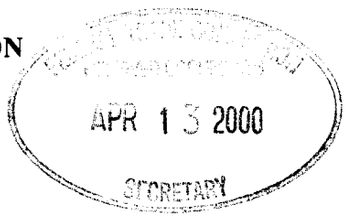
UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION



In the Matter of HOECHST MARION ROUSSEL, INC., a corporation, CARDERM CAPITAL, L.P., a limited partnership, and ANDRX CORPORATION, a corporation.	Docket No. 9293

ANSWER OF ANDRX CORPORATION

Pursuant to the provisions of the Federal Trade Commission Act and the regulations promulgated thereunder, respondent Andrx Corporation ("Andrx") hereby responds to the allegations contained in the Federal Trade Commission's Complaint dated March 16, 2000 ("Complaint"), on personal knowledge as to its own actions and on information and belief as to all other matters, as follows:

As to the preamble, the headings, and the notice of contemplated relief, Andrx states that no responsive pleading is necessary, and to the extent a response is necessary denies the allegations and states that the relief requested is unavailable on the facts and at law and would be anticompetitive and not to the interest of the public if granted.

1. Andrx denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 1 of the Complaint.

2. Andrx denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 2 of the Complaint.

3. Andrx denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 3 of the Complaint.

4. Andrx denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 4 of the Complaint.

5. Andrx admits that it is a corporation organized and existing under the laws of the State of Florida, that it is licensed to do business in Florida, and that it has its principal place of business in Ft. Lauderdale, Florida. Andrx further admits that it has developed, manufactured or marketed one or more controlled-release pharmaceutical products and states that it developed two different generic versions of Cardizem CD that were ultimately approved by the FDA as bioequivalent to Cardizem CD, one in July 1998 and one in June 1999. The first of those versions was the subject of the September 1997 Stipulation and Agreement among Hoechst Marion Roussel, Inc. ("HMR"), Carderm Capital, L.P. ("Carderm") and Andrx (the "Stipulation"). In all other respects Andrx denies the allegations of Paragraph 5 of the Complaint.

6. Andrx states that the allegations of Paragraph 6 of the Complaint constitute a legal opinion and therefore require no response, and to the extent a response is required Andrx denies the allegations of that Paragraph.

7. Andrx states that the allegations of Paragraph 7 of the Complaint constitute a legal opinion and therefore require no response, and to the extent a response is required Andrx denies the allegations of that Paragraph.

8. Andrx states that the allegations of Paragraph 8 of the Complaint constitute a legal opinion and therefore require no response, and to the extent a response is required Andrx denies the allegations of that Paragraph. Andrx further notes that approval by the FDA, although necessary, is not sufficient to permit the marketing or sale of such a product, for example, if there exists a legal basis for delaying or prohibiting that activity independent of the FDA's authority and outside of the scope of the FDA's review process.

9. Andrx states that the allegations of Paragraph 9 of the Complaint constitute a legal opinion and therefore require no response, and to the extent a response is required Andrx denies the allegations of that Paragraph. Andrx further notes that its generic drugs are not chemically identical to their branded counterparts, and that what is "typical", as alleged in that Paragraph, must be the subject of discovery and proof.

10. Andrx states that the allegations of Paragraph 10 of the Complaint constitute a legal opinion and therefore require no response, and to the extent a response is required Andrx denies the allegations of that Paragraph. Andrx further notes that if no patent infringement suit is filed by the patent holder or the NDA holder within 45 days of receipt of notification of a Paragraph IV Certification, the FDA review process may proceed. The FDA may then approve the generic product as bioequivalent to the branded product as soon as that review process is completed, but that the generic product might not be marketed after FDA approval for a variety of reasons, including product and ingredient availability, manufacturing problems, financial difficulties, marketing considerations, or independent legal barriers to such marketing or sale such as patent or product liability issues.

11. Andrx states that the allegations of Paragraph 11 of the Complaint constitute a legal opinion and therefore require no response, and to the extent a response is required Andrx denies the allegations of that Paragraph. Andrx further notes that the FDA's and the courts' interpretation of the 180-day period of market exclusivity has been and continues to be in flux and that, even as currently interpreted, may begin to run upon the entry of final judgment by any court holding the patent or patents at issue invalid or not infringed, and that a generic manufacturer may avoid another manufacturer's 180-day exclusivity period altogether by filing an NDA, rather than an ANDA, for its product.

