UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of **Hoechst Marion Roussel, Inc., et al.,** **Respondents**	Docket No. 9293

AVENTIS PHARMACEUTICALS INC.'S ANSWER TO THE COMPLAINT

Aventis Pharmaceuticals Inc., formerly known as Hoechst Marion Roussel, Inc. ("HMRI"), answers the Complaint in this matter as follows:

HMRI did not monopolize any market nor did it attempt to monopolize any market or use any unfair methods of competition. HMRI did not violate Section 5 of the Federal Trade Commission Act or any other antitrust law.

The Complaint seeks to impose antitrust liability on HMRI as a consequence of its enforcing a valid United States patent against an infringing good. It seeks to hold HMRI responsible for the secondary effects that the enforcement of its patent could potentially have had in a putative market, even though such secondary (and here, wholly theoretical) effects arise solely from the application of a federal drug licensing scheme over which HMRI has neither influence nor control. Neither is a legitimate application of the Federal Trade Commission Act.

The allegations in the Complaint arise from a proper and legitimate attempt by HMRI to enforce its valid patent rights against Andrx Pharmaceuticals, Inc. ("Andrx"), a company that had developed an infringing generic version of HMRI's Cardizem® CD. The

Stipulation and Agreement, which lies at the heart of the Complaint, was but an attempt by the litigants to fashion a negotiated preliminary injunction that would prevent HMRI from being harmed by the sale of an infringing product during the pendency of litigation and would also make Andrx whole for lost profits in the event that its product was ultimately determined not to infringe a valid HMRI patent. The Stipulation and Agreement was carefully crafted so as not to remove the incentive from either party to seek and obtain a timely judicial resolution of the patent dispute and was reasonable in achieving its limited purpose to facilitate the resolution of the patent infringement litigation.

The patent case was ultimately resolved when Andrx invented around HMRI's patent and substituted, by way of a supplemental application to the U.S. Food and Drug Administration, ("FDA"), a non-infringing reformulation for the infringing product that was the subject of the lawsuit and the Stipulation and Agreement. That the patent dispute was settled and Andrx entered the market on the day that FDA approved the reformulated, non-infringing product demonstrates that the Stipulation and Agreement achieved its limited purpose of facilitating the resolution of the patent case and did not interfere with the market entry of any non-infringing generic products. Neither consumers nor lawful competition nor the public interest was harmed by the Stipulation and Agreement, by the maintenance of the patent infringement case, or by the manner in which it was prosecuted or ultimately settled. HMRI's actions did not and could not have harmed legitimate competition in any relevant market.

Answering respondent answers the specific allegations of the Complaint as follows:

1. Answering respondent avers that Aventis Pharmaceuticals Inc. ("Aventis"), formerly known as Hoechst Marion Roussel, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its office and principal place of business located at Parsippany, New Jersey and is a wholly owned subsidiary of Aventis, S.A., a corporation organized, existing and doing business under the laws of the Republic of France with its office and principal place of business at 25 Quai Paul Doumier, 92408 Courbevoie Cedex, France. Answering respondent further avers that Aventis is engaged in the development, manufacture, distribution and sale of pharmaceutical and health care products in the United States and that among other products, Aventis manufactures and sells Cardizem® CD, a cardiovascular drug used to treat hypertension and angina. Answering respondent denies the remaining allegations of paragraph 1.

2. Answering respondent makes no response to the allegations of paragraph 2 of the Complaint, since they state a conclusion of law and contain no allegations directed against the answering respondent. To the extent any allegation in paragraph 2 of the Complaint may construed to include allegations directed against the answering respondent, it is denied.

3. Answering respondent makes no response to the allegations of paragraph 3 of the Complaint, since they state a conclusion of law and contain no allegations directed against the answering respondent. To the extent any allegation in paragraph 3 of the Complaint may be construed to include allegations directed against the answering respondent, it is denied.

