer could prove distinctiveness either by showing its product to be inherently distinctive or upon showing it had achieved secondary meaning. However, in *Wal–Mart Stores, Inc. v. Samara Bros.*, 529 U.S. 205, 120 S.Ct. 1339, 146 L.Ed.2d 182 (2000), the Supreme Court held a product's design could never be inherently distinctive and therefore, a producer seeking trade dress protection needed to show secondary meaning. *Id.* at 216. Plaintiff's opposition overlooks the *Wal–Mart* rule and argues, erroneously, that Plaintiff's designs are entitled to trade dress protection by virtue of inherent distinctiveness. [DE 121, pp. 5–6].

The burden to establish that a product achieved secondary meaning lies with the Plaintiff. *Gift of Learning Foundation Inc. v. TGC, Inc.*, 329 F.3d 792 (11th Cir.2003). The Eleventh Circuit's predecessor court indicated that the best way for a plaintiff to prove its product has achieved secondary meaning is survey evidence. *Aloe Creme Labs., Inc. v. Milsan, Inc.*, 423 F.2d 845, 849 (5th Cir.1970)[12] ("The chief inquiry is the attitude of the consumer toward the mark; does it denote to him a, 'single thing coming from a single source?' Short of a survey, this is difficult of direct proof") (internal citation omitted). The record contains neither consumer survey evidence nor other direct evidence probative of secondary meaning such as testimony from consumers attesting to their recognition that the collections' designs are associated with Pride Family Brands.[13]

12 In *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir.1981) (en banc), the Eleventh Circuit adopted as binding precedent all decisions of the former Fifth Circuit handed down prior to October 1, 1981.

13 To the extent that the record evidence contains statements by Plaintiff's principals testifying to Pride's products' superior quality or innovation, those statements are insufficient to raise a genuine disputed issue for trial. Plaintiff's obligation is to show proof that "establishes the public mind" as to whether its products are associated with their producer. *Aloe Creme Labs., Inc.* 423 F.2d at 849. As such, Plaintiff cannot rely on self-serving statements made by a principal regarding his own impressions of Pride's products, their renown, or reputation as these assertions are non-probative of the public mind.

***5** Where a Plaintiff cannot marshal direct evidence of secondary meaning, secondary meaning can still be proven by inference, but the burden is high. For evidence that a product has attained secondary meaning the Eleventh Circuit looks to: 1) the length and manner of the product's use; 2) the nature and extent of advertising and promotion; 3) the efforts made by plaintiff to promote a conscious connection in the public's mind between the trade dress and plaintiff's business; and 4) the extent to which the public actually identifies the name with plaintiffs

goods and services. *Gift of Learning Foundation, Inc.*, 329 F.3d at 800. An inference of secondary meaning cannot be drawn from this record evidence.

First, the length and manner of use factors strongly cut against a finding of secondary meaning. The Coco Isles collection had been on the market for ten years, Cabana Bay for nine. In that time Carl's Patio sold both, but when Carl's displayed the furniture, it affixed its own hangtags. Despite the overall design, a Carl's customer would likely, and reasonably, believe, that Carl's made the furniture; very little, if anything, indicates Pride Family Brands actually manufactured it. Because Pride enabled its retailer customers to customize frame finishes and fabrics to their liking, offering as many as seventeen different finishes and nineteen different fabrics depending on collection and piece, it is even less likely that customers could identify a particular piece as being a Pride product based on its design elements alone.

Skipping for the moment the second factor and turning to the third, Pride's efforts to draw a connection between its trade dress and its business, by offering its collections under three separate brands, Plaintiff has made it less likely that a given customer would link Pride furniture's trade dress with its Pride Family Brands origin. For example, a customer who bought a Coco Isles chair under Castille brand and knew Castille to be associated with Pride Family Brands, might see the same chair at different retailer but sold under the Prestige brand. This customer would be less likely to associate the Prestige brand chair with Pride, than if Pride had uniform branding.

The second factor, advertising and promotion, and the fourth factor, extent of actual identification, are not useful to the analysis because the record evidence is insufficient to draw any meaningful conclusions about secondary meaning. [14] Given that Plaintiff cannot show its claimed trade dress achieved secondary meaning summary judgment must be granted for Defendants.