12. Andrx denies that once-a-day diltiazem is a relevant product market for assessing respondents' conduct in this matter, because there are numerous products that are reasonably interchangeable with and considered therapeutic alternatives to Cardizem CD, denies knowledge or information sufficient to form a belief as to the allegations concerning sales of once-a-day diltiazem products or of Cardizem CD, and in all other respects denies the allegations of Paragraph 12 of the Complaint.

13. Andrx denies that the respondents' activities have affected commerce in any geographic market but states that since June 23, 1999, one or more Andrx affiliates have marketed Cartia XT™, its generic version of Cardizem CD, throughout the United States, and in all other respects denies the allegations of Paragraph 13 of the Complaint.

14. Andrx denies the allegations of Paragraph 14 of the Complaint.

15. Andrx denies the allegations of Paragraph 15 of the Complaint.

16. Andrx denies the allegations of Paragraph 16 of the Complaint. Specifically, Andrx denies that FDA final approval of any third party's ANDA for generic Cardizem CD was ever "blocked" by the Stipulation or that it was as a result of

respondents' activities that no company was able to obtain FDA approval of its ANDA for a generic version of Cardizem CD during the lifetime of the Stipulation. Andrx further notes that at the time the Stipulation was signed, pursuant to the Hatch-Waxman Act as it was then interpreted and implemented by the FDA, Andrx would have been entitled to 180 days of market exclusivity only if it had "successfully defended" the Patent Action — a result which would have caused the Stipulation to terminate pursuant to its terms — and that, at all relevant times, any other generic manufacturer could have started Andrx's 180-day exclusivity period running by obtaining a judgment holding HMR's patent invalid or not infringed, and could have obtained FDA approval for its own ANDA 180 days thereafter, regardless of the activities of Andrx. In addition, any other manufacturer could have filed an NDA for its generic product and thereby avoided Andrx's 180-day exclusivity period altogether. Neither Purepac Pharmaceutical Co. nor Biovail Corporation International was able to obtain such a judgment; indeed, Biovail did not even attempt to obtain such a judgment, for example by seeking a declaratory judgment against HMR. Nor did Biovail ever obtain FDA approval to market its product under its NDA. Andrx denies knowledge or information sufficient to form a belief as to the allegations concerning which other parties filed ANDAs for generic Cardizem CD, and denies in all other respects the allegations of Paragraph 16 of the Complaint.

17. Andrx states that in September 1995 it submitted an ANDA which it then believed, and later learned, to be the first ANDA submitted to the FDA for the manufacture and sale of a generic version of Cardizem CD. That submission included a certification that to the best of its knowledge Andrx's product did not infringe any of the patents then listed as covering Cardizem CD. Pursuant to the Hatch-Waxman Act as it

was then interpreted and implemented by the FDA, Andrx would have been entitled to 180 days of market exclusivity only if it had "successfully defended" the Patent Action before any other generic manufacturer or marketer was in position to receive FDA approval for its product. In November 1995, United States patent number 5,470,584 was issued and assigned to Carderm Capital, L.P. and was listed by HMR as covering Cardizem CD. The FDA accepted Andrx's ANDA submission, and Andrx's Paragraph IV certification was delivered to HMR in December 1995. Andrx denies in all other respects the allegations of Paragraph 17 of the Complaint.

18. Andrx states that HMR and Carderm commenced a patent infringement action on or about January 31, 1996 (the "Patent Action"), asserting that the product covered by Andrx's ANDA infringed the '584 patent, and that that lawsuit triggered a 30-month stay of FDA approval of Andrx's ANDA as required by the Hatch-Waxman Act. Andrx further states that both parties attempted to resolve that litigation long before the 30 months expired. Thus, in October 1996 Andrx filed a motion to dismiss HMR's claims and in February 1997 Andrx filed two motions for summary judgment and HMR filed one motion for summary judgment. In November 1998 Andrx filed yet another motion for summary judgment. Altogether, there were five dispositive motions filed. Despite these filings, and other activities intended to obtain either a prompt determination of the motions or of the case itself at trial, the Court took no action either to resolve any of these motions or to move the case toward trial. Andrx denies in all other respects the allegations of Paragraph 18 of the Complaint.

