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**UNITED STATES OF AMERICA**
**BEFORE THE FEDERAL TRADE COMMISSION**

**COMMISSIONERS:** **Edith Ramirez, Chairwoman**
**Julie Brill**
**Maureen K. Ohlhausen**
**Joshua D. Wright**
**Terrell McSweeny**

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

**COMPLAINT COUNSEL'S REPLY BRIEF**
**TO RESPONDENT'S ANSWERING BRIEF**

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Dated: April 9, 2015

## RECORD REFERENCES

**CC App. Br.** – Complaint Counsel's Opening Appeal Brief

**CC Ans. Br.** – Complaint Counsel's Answering Brief

**CCFF** – Complaint Counsel's Proposed Findings of Fact

**CCX** – Complaint Counsel's Exhibit

**CCPTB** – Complaint Counsel's Post-Trial Brief

**CCPTRB** – Complaint Counsel's Post-Trial Reply Brief

**Dep.** – Deposition transcript

**ID** – Initial Decision

**IDFF** – Initial Decision Findings of Facts

**Resp. App. Br.** – Respondent's Opening Appeal Brief

**Resp. Ans. Br.** – Respondent's Answering Brief

**RPTRB** – Respondent's Post-Trial Reply Brief

**RX** – Respondent's Exhibit

**Tr.** – Trial Transcript

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## I. INTRODUCTION

Beneath its purple prose, there is little substance in ECM BioFilms Inc.'s ("ECM") answering brief. For the most part, it rehashes the conspiracy theories spun in ECM's opening brief, reiterates the ALJ's flawed conclusions, and lobs baseless attacks at Complaint Counsel and its experts.

Peeling away the oratory, Respondent's arguments fail for five reasons. First, ECM misstates the standard of review regarding expert testimony and record evidence. Second, ECM fails to rebut overwhelming proof that it made the implied claim that plastics treated with its Additive would completely break down in a landfill in a reasonably short time. Third, ECM fails to rebut abundant evidence that its claims are false and unsubstantiated, and instead deflects by focusing on substantiation for unchallenged claims. Fourth, even the claims ECM asserts it made lack evidentiary support. Finally, its meritless arguments about the First Amendment, environmental benefits, and notice fail to undercut Complaint Counsel's arguments for a strong remedy.

## II. ARGUMENT

### A. The Standard of Review Is *De Novo*.

ECM makes three faulty arguments about the standard of review. (Resp. Ans. Br. at 11-12.) First, ECM argues that the ALJ's evaluations of the testimony of ECM and Complaint Counsel's expert witnesses are entitled to "great weight" and "special deference." (*Id.* at 11 (internal quotations and citations omitted).) This misstates the standard of review. Certainly, in considering the record as a whole, the Commission may not "'ignore'" the ALJ's findings. (*Id.* (quoting *Cinderella Career & Finishing Schools, Inc. v. F.T.C.*, 425 F.2d 583, 589 (D.C. Cir. 1970).) But the Commission's Rules do not require it to provide any special deference to the

ALJ's evaluation of experts' opinions and experience. The Commission is equally well positioned to evaluate that testimony.[1] *See POM Wonderful LLC*, No. 9344, 2013 FTC LEXIS 6, at *17 (Jan. 10, 2013) (quoting 16 C.F.R. § 3.54 ("The Commission reviews the record *de novo* by . . . exercis[ing] all the powers which [the Commission] could have exercised if it had made the initial decision."). (*See also* CC App. Br. at 9 n.8 (citing *POM*, No. 9344, 2013 FTC LEXIS 6, at *100 n.23 (noting that the Commission may reach different conclusions than the ALJ about the consistency and rationality of expert testimony)).

Second, ECM argues that Complaint Counsel "improperly" relied on its proposed findings of fact rather than citing the ALJ's Initial Decision. (Resp. Ans. Br. at 12.) According to ECM, this "violation" of Rule 3.52(c) was so egregious that it warrants "summary denial of [Complaint Counsel's] appeal." (Resp. Ans. Br. at 8.) This absurd argument fails for two reasons. First, Rule 3.52(c) states that the parties' appeal briefs shall provide "specific page references to the record and the legal or other material relied upon." 16 C.F.R. § 3.52(c)(iv). Nowhere does this rule limit the parties to citing the ALJ's Initial Decision to the exclusion of other evidence. Indeed, it would be nonsensical for the Rules to permit citation only to the Initial Decision, when the Commission has *de novo* review over the ALJ's determinations on the admissibility of evidence. *See* 16 C.F.R. § 3.43(i) ("Rejected exhibits . . . shall be retained in the record so as to be available for consideration by any reviewing authority."). Moreover, contrary to ECM's assertion, Complaint Counsel did not merely rely on its own proposed