14 Pride's collections were pictured in sales catalogs the company produced at an annual cost of $75,000 and also in the magazines Hearth & Home, Casual Living, Luxe, and Florida Design. With respect to the catalog expenditures, the relevant inquiry is not how much Plaintiff spent on advertising, but how effective it was in fostering a consciousness of origin. *Aloe Creme Labs., Inc.* 423 F.2d at 850 (5th Cir.1970). There is no record evidence to suggest what, if any, affect the catalogs had on the public, nor is there any objective evidence from which to infer what that impact might have been. The record is silent as to how many catalogs were produced, where they were distributed apart from the trade shows, to whom they were distributed, and how they were distributed. Similarly, there is insufficient evidence as to the distribution of Hearth & Home, Casual Living, Luxe, and Florida Design magazines to make any reliable conclusions. There is no record evidence concerning how frequently the collections were advertised or the extent to which the advertisements linked either the Coco Isles or Cabana Bay collections to Pride Family Brands. With respect to the fourth factor, evidence of actual identification of the manufacturer by the public based on the mark, there is no evidence in the record that would support such a conclusion.

c. There is No Record Evidence of Product Confusion

Assuming further still that non-functionality and secondary meaning had been established, the entry of summary judgment for Defendants would nonetheless be required for a third reason—the record evidence does not support a finding of customer confusion based on Woodard's using similar trade dress. In the Eleventh Circuit, courts must weigh each of the following seven factors to determine if a consumer is likely to be confused by similarity in the parties' trade dress: (1) the strength of the trade dress, (2) the similarity of design, (3) the similarity of the product, (4) the similarity of retail outlets and purchasers, (5) the similarity of advertising media used, (6) the defendant's intent, and (7) actual confusion. *AmBrit, Inc. v. Kraft Inc.*, 812 F.2d 1531 (11th Cir.1986). Of these seven factors, the first, strength of trade dress, and last, actual confusion, are the most important. *Star Steakhouse and Saloon, Inc. v. Lone Star Steakhouse & Saloon of Georgia, Inc.*, 122 F.3d 1379, 1382 (11th Cir.1997). The burden of showing confusion is on the Plaintiff. *Leigh v. Warner Bros., Inc.* ., 212 F.3d 1210, 1216 (11th Cir.2000). [15] The

seven factors are discussed out of order. Factors one and seven are discussed first, factors three, four, five, and two are discussed next, and factor six is discussed last.

15 Plaintiff claims Defendant carries the burden on likelihood of confusion. [DE 121, p. 6]. Plaintiff seems to have overlooked that when the Federal Circuit reviews Lanham Act claims it applies the law of the regional circuit in which the claim originated. *CPG Prods. Corps. v. Pegasus Luggage, Inc.*, 776 F.2d 1007, 1011 (Fed.Cir.1985). As such, Eleventh Circuit law, not the Second Circuit case law on which Plaintiff has relied, controls.

i. Factors One and Seven

***6** Strong trade dress indicates the product's source. For example, by observation of just the Coca Cola contoured bottle, a consumer knows the origin of that soda. *See Rock and Roll Hall of Fame and Museum, Inc. v. Gentile Prods.*, 134 F.3d 749 (6th Cir.1998). It follows that where a product has a strong trade dress and a rival appropriates it, the consumer is more likely to be confused as to the rival product's origin. Turning to Pride's claimed trade dress, it is apparent that is not the case here. As discussed above in relation to secondary meaning, the features Pride claims as trade dress are generic aesthetic elements of the tropical motif. There is no evidence from which to conclude that if a hypothetical consumer saw an unlabelled Coco Isles or Cabana Bay furniture piece he would recognize, based on its design alone, that it was made by Pride.