19. Andrx denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 19 of the Complaint.

20. Andrx denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 20 of the Complaint.

21. Andrx denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 21 of the Complaint.

22. Andrx denies the allegations of Paragraph 22 of the Complaint and states that beginning in the Spring of 1997 Andrx and HMR had discussions concerning the parties' respective positions in the Patent Action, the numerous pending dispositive motions in that litigation, and the Court's refusal to address those motions or to do anything to move the case toward trial. In the context of these discussions, HMR indicated that if the case was not resolved before the 30-month stay expired in July 1998, it intended to seek a preliminary injunction to prevent Andrx from marketing its product prior to the resolution of HMR's infringement claims. For its part, Andrx did not intend to market its product while the Patent Action was pending, due in part to the risk of substantial damages if it did so and then lost the Patent Action. Given Andrx's financial condition at the time, such damages would unquestionably have been greater than Andrx could afford to pay. Although Andrx did not discuss this analysis with HMR or reveal its intention not to market its product during the pendency of the Patent Action, the parties began to discuss, as an alternative to incurring the cost, risk and potential downside for both parties of a motion for preliminary injunction, whether they could agree to maintain the status quo until the Patent Action could be resolved while providing Andrx the protection it would receive under a preliminary injunction.

23. Andrx admits that on or about September 24, 1997, it entered into the Stipulation with HMR and Carderm. Andrx further notes that the Stipulation itself is the

best evidence of its terms, refers to that document in response to the specific allegations of Paragraph 23 of the Complaint, and to the extent any other responsive pleading is necessary denies the allegations of that Paragraph. Specifically, Andrx denies that it agreed to refrain from selling or distributing any generic version of Cardizem CD produced by another manufacturer, notes that the Andrx subsidiary that would undertake such activity, its sales and distribution arm, was not even covered by the Stipulation, and denies that there was any other generic or bioequivalent version of Cardizem CD that could be marketed. Andrx further notes that regardless of the terms of the Stipulation, under the FDA's then-existing interpretation of the Hatch-Waxman Act, the provision of the Stipulation limiting Andrx's ability to relinquish or otherwise compromise its right to market exclusivity could never have had any effect, because Andrx would not even be eligible for such exclusivity unless and until it had successfully defended the Patent Action, at which point the entire Stipulation would have terminated pursuant to its terms. Moreover, Andrx reserved for itself the right assign or waive any rights accruing under its ANDA. At no time during the lifetime of the Stipulation was any other generic manufacturer in a position even to request that Andrx transfer, waive or relinquish its exclusivity, because no other manufacturer was able to obtain even tentative FDA approval to market its own generic product without infringing HMR's patents.

24. Andrx denies the allegations of Paragraph 24 of the Complaint and refers to the Stipulation for its terms.

25. Andrx denies the Allegations of Paragraph 25 of the Complaint and refers to the Stipulation for its terms.

26. Andrx denies the Allegations of Paragraph 26 of the Complaint and refers to the Stipulation for its terms.

27. Andrx states that it received final FDA approval of its ANDA for the first of its generic versions of Cardizem CD on or about July 9, 1998, but denies that that approval meant that it could begin marketing that product before the Patent Action was resolved. Andrx denies in all other respects the allegations of Paragraph 27 of the Complaint.