[1] As noted in Complaint Counsel's opening brief, the ALJ's "credibility" findings were not based on demeanor, tone, or any other factor requiring direct observation of the witnesses. (CC App. Br. at 8 n.9.)

findings of fact. In fact, Complaint Counsel's opening brief cited the Initial Decision forty times. *See generally* CC App. Br.[2]

Finally, ECM falsely accuses Complaint Counsel of "misrepresent[ing] the evidence of record" in two ways. (Resp. Ans. Br. at 12.) First, ECM claims that Complaint Counsel improperly "charge[d]" ECM with having hidden Dr. Michel's peer-reviewed article (demonstrating that ECM's Additive does nothing) from its customers. (Resp. Ans. Br. at 12 (citing CC App. Br. at 4).)[3] ECM misstates Complaint Counsel's brief. The opening brief stated that Respondent was aware of negative results (not Dr. Michel's study specifically) and "hid them [negative results] from prospective customers, by steering them away from labs that provided negative results and towards labs whose dubious testing protocols provided the semblance of positive results." (CC App. Br. at 4 (emphasis added).)

As uncomfortable as it may be for Respondent, the evidence demonstrates that ECM concealed bad results in precisely this way. For example, in January 2012, customer Shields Bag and Printing Company ("Shields") reported to ECM that the testing lab O.W.S. observed no biodegradation of plastic containing the ECM Additive. (CCX-422 at 55.) At this time, ECM was already on notice of adverse foreign and National Advertising Division ("NAD") decisions,[4]

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[2] ECM also argues that Complaint Counsel "ignored" the record because it did not give specific responses to 2,776 of ECM's proposed findings of fact. (Resp. Ans. Br. at 7.) Complaint Counsel had "'no specific response'" because it had already carried its burden of proof in making and responding to hundreds of other proposed findings of fact. There was no need to indulge Respondent's penchant for prolixity.

[3] ECM then accuses Complaint Counsel of having hidden the study from ECM. (Resp. Ans. Br. at 12.) Complaint Counsel's answering brief already debunked this baseless accusation. (CC Ans. Br. at 17-22).

[4] ECM attempts to characterize the NAD decisions regarding plastic products treated with the ECM Additive ("ECM Plastic") as not truly challenging the plastic's biodegradability. (Resp. Ans. Br. at 10). This is nonsense. *See* CCX-26 at 9 (NAD decision regarding Dispoz-o, concluding that there was no "competent and reliable scientific evidence" that ECM Plastic will "completely break down and return to nature within a reasonable [sic] short period of time after

as well as other negative test results as well as academic and industry criticism. (*See* CC App. Br. at 5 (collecting examples); CC Ans. Br. at 19 n.18 (additional examples).) Rather than admit to Shields that such doubts were the norm, ECM CEO Robert Sinclair accused the testing lab of being a biased outlier: "We knew this lab was against us but we didn't think they would skew the testing such that the results are so different than any other lab around the world . . . ." (CCX-422 at 55.) Mr. Sinclair then directed Shields to a different lab, Eden, (*id.* at 57), whose flawed test methods occasionally produced the appearance of positive results. (CCFF ¶ 173.) Similarly, when another customer, Kleertech, informed ECM of negative test results the very next month, Mr. Sinclair blamed "fundamental problems" in the testing, did not mention any doubts or other negative results, and re-directed Kleertech to friendly labs. (CCX-325 at 2-3.)

ECM also claims that Complaint Counsel "misrepresent[ed]" Dr. Frederick's testimony. (Resp. Ans. Br. at 12.) Specifically, ECM argues that Dr. Frederick did not opine that each of the four studies in the record—including ECM's own study—supports Complaint Counsel's position regarding consumer perception of unqualified biodegradable claims. (Resp. Ans. Br. at 12, 22 n.17.) ECM is simply wrong. Each study—including Respondent's—does indeed support Complaint Counsel's position, and Dr. Frederick explained that fact both in his rebuttal expert report and at trial. (CCX-865 at 8-9; Tr. 1177, 1366-67, 1369.) The ALJ and Respondent misstated this straightforward evidence. (Resp. Ans. Br. at 12 (citing ALJID at 208 n.34).)

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customary disposal in landfills"); CCX-27 at 9 (NAD decision regarding Masternet Ltd., finding "insufficient" evidence "to substantiate that [ECM Plastic] products were biodegradable through customary disposal within a reasonably short period of time"); CCX-28 at 18 (NAD decision regarding FP International, concluding that "there was insufficient evidence to support an unqualified biodegradable claim or the advertiser's more limited claim that Super 8 Loosefill would biodegrade in a landfill within 9 to 60 months."). In addition, by the time of this exchange with Shields in 2012, an Italian consumer protection authority had already found "biodegradable" claims for ECM Plastic misleading. *See* CCX-186 at 27 (English translation).