Nor is there any evidence that any actual consumer has mistaken a Jumby Bay piece for one made by Pride. Plaintiff claims that "there was definitely confusion on the part of the consumer" and cites to the deposition of CEO Steve Lowsky for factual support. [DE 121–1, ¶ 2]. Lowsky discusses two instances from Pride's investigation, but neither amounts to actual consumer confusion. [DE 111–4 199:5–10; pp. 197–198]. In the first instance, a Pride investigator posed as a consumer and was told by different retailers that Jumby Bay furniture was better and cheaper than Coco Isles or was told that Pride could no longer supply the store. In the second instance, a retailer in New York called Lowsky to report that a Woodard salesman offered to sell him a "Coco Isle look-alike." Neither of these is evidence of actual confusion by a consumer based on Woodard's use of similar trade dress. As such, the seventh prong counsels against a finding of consumer confusion.

ii. Factors Two, Three, Four, and Five

Trade dress cannot be viewed in a vacuum. How the trade dress functions in the market place is an important consideration in determining market confusion. *See e.g., Dippin' Dots, Inc.*, 369 F.3d at 1028 (11th Cir.2004) (Noting that design similarity increased likelihood of confusion because ice cream novelties are impulse items, sold to hurried shoppers.); *Gray v. Meijer, Inc.*, 295 F.3d 641 (6th Cir.2001) (Finding a low likelihood of confusion between store brand popcorn and national brand popcorn with similar labels because store brand popcorn was on a shelf with other store brand snack food.) Thus, when evaluating factors two, three, four, and five-similarity of design, similarity of the product, similarity of retail outlets and purchasers, and similarity of advertising media used-the way the trade dress actually works in the market influences each facet of the analysis.

Factors three, four, and five, do not strongly favor a likelihood of confusion. Factor three considers the similarity of the product. Here, the products are both outdoor furniture collections in the tropical motif. Similarly, the record evidence as to the fourth factor, similarity of retail outlets and purchasers, shows both Pride and Woodard sold their collections to the same customers, outdoor furniture retailers including Carl's Patio. The record evidence is insufficient to draw any conclusions as to factor five, the similarity of Pride's and Woodard's advertising.

***7** The second factor, similarity of design, strongly *disfavors* that there was confusion between Plaintiff's and Woodard's collections. Plaintiff alleges that Woodard's Jumby collection is identical in every way to Plaintiff's Coco Isle and Cabana Bay collections. 16 Even if it were assumed that Woodard's and Plaintiff's collections were identical, the Eleventh Circuit requires that similarity of design is evaluated in the "context of the trade dress as

whole." *AmBrit, Inc.*, 812 F.2d at 1540. Here, the way the collections are marketed makes confusion between the two highly unlikely. Pride sells its furniture exclusively to retailers.[17] As industry participants, retailers are a sophisticated customer base who, it can be assumed, know the different market players and are familiar with developments in designs and changes in pricing. The marketing channels in the patio furniture industry are well-established. Manufacturers, including Pride, show their collections at twice-yearly trade shows, a pre-show in July and a main show in September. Pride leased large display showrooms at these trade events where only its collections were displayed. Additionally, a manufacturer might send a sales representative to call on a retailer customer. Sales representatives only sold one manufacturer's line of furniture. As Steven Lowsky testified, "you know when a sales rep walks in from Woodard, he's selling Woodard product." [DE 111–4, 218:4–9].

16 Plaintiff does not address the apparent logical inconsistency of its position given that Plaintiff's CEO explained that Cabana Bay is different from Coco Isles in that it is made from larger tubing, has a more "nautical feel," and was designed to appeal to a different customer.

17 Even if the relevant customer demographic for the confusion analysis were end-use consumers, the likelihood of confusion is low. First, as is noted elsewhere, brand recognition in the patio furniture industry is low. Steven Lowsky stated in his deposition that the most important factors in a customer's buying decision were price, comfort, and appearance. This suggests that a consumer does not make purchasing decisions based on brand. Second, outdoor patio furniture is not an impulse item. The record evidence shows that outdoor furniture pieces can retail for more than $1,000 dollars. So while Pride and Woodard might be considered by the same end-user, a consumer looking for Pride-made furniture would likely undertake some investigation given what the product costs.

iii. Factor Six

Finally, the sixth factor considers a defendant's intent in co-opting Plaintiff's trade dress. Plaintiff has vigorously argued that Defendants Coogan and Woodard copied Pride's designs, not just to capitalize on Pride's goodwill in the industry, but out of bad faith. Jamie Lowsky, Pride's President, goes so far as to state in his deposition that Coogan was "so hateful of Pride that no matter where he went he was vengeful to come after us ..." (Deposition of Jamie Lowsky, DE 61, 94:1–10). Lowsky's speculations as to Coogan's motives are unsupported by the record evidence. Moreover, though Pride reads Woodard's successful effort to displace Pride's collections in the market as evidence of bad faith, the record evidence supports a finding that Woodard engaged in *fair* competition.