28. Andrx states that as a result of extensive research efforts it developed a reformulated version of its product and that on or about September 11, 1998, Andrx submitted a Supplemental ANDA to the FDA seeking approval to market that product. That Supplemental ANDA included a Paragraph IV certification. Following several months of discussion with HMR concerning the reformulated product, HMR agreed that if Andrx would guarantee that its reformulated product would meet certain criteria that were consistent with but not required by Andrx's Supplemental ANDA then pending before the FDA, HMR would not assert that the product infringed the '584 patent. As a result of that agreement and Andrx's commitment that it would market only its further reformulated product, the parties agreed to resolve the Patent Action. On or about June 8, 1999, the same day that Andrx received FDA approval to market its reformulated product, HMR agreed to dismiss the Patent Action. As a result of that dismissal, the 1997 Stipulation expired pursuant to its terms. Andrx immediately began taking orders for its reformulated product and as soon as it could manufacture sufficient quantities of that product, on or about June 23, 1999, Andrx began shipping that product to customers. As of the date upon which Andrx began marketing its product, no other generic

manufacturer had reached the stage of FDA approval at which it was waiting only for the expiration of Andrx's 180 days of market exclusivity to begin marketing its own generic Cardizem CD product in the absence of claims of patent infringement by HMR. Andrx has never marketed the product that was the subject of the Stipulation and that product has never been found, held or determined not to infringe the '584 patent. Andrx denies in all other respects the allegations of Paragraph 28 of the Complaint.

29. Andrx denies the allegations of Paragraph 29 of the Complaint.

30. Andrx denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 30 of the Complaint, and to the extent Andrx has knowledge concerning those allegations denies those allegations.

31. Andrx denies the allegations of Paragraph 31 of the Complaint.

32. Andrx denies the allegations of Paragraph 32 of the Complaint.

33. Andrx denies the allegations of Paragraph 33 of the Complaint.

34. Andrx denies the allegations of Paragraph 34 of the Complaint and states that the Stipulation had numerous procompetitive benefits, including assuring the entry of generic competition by no later than January 2000, regardless of whether Andrx prevailed in the Patent Action or whether the Patent Action was resolved before that date, and providing Andrx with funding that permitted it to develop its non-infringing reformulated product, reducing transaction and litigation costs, avoiding uncertainty, achieving the goals of the Hatch-Waxman Act (for this product and others), and resolving the Patent Action so that it could begin marketing its product long before it otherwise would have been able to do so had the parties not entered into the Stipulation.

35. Andrx denies the allegations of Paragraph 35 of the Complaint.

36. Andrx denies the allegations of Paragraph 36 of the Complaint.

37. Andrx denies the allegations of Paragraph 37 of the Complaint except states that it is without knowledge or information sufficient to form a belief as to the allegations of that Paragraph concerning HMR's specific intent.

38. Andrx denies the allegations of Paragraph 38 of the Complaint except states that it is without knowledge or information sufficient to form a belief as to the allegations of that Paragraph concerning HMR's and Carderm's specific intent.

39. Andrx denies the allegations of Paragraph 39 of the Complaint.

FIRST DEFENSE

40. The Complaint fails in whole or in part to state a claim for relief under § 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

SECOND DEFENSE

41. The conduct challenged in the Complaint does not violate the law because Andrx's actions are fully consistent with the Hatch-Waxman Act and the regulations promulgated thereunder, as the court held in *Andrx v. Friedman*, Civ. No. 98-0099 (JGP) (D.D.C. Order dated January 6, 2000).

THIRD DEFENSE

42. The Complaint and the relief sought therein are barred because the claims asserted and the relief sought are inconsistent with and preempted by the Hatch-Waxman Act.

FOURTH DEFENSE

43. The Complaint and the relief sought therein are barred because the claims asserted and the relief sought are inconsistent with and preempted by the statutory rights granted to HMR and Carderm as the holders of the '584 patent under the Patent Act, 35 U.S.C. §§ 271 *et seq.* That patent is statutorily presumed to be valid and has never been adjudged or determined to be invalid.

FIFTH DEFENSE

44. The Complaint and the relief sought therein are barred because the conduct alleged had no anticompetitive effect. The Commission acknowledges as much when it is reduced to alleging that respondents' conduct had the "tendency" or "capacity" to cause harm without identifying a single element of actual harm. A claim based on the "tendency" or "capacity" of an agreement is improper under the antitrust laws, the FTC Act, and is unconstitutionally vague.