**B. Abundant Evidence Demonstrates That ECM Made The Implied Claim.**

Next, ECM attempts to refute the overwhelming evidence that its unqualified biodegradable claim and claim of biodegradation in "some period greater than a year" implied complete landfill breakdown in a reasonably short period. As described below, each of ECM's arguments fails.

First, ECM argues that Complaint Counsel improperly raises a new argument on appeal—that a "reasonably short period" entails breakdown within five years or less. (Resp. Ans. Br. at 7 n.9, 13-14.)[5] In fact, Complaint Counsel has consistently argued that ECM made implied claims of biodegradability in a reasonably short time of one or five years. *See, e.g.*, CCPTB at 26-28; Tr. 20-21, 48, 51) (pre-trial and trial argument regarding implied claim of five years or less). Complaint Counsel's appeal brief does no more than reiterate these arguments.

Second, ECM argues that reasonable consumers do not perceive any timeframe, much less a short timeframe, for biodegradation because biodegradation is a long and variable process. (Resp. Ans. Br. at 15-16.) This is wrong. As explained in Complaint Counsel's appeal brief (CC App. Br. at 6), an interpretation is reasonable if shared by a significant minority of consumers. FTC Policy Statement on Deception, 103 F.T.C. 174, 177 n.20 (1984) ("*Deception Statement*") (citing *In re Kirchner*, 63 F.T.C. 1282 (1963)); *see also POM*, 2013 FTC LEXIS 6, at *20; *In re Telebrands Corp.*, 140 F.T.C. 278, 291 (2005). Here, significant minorities (at least 25%), and in some cases majorities, of consumers understand the claims "biodegradable" and "biodegradable in some period greater than a year" to mean complete breakdown in about a year or, at most, in five years. (CC App. Br. at 7-8.) As the consumer perception evidence shows,

[5] ECM's argument is complicated by the fact that ECM appears to misunderstand what constitutes an implied claim. For example, ECM argues that "[a]n implied '5 year' claim would have required end-use consumers who purchased plastics to have actually seen the [express] '5 year' claim." (Resp. Ans. Br. at 14.)

many consumers share this view. This interpretation is not an example of an "'outlandish'" belief held by "'a few misguided souls,'" as ECM suggests. (Resp. Ans. Br. at 16 (quoting *Kirchner*, 63 F.T.C. 1282, at *6).) In short, Respondent cannot evade responsibility for its implied claims simply by arguing that it believes that informed consumers should not hold this view.

Next, ECM argues that Dr. Stewart's testimony and survey establish that ECM did not make any implied rate claims. (Resp. Ans. Br. at 17-18.) Then, after chastising Complaint Counsel for misdeeds ranging from "misrepresent[ing]," "opining," and "data manipulation" to "wishful thinking" (Resp. Ans. Br. at 19-21), ECM reiterates the ALJ's unsound criticisms of Dr. Frederick's opinions and study. (Resp. Ans. Br. at 21-34.) Complaint Counsel already debunked each point in its opening brief. (CC App. Br. at 7-26.) Only the few points below warrant additional response.

First, ECM, like the ALJ, misunderstands convergent validity, construing it to mean that "serendipitous similarity of results from three flawed studies ... validate[s] those results." (Resp. Ans. Br. at 21.) This is incorrect. Dr. Frederick explained that each of the four studies in the record, though containing varying degrees of imperfection, was reasonably reliable and valid. (*See* CC App. Br. at 9.) Because of this baseline reliability and validity, each study is a useful data point, and the convergence of their conclusions is a strong indication of the results' accuracy. (*Id.*)

Second, ECM faults Dr. Frederick for not designing his study with the Manual for Complex Litigation in mind. (Resp. Ans. Br. at 23-25.) The fact that Dr. Frederick, a prominent academic and first-time witness, is unfamiliar with a litigation treatise or legal standard is

irrelevant to whether his research did in fact conform with the legal standard (which it did).[6] Indeed, in its opening brief, Complaint Counsel explained at length why Dr. Frederick's study is methodologically sound (the standard the Commission applies to survey evidence). *See* CC App. Br. at 13 (citing *POM*, No. 9344, 2013 FTC LEXIS 6, at *45); *see also id.* at 13-26 (explaining that Dr. Frederick's study drew representative samples from the appropriate population, asked appropriate questions in ways that minimized bias, and correctly analyzed results).