4. Answering respondent makes no response to the allegations of paragraph 4 of the Complaint, since they state a conclusion of law and contain no allegations directed against

the answering respondent. To the extent any allegation in paragraph 4 of the Complaint may be construed to include allegations directed against the answering respondent, it is denied.

5. Answering respondent admits that Andrx developed a generic or bioequivalent version of Cardizem® CD, which has been approved by the FDA for sale in the United States. The remaining allegations of paragraph 5 are denied by answering respondent for lack of knowledge or information. To the extent the remaining allegations of paragraph 5 may be construed to include allegations directed against the answering respondent, they are denied.

6. Answering respondent makes no response to the allegations of paragraph 6 of the Complaint, since they state a conclusion of law and contain no allegations directed against the answering respondent. To the extent any allegation in paragraph 6 of the Complaint may be construed to include allegations directed against the answering respondent, it is denied.

7. Answering respondent makes no response to the allegations of paragraph 7 of the Complaint, since they state a conclusion of law and contain no factual allegation directed against the answering respondent. To the extent any allegation in paragraph 7 of the Complaint may be construed to include allegations directed against the answering respondent, it is denied.

8. Answering respondent makes no response to the allegations of paragraph 8 of the Complaint, since they state a conclusion of law and contain no allegations directed against the answering respondent. To the extent any allegation in paragraph 8 may be construed to include allegations directed against the answering respondent, it is denied.

9. Answering respondent makes no response to the allegations of paragraph 9 of the Complaint, since they state a conclusion of law and contain no allegations directed against

the answering respondent. To the extent any allegation in paragraph 9 may be construed to include allegations directed against the answering respondent, it is denied.

10. Answering respondent makes no response to the allegations of paragraph 10 of the Complaint, since they state a conclusion of law and contain no allegations directed against the answering respondent. To the extent any allegation in paragraph 10 is construed to include allegations directed against the answering respondent, it is denied.

11. Answering respondent makes no response to the allegations of paragraph 11 of the Complaint, since they state a conclusion of law and contain no allegations directed against the answering respondent. To the extent any allegation in paragraph 11 may be construed to include allegations directed against the answering respondent, it is denied.

12. Answering respondent admits that diltiazem belongs to a group of drugs known as "calcium channel blockers," and is used principally to treat high blood pressure ("hypertension") and to decrease the occurrence of chronic chest pain ("angina"). Answering respondent further admits that once-a-day diltiazem is a time-release version of diltiazem, in capsule form, that is designed to be taken once every 24 hours. Answering respondent denies the remaining allegations of paragraph 12 of the Complaint.

13. Answering respondent admits that the relevant geographic market is the United States.

14. Answering respondent admits that HMRI distributed Cardizem® CD. Answering respondent denies the remaining allegations of paragraph 14 of the Complaint.

15. Answering respondent makes no response to the allegations of paragraph 15 of the Complaint, since they state a conclusion of law and contain no allegations directed

against the answering respondent. To the extent any allegation in paragraph 15 may be construed to include allegations directed against the answering respondent, it is denied.

16. Answering respondent admits that other than Andrx, only two companies – Purepac Pharmaceutical Co. ("Purepac"), a subsidiary of Faulding Inc., and Biovail Corporation International ("Biovail") -- had submitted ANDAs to the U.S. Food and Drug Administration for a generic version of Cardizem® CD. Answering respondent further admits that Purepac and Biovail did not receive final FDA approval until Andrx's 180-day Exclusivity Period expired in December 1999. Answering respondent makes no response to the remaining allegations of paragraph 16 of the Complaint, since they state a conclusion of law and contain no allegations directed against the answering respondent. To the extent that any of the remaining allegations of paragraph 16 may be construed to include allegations directed against the answering respondent, they are denied.

17. Answering respondent admits that Andrx filed the first ANDA with the FDA for the manufacture and sale of a generic version of Cardizem® CD in or around September 1995. Answering respondent further admits that Andrx certified to the NDA holder of Cardizem® CD that the product covered by its ANDA did not infringe any of the patents covering Cardizem® CD. Answering respondent makes no response to the remaining allegations of paragraph 17 of the Complaint, since they state a conclusion of law and contain no allegations directed against the answering respondent. To the extent that any of the remaining allegations of paragraph 17 may be construed to include allegations directed against the answering respondent, they are denied.