SIXTH DEFENSE

45. The Complaint and the relief sought therein are barred because even assuming arguendo that the conduct alleged had the capacity or potential or even had an anticompetitive effect, the procompetitive benefits of the Stipulation far outweighed any such alleged anticompetitive effect. As a direct result of signing the Stipulation, the parties avoided significant and otherwise unavoidable risks of proceeding with a motion for preliminary injunction and reduced their transaction and litigation costs. Andrx was able to reformulate its product and secure FDA approval for that new product, thereby achieving the primary goal of the Hatch-Waxman Act, and the parties were able to negotiate a resolution of the Patent Action long before they ever could have obtained

such a resolution from the court handling that action. As a result, Andrx was able to begin taking order for its reformulated product immediately upon receiving FDA approval for that product, and began shipping that product to customers within weeks.

SEVENTH DEFENSE

46. The Commission has not (and cannot) establish that this proceeding is "to the interest of the public". In this proceeding, the Commission, the agency charged by Congress with the responsibility to protect of consumers, seeks relief that is itself anticompetitive and that would deprive consumers of lower-priced generic pharmaceutical products.

EIGHTH DEFENSE

47. This proceeding is not "to the interest of the public" because the conduct that is the subject of the Complaint is over, the Stipulation terminated pursuant to its terms, and Andrx has been marketing its lower-priced generic product since it received FDA approval to do so. The relief sought would not alter that situation and would only restrict Andrx's ability to develop and market future generic products, which would harm, rather than benefit, consumers.

NINTH DEFENSE

48. The Complaint and the relief sought therein are barred because they have been motivated by and addresses a purely private controversy and did not and does not threaten harm to the public, and therefore fails to comply with 16 C.F.R. § 2.3 as well as § 5 of the FTC Act, 15 U.S.C. § 45(b), as interpreted by the Supreme Court in, among others, *Federal Trade Commission v. Klesner*, 280 U.S. 19 (1929).

TENTH DEFENSE

49. The Complaint and the relief sought therein are barred because there is a total absence of any causal connection between the Stipulation and any alleged harm to competition or to consumers. Andrx would not have marketed its product during the pendency of the Patent Action, a reality repeatedly recognized by the FDA, because of, among other reasons, the potential for catastrophic damages. Had Andrx even tried to do so, HMR would likely have obtained a preliminary injunction preventing it from doing so. Moreover, Andrx was unable to manufacture commercial quantities of the product that received FDA approval in July 19998 and that was the subject of the Stipulation. The provisions of the Stipulation that are the subject of the Complaint are thus restraints in the air that do not even rise to the level of potentially anticompetitive provisions and that could not have produced any anticompetitive effects.

ELEVENTH DEFENSE

50. The Complaint and the relief sought therein are barred because they are based not on the law, regulations or issues as they were understood or interpreted at the time the Stipulation was signed or went into effect but rather alleges that respondents' conduct had particular "tendencies" or "capacities" based on the law, regulations and issues as they have been refined and revised since the Stipulation was signed or went into effect.

TWELFTH DEFENSE

51. The Complaint and the relief sought therein are barred because they focus on provisions of the Stipulation that were, if anything, ancillary to that agreement's primary purposes, that had no demonstrable effect on the parties' behavior, and that were

necessary to ensure that the parties could not evade their obligations under the Stipulation. Similar ancillary restraints are typically found in agreements and are necessary to achieve the procompetitive benefits such agreements. For example, such "restraints" are found in the March 31, 1998, agreement between Abbott Laboratories and Zenith Goldline Pharmaceuticals, an agreement as to which the Commission has publicly indicated that it will take no action because it believes the agreement to be lawful. Specifically, that agreement provided in part that:

- Zenith would not sell, offer for sale or distribute *any generic form* of Terazosin Hydrochloride;
- Zenith would not take any action or assist any other party in taking action to challenge any of Abbott's patents on Terazosin Hydrochloride;
- Zenith specifically acknowledged the validity and enforceability of Abbott's patents;
- Zenith would not assign or transfer any of its rights under its ANDA for a generic form of Terazosin Hydrochloride; and
- Zenith would not assist any other party in gaining FDA approval for a generic form of Terazosin Hydrochloride.

These typical provisions are not anticompetitive restraints in the context of the HMR/Andrx Stipulation. The FTC is acting unlawfully and arbitrarily in attempting to single out Andrx for challenge with respect to these commonplace provisions.