Finally, as in its opening brief, ECM resorts to an array of *ad hominem* attacks. Each misses its mark. Specifically, ECM accuses Dr. Frederick of "dissembl[ing] on cross-examination," "avoid[ing] quality research" so that he could "pocket[]" more money, and improperly asking survey respondents questions about hypothetical products that displayed ECM's claims. (Resp. Ans. Br. at 3, 26, 31.) Tellingly, Respondent neglects to mention how Dr. Frederick allegedly "dissembled," perhaps because ECM simply uses this epithet to describe Complaint Counsel's experts as a matter of course. *See* Resp. Ans. Br. at 37 (Dr. McCarthy allegedly "dissembling"); Resp. App. Br. at 10 (same); *id.* at 46 (Dr. Michel allegedly "dissembled"). Complaint Counsel's opening brief addresses the ridiculous argument about Dr. Frederick's compensation. (CC App. Br. at 15 n.13.) Finally, Dr. Frederick openly explained in his expert report, and at trial, that he used "photoshopped" images of plastic products with the ECM logo so that he could ask respondents about generic plastic products like bags and containers (*i.e.*, images untainted by other advertising). (CCX-865 at 13; Tr. 1265-66.) In short, there is no substance to Respondent's accusations.

[6] In fact, one might argue that this fact enhances his credibility, compared to a career litigation expert.

### C. ECM's Express And Implied Biodegradable Claims Are False And Unsubstantiated.

At least a significant minority, and likely a majority, of consumers and ECM customers understand ECM's unqualified biodegradable and "some period greater than a year" claim to mean that ECM Plastic will completely breakdown in one year (or less than five years) in a landfill.[7] ECM admits that these claims are false and unsubstantiated.[8] Thus, ECM does not (and could not) argue that any test in the record supports the challenged express and implied claims. Instead, ECM argues that Complaint Counsel "ignores" the ALJ's findings that "twenty (20) competent and reliable tests that prove the ECM additive causes plastics to biodegrade to a significant extent where untreated plastics do not."[9] (Resp. Ans. Br. at 35.)

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[7] *Supra*, at 5-8.

[8] ECM concedes that nothing biodegrades completely in a landfill within five years, thus ECM's express and implied claims that ECM Plastics will completely biodegrade in less than five years in landfills are false. (CCPTB at 29-54, 86-88; *see* RPTB at 56-58 (admitting that it made the claim); CCFF ¶ 188 (Dr. Sahu stating it could take 30-100 years for ECM Plastic to completely biodegrade); *see also* CCPTB at 55-61).) In addition, well-documented anaerobic tests, including one study published in a peer-reviewed scientific journal (CCX-164), show no statistically significant biodegradation, further proving ECM's express and implied claims are false. (CCFF ¶¶ 453; 454.)

[9] In fact, the ALJ only characterizes 17, not 20, tests as showing increased biodegradation. (ALJFF ¶¶ 1043-1424.) ECM included two O.W.S. tests (Resp. Ans. Brief at 1, citing ALJFF ¶¶ 1448-1465), which the ALJ discounted because the "OWS studies, with no supporting fact or expert testimony . . . are not given significant weight . . . ." (ALJID at 261.) Nonetheless, these two tests are irrelevant to ECM's asserted claims. One, RX-265 is a test of the ECM additive alone, and therefore does not reflect biodegradation of ECM Plastic and merely proves that the ECM Additive itself is biodegradable. The second test, RX-268, is likewise unavailing. The test reports 3.9%±1.1% biodegradation after 15 days. But the percent of ECM Additive is not reported; additionally, the test concludes that "no further biodegradation is expected. It seems that only a minor component or some minor residual chemicals (monomers) are degradable." (RX-268.) ECM also included a weight loss test among the "positive" tests, but the ALJ appropriately found weight loss tests unreliable. (RX-399, Bio-Tec Environmental; ALJFF ¶¶ 741-742.)

As explained below, these tests are either fatally flawed, show no biodegradation, or both. However, whether they showed some biodegradation (which they do not) is irrelevant. As we explained in our Post-Trial Reply Brief, "even if ECM's advertisements also conveyed a different, truthful claim, Complaint Counsel need only prove one reasonable interpretation of the advertisement is false or unsubstantiated to establish liability for deception under the FTC Act." (CCPTRB at 8, citing cases.) While Complaint Counsel need not prove this comparative claim is untruthful or unsubstantiated to prevail, there is in fact no evidence to support it.[10]

**D. The Claim ECM Asserts It Made Is False And Unsubstantiated.**

To reach his conclusion that ECM Plastic is biodegradable under some definition, the ALJ relied completely on tests run by two small labs: North East Labs ("NEL") and Eden Research Laboratories ("ERL") (ALJFF ¶¶ 1006-1425).[11] (CC App. Br. at 30-47.) The tests conducted by these labs, however, are fatally flawed and wholly unreliable for two reasons. First, both labs used hopelessly flawed, unreliable testing methods.[12] Second, even ignoring