18. Answering respondent admits that on January 31, 1996, HMRI and Carderm filed a lawsuit against Andrx in the U. S. District Court for the Southern District of Florida, alleging infringement of a patent covering Cardizem® CD. Answering respondent makes no response to the remaining allegations of paragraph 18 of the Complaint, since they state a conclusion of law and contain no allegations directed against the answering respondent. To the extent that any of the remaining allegations of paragraph 18 may be construed to include allegations directed against the answering respondent, they are denied.

19. Answering respondent admits that in January 1997, Purepac filed an ANDA with the FDA for the manufacture and sale of a generic version of Cardizem® CD. Answering respondent further admits that on January 31, 1997, HMRI filed a lawsuit against Purepac in the U. S. District Court for the District of New Jersey, alleging patent infringement. Answering respondent makes no response to the remaining allegations of paragraph 19 of the Complaint, since they state a conclusion of law and contain no allegations directed against the answering respondent. To the extent that any of the remaining allegations of paragraph 19 may be construed to include allegations directed against the answering respondent, they are denied.

20. Answering respondent admits that on or about June 19, 1997, Biovail filed an ANDA with the FDA for the manufacture and sale of a generic version of Cardizem® CD. Answering respondent denies the remaining allegations of paragraph 20.

21. Answering respondent admits that representatives of HMRI met with Biovail in early August 1997 to discuss the development of a new indication or use for the drug Probucol, a product for which HMRI held an approved NDA that was not then being marketed or sold. Answering respondent further admits that the purpose of the meeting was also to discuss

the resolution of a potential patent infringement action relating to Biovail's generic version of Cardizem® CD. Answering respondent further admits that it has not sued Biovail Corporation International for patent infringement with respect to Biovail's generic or bioequivalent version of Cardizem® CD. Answering respondent denies the remaining allegations of paragraph 21.

22. Answering respondent admits that late July 1997, representatives of HMRI and Andrx engaged in discussions regarding a possible agreement in connection with HMRI's then pending patent infringement lawsuit against Andrx. Answering respondent denies the remaining allegations of paragraph 22 of the Complaint.

23. Answering respondent admits that on September 24, 1997, HMRI, Carderm and Andrx entered into a Stipulation and Agreement. Answering respondent further admits that the Stipulation and Agreement did not settle the lawsuit and that the Stipulation and Agreement specifically contemplated that the parties would continue the litigation to final judicial resolution. Answering respondent denies the remaining allegations of paragraph 23 and refers to the Stipulation and Agreement for the terms thereof.

24. Answering respondent admits that under the Stipulation and Agreement, HMRI agreed to make interim payments to Andrx of $10 million per quarter, beginning upon final FDA approval of Andrx's ANDA and continuing until the first to occur of: (1) the Effective Date of Final Judgment in *Hoechst Marion Roussel, Inc. et al. v. Andrx Pharmaceuticals, Inc.*, No. 96-06121-CIV Roettger (S.D. Fla.); (2) HMRI providing notice that it intended to license a third party or sell its own generic version of Cardizem® CD pursuant to Section 5.B of the Stipulation; or (3) the effective date of any license agreement that might arise as a result of Andrx exercising its rights pursuant to Section 6.A.ii of the Stipulation. Answering respondent

further admits that the Stipulation and Agreement provided that HMRI would pay Andrx an additional $60 million per year for that same time period if HMRI were not to prevail in the patent infringement suit. Answering respondent denies the remaining allegations of paragraph 24 and refers to the Stipulation and Agreement for the terms thereof.

25. Answering respondent admits to the allegations of paragraph 25 and refers to the Stipulation and Agreement for the terms thereof.

26. Answering respondent denies the allegations of paragraph 26 and refers to the Stipulation and Agreement for the terms thereof.