THIRTEENTH DEFENSE

52. The Complaint and the relief sought therein are barred because they misinterpret the provisions of the Stipulation, alleging that Andrx improperly gave up

rights that it never possessed in the first place, alleging that provisions prevent Andrx from marketing products although those provisions do not even read on Andrx's marketing arm, suggesting that Andrx was precluded from assigning or waiving any rights it had under its ANDA although the negotiating history and the testimony of Andrx witnesses confirms that Andrx never agreed to any such terms, and incorrectly implying that there was any other generic manufacturer with a product that Andrx could have marketed or to whom Andrx might otherwise have assigned its exclusivity.

FOURTEENTH DEFENSE

53. The Complaint is contrary to the public policy in favor of encouraging the negotiated resolution of litigation, including particularly patent litigation.

FIFTEENTH DEFENSE

54. The Complaint and the relief sought therein are barred because both Andrx and HMR did everything they could to convince the district court hearing the Patent Action to rule on the numerous dispositive motions or to take any other steps to move the case toward trial or any other outcome. The Complaint contains no allegation that the parties delayed the Patent Action or that that litigation was a sham or was not filed or prosecuted in good faith.

SIXTEENTH DEFENSE

55. The Complaint and the relief sought therein are barred because the parties' good faith efforts to resolve issues arising in the Patent Action are immune from antitrust scrutiny under the *Noerr-Pennington* doctrine, and the Commission has not alleged and cannot prove that that litigation was a sham or was undertaken by HMR in bad faith.

SEVENTEENTH DEFENSE

56. The Complaint and the relief sought therein are barred by the doctrines of laches, waiver, estoppel, and unclean hands. In September 1997, when HMR and Andrx entered into the Stipulation, but over nine months before it took effect, the parties publicly disclosed the Stipulation's principal terms. Thereafter, Andrx produced to the Commission a copy of the Stipulation in connection with the Commission's investigation into, among other things, the Stipulation. The Commission studied the Stipulation and its potential impact on competition and consumers. In early 1998, staff counsel informed Andrx that the Commission's investigation was closed. The Commission offered no comment, made no challenge, asserted no complaint and filed no proceeding concerning the Stipulation. Furthermore, at no time prior to the time the conduct challenged here occurred — ten months after the Stipulation was executed — did anyone from or on behalf of the Commission inform Andrx that the Commission had any concern at all about the Stipulation, nor did anyone from or on behalf of the Commission make any effort to intervene in the Patent Action or otherwise seek to bring any issues relating to the Stipulation to the attention of the court hearing that litigation. The FTC's conduct confirms the absence of any legitimate challenge to the Stipulation. Furthermore, having stood by idly, when among other things the outcome of the Patent Action and the FDA's interpretation of the Hatch-Waxman Act were both very much in doubt, the Commission may not now, with the benefit of hindsight, attack as unreasonable the respondents' attempts to deal with and resolve those uncertainties.

EIGHTEENTH DEFENSE

57. The Complaint and the relief sought therein are barred as not "to the interest of the public", because the only public interest that supports the Commission's filing of this proceeding arose from and was inspired by the improper and illegal publicity campaign that surrounded the Commission's purportedly non-public investigation of Stipulation. That publicity stems from information improperly disclosed to the public from within the Commission or its staff — disclosures that are expressly prohibited by statute and by the Commission's own rules of confidentiality. The examples known to Andrx of such improper disclosure include:

- In March 1999, The Wall Street Journal reported that the Commission had widened its investigation into the generic pharmaceutical industry to include the HMR/Andrx Stipulation.
- On September 30, 1999, USA Today reported that "Federal antitrust enforcers plan to recommend an antitrust lawsuit against brand-name drugmaker Hoechst Marion Roussel". The article also quoted George Cary, the former Deputy Director of the Bureau of Competition, now representing Biovail, commenting on the likelihood that the Commission would take action against HMR and Andrx.
- On or about December 17, 1999, David Balto, the Director of Policy Planning for the Bureau of Competition, gave a speech to the Food and Drug Law Institute Educational Conference in which he commented on the Commission's ongoing investigation of the HMR/Andrx Stipulation. Shortly after that speech, Andrx representatives received several inquiries

from reporters seeking comment on Balto's disclosures concerning the Commission's investigation. When Andrx subsequently requested from the Commission a copy of Balto's speech, that request was denied on the grounds that the speech discussed ongoing, nonpublic investigations.