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[10] In an attempt to bolster its experts' opinions, ECM grossly mischaracterizes our experts' testimony. Much of this is addressed in our Opening and Answering Briefs, but a few additional points are noteworthy. ECM claims that Dr. Tolaymat concedes Dr. Barlaz as "the authority" in biodegradation research (Resp. Ans. Br. at 37.) Not so. Dr. Tolamat describes him as "an authority" and further clarifies that Dr. Barlaz consulted for him. (Tolaymat, Tr. at 233-234.) ECM again tries to use Dr. Tolaymat to bolster Dr. Barlaz by claiming Dr. Tolaymat agreed with Dr. Barlaz's statistical analysis. (Resp. Ans. Br. at 45.) But the citation to ALJFF ¶ 723 has nothing to do with Dr. Barlaz's statistical analysis; it merely states that Dr. Tolaymat agrees that "accelerated testing to demonstrate biodegradation is possible." In fact, Dr. Tolaymat repeatedly stressed that one data point for a given specimen was insufficient from which to draw a conclusion one way or the other regarding the results. (Tolaymat, Tr. 306-313.)

[11] Interestingly, the ALJ did not rely on any of the actual substantiation materials ECM provided to Complaint Counsel during the pre-complaint investigation.

[12] Of course, the results from these labs are more suspect because they are the **only labs** whose anaerobic results purport to show any biodegradation. Nonetheless, their undocumented, unorthodox modifications to the test utilizing methods such as re-inoculation make their results unreliable (CCFF ¶¶ 142-143.)

these dramatic methodological problems, the data from each test suffered from additional severe flaws.[13] (CCPTB at 59-61; CCPTRB at 12-19; CC App. Br. at 46-47.) Therefore, the test results are not competent and reliable scientific evidence of increased anaerobic biodegradation of the conventional plastic component of ECM Plastic. Without such evidence, ECM cannot substantiate a claim that an ECM Plastic will biodegrade comparatively faster, or to a greater extent, than untreated plastic—let alone the stronger claims they actually made.

**1. The NEL And ERL Tests Are Methodologically Flawed.**

All seventeen (17) tests relied upon by the ALJ had fatal methodological flaws. The ALJ identified nine ASTM D5511 tests conducted by NEL that purport to show anaerobic biodegradation of ECM Plastic. (*See* ALJID at 136-151). During the trial, Alan Johnson, the current owner of NEL (Johnson, Tr. 1554) testified that, for all nine tests:[14]

- NEL did not maintain anaerobic conditions throughout the duration of the extended anaerobic ASTM D5511 tests (Johnson, Tr. 1574);[15]
- NEL conducted tests beyond the 30-day period permitted by ASTM D5511(Johnson, Tr. 1583);

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[13] (CCX-891, ¶¶ 87-89); *see also* RPTRB at 97-98, stating that lack of information concerning the test plastic itself, the load rate, as well as other gas volume data renders a test severely methodologically flawed. Moreover, none of the statistical analyses takes into account the priming effect. (CCPTB at 75-76.) Thus, a detailed, point-by-point refutation of Dr. Barlaz's test is further misplaced.

[14] Although NEL produced Alyssa Ullman as the corporate representative most knowledgeable about the biodegradation studies lab, ECM called Alan Johnson as a witness. The ALJ refused to grant Complaint Counsel leave to depose him as a witness prior to his trial testimony. (Order Denying Complaint Counsel's Motion for Leave to Take Deposition of Alan Johnson, July 11, 2014.) Alyssa Ullman testified that she is the project manager of the biodegradation studies lab and is responsible for conducting biodegradation tests (CCX-815, Ullman Dep. Tr. at 14.)

[15] (CCFF ¶¶ 142-143.)

- NEL uses an inverted cylinder and metal paint cans for gas monitoring. NEL had no way to identify a small leak in the system from gas generation. (Johnson, Tr. 1584);
- NEL waited for a paint can to rust before replacing it with a new one (Johnson, Tr. 1585 (when the paint can rusts during extension testing, replace it with a new one)); and only replaced the one that has been rusted (Johnson, Tr. 1592-1593), any of which could introduce oxygen or otherwise affect the results;
- NEL did not consider whether the rusting test vessel affected results of biodegradation testing (Johnson, Tr. 1586);
- The methane readings produced by the IR machine used to take them has a precision of plus or minus 20% for low volumes of methane readings, (Johnson, Tr. 1587),[16] placing several results within the margins of error of the test;
- The protocol for extended ASTM testing was set up by Dr. Bill Ullman (now deceased) (Johnson, Tr. 1560) and has never been independently evaluated since that time (Johnson, Tr. 1583); and
- NEL does not undergo any audits, does not hold any certifications, and has never been evaluated (Johnson Tr, 1580-1581).

The ALJ also identified eight tests conducted by ERL that purport to demonstrate anaerobic biodegradability of ECM Plastic. (ALJID 121-136.) Thomas Poth, the owner of ERL, admitted to fatal flaws with ERL's methodology for these eight tests, specifically:

[16] Johnson concedes that methane readings in the single-digits are low. (*See* Johnson, Tr. 1569.)