The Supreme Court recognized in *TrafFix Devices, Inc. v. Mkt'g Displays, Inc.*, 532 U.S. 23, 29, 121 S.Ct. 1255, 149 L.Ed.2d 164 (2001), that in the trade dress realm "in many instances there is no prohibition against copying goods and products." This is especially true where the claimed trade dress is the product's design. As the Court explained: "Allowing competitors to copy will have salutary effects in many instances. Reverse engineering of chemical and mechanical articles in the public domain often leads to significant advances in technology." *Id.* (internal quotation marks and citation omitted).

Woodard developed the Jumby Bay line in consultation with Carl's, who previously bought Pride's collections. Woodard changed its prototype designs based on Carl's recommendation to add lashings and to flare the chair arms. As is discussed above, Pride does not have a monopoly on the application of lashing or any other generic element of the tropical motif. Without more, Woodard's efforts to reengineer products to conform to a customer demands cannot be found to be a bad faith attempt to engage in deliberate confusion.

***8** To the extent Plaintiff attempts to claim that Coogan's reservations about adding lashings are indicative of his knowledge that Woodard deliberately copied Pride's products for the purpose of confusing customers, Plaintiff overextends the record evidence. Coogan stated that he did not want to add lashings simply because he had done that before while designing for Pride. [DE 83–2, pp. 52–53.]. While Plaintiff seems to impute consciousness of guilt to that sentiment, Coogan's hesitance might equally be ascribed to a designer's desire not to tread ground he has already covered. Plaintiff also cites Woodard's use of a Coco Isles chair in the development of the Jumby

Bay collection. As noted above, reverse engineering is not uncommon is a valuable tool which often furthers competition in the marketplace. Here, Defendant's chief engineer Reed Stauffer testified Woodard's design team studied the Coco Isles chair in order to surpass its level of comfort. On balance, it is evident that the record evidence does not support Plaintiff's contention that defendants engaged in bad faith to the extent they incorporate elements of Plaintiff's trade dress. Overall, based on the record evidence, Plaintiff cannot show a likelihood of confusion in the minds of consumers between Jumby Bay and Coco Isles or Cabana Bay furniture. For this additional reason, summary judgment on Plaintiff's trade dress infringement claim must be entered for Defendants.

IV. THE REMAINING CLAIMS

None of Plaintiff's remaining claims, Common Law Unfair Competition (Claim III), Unjust Enrichment (Claim IV), and Unfair or Deceptive Acts and Practices (Claim V), allege any facts or injury independent of those related to Plaintiff's Patent Infringement (Claim I) and False Designation of Origin claims (Claim II). Because Defendant's did not infringe Plaintiff's design patents or trade dress, these claims necessarily fail and summary judgment must be entered for Defendants on each claim.

V. CONCLUSION

Given that the record evidence fails to establish (i) that Plaintiff's trade dress is nonfunctional; (ii) that Plaintiff's products had achieved secondary meaning; (iii) and that Defendant's Jumby Bay collection would cause consumers to be confused about its designation of origin, based on the foregoing, summary judgment must be entered for defendant as to Claim I. In light of this and the earlier finding that two of Plaintiff's design patents were invalid and Defendants did not infringe Plaintiff's valid design patents, summary judgment must be granted as to all remaining claims. Therefore, it is

ORDERED THAT

(1) Defendant's Second and Final Motion for Summary Judgment [DE 111] is **GRANTED.**

(2) **Except for Docket Entry 22,** Agreed Plaintiff's Motion to Seal DE 121 and Exhibits, which is resolved by separate Order, all pending motions are **DENIED AS MOOT.**

(3) The Court shall separately enter judgment following the resolution of the forthcoming Order to Show Cause. [*See* DE 132, p. 1., n.l].

***9** DONE AND ORDERED in Miami, Florida, this *29th* day of January 2014.

End of Document