- On January 7, 2000, Bloomberg News reported that Commission staff lawyers were recommending suit against Abbott Laboratories and were also considering recommending suit against HMR and Andrx.
- On February 7, 2000, The Wall Street Journal reported that the Commission staff had "recently" recommended suit against HMR and Andrx.
- On or about March 10, 2000, at least five or days before the Commission could have lawfully voted on the staff's recommendation to commence this proceeding, Andrx began receiving inquiries from reporters concerning what they characterized as the Commission's decision to sue Andrx. Andrx repeatedly confirmed with Commission staff that no decision had been made at the time of these contacts, and that the investigation was still, in the Commission's view, nonpublic. In response to these repeated inquiries concerning a Commission action that had not yet been taken, Andrx representatives asked several reporters where they had received their information. One reporter responded by stating that if she revealed her sources the lawyers at the FTC would not provide her with information in the future.

- On March 15, 2000, ABC News broadcast an article concerning the HMR/Andrx Stipulation, which it introduced by announcing that "Tomorrow at 1:00 p.m. the FTC will announce" that it had authorized an action against HMR and Andrx, although Andrx was again informed that no vote by the Commission had yet taken place.
- Beginning in late February 2000, staff counsel informed Andrx of inquiries that had been received from members of both the Senate Special Committee on Aging and the Antitrust Subcommittee of the Senate Judiciary Committee, seeking information on the current status of the investigation. On information and belief, these supposedly independent inquiries were the result of further disclosures by the staff of the Commission that were made for the specific and improper purpose of instigating the inquiries in order to make it appear to the Commission that there was more public support for the investigation than there in fact was.

58. Andrx complained about the improper leaks and disclosures. Yet nothing was done to stop them. The numerous, repeated improper and illegal disclosures were designed to ensure that the public was constantly kept aware of the status of and given a distorted view of the Commission's investigation and of the time and effort being invested by Commission in that investigation and was misled into believing that the Commission staff and the Commission had decided to take action concerning this matter before they had actually done so. As a result, when Andrx met with Commission Chairman Robert Pitofsky on February 18, 2000, Andrx was told that a proceeding was likely because, given the public awareness of the Commission's investigation, it would

"send the wrong signal" for the Commission not to commence this proceeding. It is inappropriate, inequitable and violative of Andrx's rights for the Commission to use this proceeding to "send a message" to other manufacturers, where the need to send such a message would not have arisen but for the repeated and flagrant violations of the law and Commission's own rules of confidentiality.

NINETEENTH DEFENSE

59. This proceeding is not to the public interest because, on information and belief, many if not all of the improper disclosures described in the preceding paragraphs that have occurred over the course of this investigation have been made by or with assistance from Biovail, which was represented by former George Cary, the former Deputy Director of the Bureau of Competition, solely for the purpose of assisting and promoting the private interests of Biovail and harming Andrx and in order to ensure that the Commission would have no alternative but to authorize this proceeding. Clearly, this is an improper and illegal use of the Commission's confidential, nonpublic information and an improper manipulation of the Commission and a misuse of the FTC Act.

WHEREFORE, respondent Andrx Corporation demands judgment declaring that respondents are not in violation of Section 5 of the FTC Act and dismissing

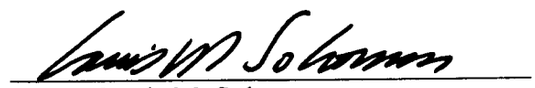
this complaint with prejudice and costs, and awarding such other and further relief as shall be deemed just and proper.

Dated: April 12, 2000

Respectfully submitted,

SOLOMON, ZAUDERER, ELLENHORN,
FRISCHER & SHARP

by



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CERTIFICATE OF SERVICE

I, Colin A. Underwood, hereby certify that on April 12, 2000, I caused a copy of the Answer of Andrx Corporation to be served upon the following persons by Federal Express:

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