- ERL does not report statistical information, so it does not know if the test results are statistically significant (Poth, Tr. 1512-1513, 1538);
- ERL provides primarily quick-and-dirty updates that are not given the same level of rigorous review as the reports (Poth, Tr. 1499-1500); and[17]
- ERL's reports do not reflect the composition of the test material, *e.g.*, whether additive was added to conventional or a starch-based plastic. (CCX-805, Poth Dep. Tr. at 108-109.)

Dr. McCarthy highlights these and other deficiencies and explains why they call into question the reliability of the test results. (CCX-891 ¶¶87-89; McCarthy, Tr. 453-455, 467-472.) For instance, Dr. McCarthy explains that replacing the inoculum would likely lead to overestimation of biodegradation, by exposing the inoculum to oxygen. (CCX-891 ¶¶87-89; *see also infra* at note 24.) Similarly, deviating from the method and going beyond the 30-day validation period makes the data unreliable because each test is designed to have a period of time in which results will be accurate.[18] (CCX-891 ¶¶87-89; Tr. 467-472.)

Moreover, these labs did not report several categories of critical information required under the methodology, making it impossible to validate the data. (CCX-891 ¶¶87-89; Tr. 453-455; *see also* Sahu, Tr. 1959, explaining the importance of having the underlying data.) For example, of the seventeen tests identified by the ALJ, not one of them reported the results of the 95% confidence limits, (CCX-83 at 4, ASTM D5511-11 Section 14.1.4) or information

[17] Moreover, Poth testified at his deposition that they refresh the inoculum during a test at a customer's request, but then denied doing this at trial. (*Compare* CCX-805, Poth Dep. Tr.at 72-73 *with* Poth, Tr. 1474.)

[18] Some tests not only exceeded the validation period, but also went beyond the approved duration of the test by running even after the positive control and the sample showed zero biodegradation for five days. (*See* CCX-85, ASTM D5511-11 at Section 11.2.1.2.)

necessary to validate the test (CCX-83 at 3, ASTMD5511-11 Section 13.2-13.4; and 11.2.1.1-11.2.2). Most of ERL's tests did not include load rate or triplicate data.[19] (CCX-546, CCX-548, CCX-534, CCX-547.) And neither lab determines the carbon content of the samples themselves, instead relying on information provided by the customer. (CCX-805, Poth Dep. Tr. at 77; Johnson, Tr. 1564.) Even Dr. Sahu acknowledged that information such as load rates, plastic types, and other critical information are necessary to understand and evaluate the data was missing. (Sahu, Tr. 1932-1933; 1940, 1961.)

These tests stand in stark contrast to the well-documented studies conducted by such labs as Stevens Ecology (CCX-174 and CCX-176), O.W.S. (CCX-169-171), North Carolina State University (CCX-946-948), and Ohio State University (CCX-164) that show no statistically relevant biodegradation of ECM Plastics under a variety of conditions. Given the severe methodological flaws in how NEL and ERL conducted the tests, the results are exceedingly unreliable and cannot reliably demonstrate that any significant biodegradation of the plastic took place. In addition to their flawed methodology, the data reflected in the labs' summary reports are full of anomalies, inconsistencies, and impossibilities rendering it completely unreliable.

**2. The NEL And ERL Test Data Is Unreliable.**

None of the data shows complete biodegradation or biodegradation in landfills in relevant timeframes. (CCPTB 71-75.) Moreover, none of the statistical analyses takes into account the priming effect. (CCPTB at 75-76.) Thus, a detailed, point-by-point refutation of Dr. Barlaz's statistical analysis and the ALJ's findings is unnecessary.[20] Nonetheless, for each of the

[19] Under ASTM D5511, each of the positive controls, the test specimen, negative control, and inoculum blanks are required to have three replicates, or triplicate data, because such data is necessary to determine the statistical significance of the data. (CCX-83 at 3, ASTM D5511 Section 11.)

[20] Notably, several tests for which Dr. Barlaz could have performed a statistical analysis, he did not. (*See, e.g.*, RX-836, PPC data only analyzed through day 77, although 900 days of

seventeen studies on which the ALJ cites as showing increased levels of biodegradation,[21] there are numerous fatal flaws in the data.

**(a) NEL test data is flawed.**

Each of the nine NEL tests is so severely flawed it cannot substantiate ECM's alleged comparative claim. **Seven** produced biodegradation results **within the margins of error** for the test as identified in the precision and bias section of the ASTM D5511 standard and the equipment used to take the measurements. (RX-392; RX-393; RX-394; RX-395; RX-396; RX-398; and RX-405.) Given NEL's significant deviations from the protocol and other severe testing flaws, its margin of error likely far exceeds that established by ECM based on data from sound testing.[22]

The data from the two NEL extension tests (which both exceeded the ASTM validation period) are also hopelessly flawed. The results for one test were barely outside the error rate of the test method with no observable biodegradation weeks before the conclusion.[23] In fact, less than halfway through the test period, the measurements of methane are so low that the margin of error for the equipment taking the readings would render any reading unreliable. (*See* Johnson,

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data reported; RX-396, triplicate data for Ecosmart Plastics II not analyzed; RX-392 Transilwrap data available in Excel spreadsheet RX-447-RX-449, but not analyzed; RX-394, Tycoplastic data only analyzed through first 15 days of testing although several months of raw data was reported in RX-450.)

[21] These include some, but not all, of the seventeen tests that Dr. Barlaz analyzed. The ALJ's findings did not include the test for Dankso and Smithers Oasis, which were included in Dr. Barlaz's analysis, but did include EcoSmart Plastics and FP International, which were omitted by Dr. Barlaz.

[22] ASTM D5511 Section 15 precision and bias states that the within-laboratory repeatability of the test has a mean variance on the positive control of 5.1% and 95% confidence interval of ±10.2% for four runs.

[23] (RX-838, Minigrips test; Johnson, Tr. 1590.)

Tr. 1569, 1587, explaining that the machine responsible for taking methane readings has a precision of ±20% for low volumes of methane readings, *i.e.*, methane readings in the single digits.) Moreover, Dr. Barlaz's statistical analysis of the triplicate data identified missing weeks of data with other data reported twice. (*See* RX-838, Minigrip test.)

The other extension test, conducted for 900 days (which means the inoculum was "refreshed" multiple times during the test), shows biodegradation of the positive control in excess of 100%.[24] This impossible result is either an error or due to the priming effect—either invalidates the biodegradation results.[25]

**(b) ERL test data is also flawed.**

Likewise, multiple discrepancies in the data from the eight ERL tests render it completely unreliable. (*See, e.g.*, McCarthy, Tr. 454-455.) Importantly, all but two of ERL's tests are summary updates, with no rigorous data analysis. (Poth, Tr. 1499-1500.) But even the two full reports, whose data was supposedly more scrutinized for error, lack reliability. For each of the full reports, the data for weekly gas volumes for the inoculum and positive controls are inexplicably **identical** down to the decimal point for multiple entries. (RX-839 at 2, inoculum

[24] (RX-836; Tr. 424, 476-477 (Dr. McCarthy explaining biodegradation above 100% is due to priming effect); Tr. 194 (Dr. Tolaymat testified that it's not plausible to achieve more than 100% biodegradation).) Dr. Tolaymat similarly testified that the way this test was conducted was not conducive to providing reliable results:

> We're talking about conducting a test in paint cans and pulling out samples and treating them under a hood and then putting them back in different paint cans for three years. I -- the uncertainties and the amount of error that would go into conducting this type of test over a period of 900 days outweighs any result that would come out of a test like that, in my opinion.

Tolaymat, Tr. 312.

[25] Notably, Dr. Barlaz only provided statistical information for data through day 77, the point in which the positive control exceeded 100% biodegradation. (*Compare* RX-968 *with* RX-836 at 16.)

control IA and IB the same for weeks ending February 8, 15, 22, 29, March 7, March 14, and July 4, 2012. Positive control PB and PC the same for weeks ending February 15, 22, 29, March 7, 14; RX-248, same for multiple entries.) One of these tests also shows another impossible result—a decrease in biodegradation as the study progresses. (RX-839, reporting 8% biodegradation of the treated sample at approximately 15 weeks and 7% biodegradation at week 17.) There is simply no reasonable explanation for this anomalous data.

The six summary test reports have significant additional flaws. Data from one of these, the Fellowes test (RX-403), is completely irrelevant because it tested an *already biodegradable material* amended with ECM Additive. (CCX-805, Poth Dep. Tr. at 103-102, 108.) This information is not included in the report, giving the misleading impression that ECM-treated conventional plastic achieved a high degree of biodegradation. Similarly, the ERL test for EcoLab (which includes three summaries of cumulative gas data reported for two samples containing unknown amounts of ECM Additive, in an unidentified plastic) is likely a biodegradable plastic amended with the ECM Additive. (*Compare* RX-547 *with* RX-403, which Poth identified as containing a biodegradable plastic; CCX-805, Poth Dep. Tr. at 108-109.)

Of the remaining four tests, each has other significant flaws. One report does not indicate the test method at all (CCX-546), while two follow an undocumented, unapproved ASTM protocol, (RX-402, RX-548; Poth, Tr. 1537-1538), identified only as "ASTM DXXXX"—a method that Mr. Poth (who conducted the tests) testified at his deposition that he was not "comfortable with" and was still trying to "hone confidence in." (CCX-805 at 43, 144.) And, in one of the tests cited by the ALJ as demonstrating biodegradation, Poth testified at his deposition that the test was a "mess" and he should have "chuck[ed] it." (CCX-805, Poth Dep. Tr. at 115, discussing the MicroTek test, RX-534.)

In addition to these issues, the tests across the board demonstrate sloppy, inattentive data recording inconsistent with good lab practices.[26] Based on these, and other, inconsistencies and anomalies in the data, Drs. McCarthy and Tolaymat concluded that the ERL and NEL test data is unreliable. (CCPTB at 59-61; CCPTRB at 12-19; CC App. Br. at 46-47.) Therefore, drawing conclusions about biodegradability of the test samples from this inconsistent, anomalous data is improper.

**E. A Strong Remedy Is Necessary.**

Finally, ECM argues that a stronger remedy is unjustified, arbitrary, and capricious, because it violates ECM's First Amendment rights, would "redound to the detriment of the environment," and ECM did not have notice of the falsity of its claims and technology. (Resp. Ans. Br. at 49-52.) Each argument is wrong. Complaint Counsel already addressed the specious environmental benefit argument in its answering brief, (CC Ans. Br. at 27-29), and the notice argument in each of its briefs (CC App. Br. at 5; CC. Ans. Br. at 19 n.18; *supra* at 3). As discussed below, the First Amendment argument is equally without merit.

It is well-established that the government can regulate deceptive commercial speech through adjudication. *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 64 (1983). "Since advertising is the sine qua non of commercial profits, there is little likelihood of its being chilled by proper regulation and forgone entirely." *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council,* 425 U.S. 748, 772 n.24 (1976). Importantly, for commercial speech to

[26] For example, ERL produced two reports for the same samples on the same date, which showed two different biodegradation percentages and different additives. (*Compare* RX-248 *with* CCX-1097; Poth, Tr. 1502, testifying to two different numbers for the same sample and same length of time; *see also* Poth Tr. 1504, Poth testified that another inconsistency between the two reports is that one identified EcoPure, not an ECM product.) ERL also reported data for the EcoLab test where the test sample identifiers were inconsistent between the numerical data and the graphical data. (CCX-547, identifying samples as 538A and 539A in the table, but as 538B and 539C in the graph.)

receive the protections of the First Amendment, the commercial speech "at least must concern lawful activity and not be misleading." *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980). Here, ECM's ongoing marketing is deceptive, and will continue to mislead consumers without appropriate injunctive relief. Furthermore, unlike its customers and end-use consumers, who lack the ability to independently verify ECM's claims, ECM has "extensive knowledge of both the market and [its] products" and is thus "well situated to evaluate the accuracy of [its] messages and the lawfulness of the underlying activity." *Central Hudson*, 447 U.S. at 564 n.6.

Similarly, ECM's reliance on *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), is misplaced. (Resp. Ans. Br. at 51.) *Pearson* held that an FDA rule effectively banning specific health claims was an unduly restrictive means to regulate potential deceptive speech, and that the FDA needed to consider possible curative disclosures. 164 F.3d at 659-660. By contrast, this case involves adjudication of actual deceptive claims in commerce. The Commission recently rejected this argument in *POM*, reasoning that:

> [T]he Commission's approach to address misleading advertising, which is a case-by-case adjudication *after* ads have been disseminated, differs from regulatory efforts that prohibit categories of speech or rely on *prior* approval of the language to be used. The latter serve as illustrations of "bars" on commercial speech and are inapplicable to the detailed *ex post* analysis we engage in here, based on a full record about the ads in question.

*POM*, No. 9344, 2013 FTC LEXIS 6, at *138-39.

Complaint Counsel's proposed order is not a ban. If ECM could substantiate them, nothing would prevent ECM from making truthful, appropriately qualified claims. (CC Ans. Br. at 29.)

## III. CONCLUSION

For the reasons stated herein and in Complaint Counsel's other briefs, the Commission should set aside the erroneous portions of the Initial Decision and Order, reject Respondent's appeal, and enter an injunction consistent with the proposed Notice Order filed with Complaint Counsel's Appeal Brief.

Respectfully Submitted,

/s/ Katherine Johnson

Dated: April 9, 2015

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## CERTIFICATE OF SERVICE

I hereby certify that on April 9, 2015, I caused a true and correct copy of the foregoing to be served as follows:

One electronic copy, one copy through the FTC's e-filing system, and twelve hard copies to the **Office of the Secretary**:

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One electronic copy to the **Office of the Administrative Law Judge:**

The Honorable D. Michael Chappell
Administrative Law Judge
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I further certify that I possess a paper copy of the signed original of the foregoing document that is available for review by the parties and the adjudicator.

Date: April 9, 2015

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