27. Answering respondent admits that the FDA granted final approval for Andrx's ANDA for a generic version of Cardizem® CD on July 9, 1998. Answering respondent further admits that Andrx did not commence the commercial sale of that product. Answering respondent further admits that, following July 9, 1998, HMRI began making the quarterly interim payments provided for in the Stipulation and Agreement. Answering respondent denies the remaining allegations of paragraph 27.

28. Answering respondent admits that Andrx submitted a supplemental ANDA to the FDA on September 11, 1998, which reflected a reformulation of its generic Cardizem® CD product. Answering respondent further admits that Andrx filed a Paragraph IV Certification with HMRI regarding that supplemental ANDA. Answering respondent further admits that the supplement to Andrx's ANDA was approved by the FDA on June 8, 1999 and that Andrx began marketing the reformulated generic product on or about June 23, 1999. Answering respondent further admits that on or about that same day, HMRI and Andrx entered into the Stipulation and Order that settled the lawsuit and ended the Stipulation and Agreement.

Answering respondent makes no response to the remaining allegations of paragraph 28 that refer to the Paragraph IV Certification, since they are a characterization of the Federal Food Drug and Cosmetic Act and the regulations promulgated thereunder and the Hatch-Waxman Amendments thereto and contain no allegations directed against the answering respondent. Answering respondent denies the remaining allegations of paragraph 28.

29. Answering respondent denies the allegations of paragraph 29.

30. Answering respondent admits that its forecasts projected that a generic version of Cardizem® CD, sold at 70% of the brand price, would capture roughly 40% of Cardizem® CD sales within the first year. Answering respondent denies the remaining allegations of paragraph 30.

31. Answering respondent denies the allegations of paragraph 31.

32. Answering respondent denies the allegations of paragraph 32 and refers to the Stipulation and Agreement for the terms thereof.

33. Answering respondent denies the allegations of paragraph 33 and refers to the Stipulation and Agreement for the terms thereof.

34. Answering respondent denies the allegations of paragraph 34.

35. Answering respondent denies the allegations of paragraph 35 and refers to the Stipulation and Agreement for the terms thereof.

36. Answering respondent denies the allegations of paragraph 36.

37. Answering respondent denies the allegations of paragraph 37.

38. Answering respondent denies the allegations of paragraph 38.

39. Answering respondent denies the allegations of paragraph 39.

Except as specifically admitted and denied, answering respondent is without knowledge sufficient to admit or deny the allegations of the Complaint and on that basis, denies them.

FIRST ADDITIONAL DEFENSE

The Complaint fails to state, in whole or in part, a claim upon which relief can be granted for various reasons, including, but not limited to the fact that the Complaint fails to identify or specify any anticompetitive effect arising from the conduct that serves as the basis of the Complaint.

SECOND ADDITIONAL DEFENSE

The Complaint fails to comply with the requirements of Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. § 45(b), because the Federal Trade Commission has no reason to believe that HMRI violated the Federal Trade Commission Act.

THIRD ADDITIONAL DEFENSE

The Complaint fails to comply with 16 C.F.R. § 2.3 because this is a matter of private controversy and does not tend to adversely affect the public interest.

FOURTH ADDITIONAL DEFENSE

HMRI's efforts to enforce its valid intellectual property rights through the judicial system, including all actions taken that are reasonably attendant to such efforts, are protected by the First Amendment to the United States Constitution and the *Noerr-Pennington* Doctrine.

FIFTH ADDITIONAL DEFENSE

HMRI's efforts to enforce its valid United States patent and prevent the sale of an infringing good, including all actions that are reasonably attendant to such efforts, are protected by the Patent Act, 35 U.S.C. § 271 et seq.

SIXTH ADDITIONAL DEFENSE

HMRI has an absolute right to exclude from the market goods that infringe one or more of its valid United States patents.

SEVENTH ADDITIONAL DEFENSE

HMRI has no obligation to restrict, limit or impair its legitimate rights to enforce its valid patents or to prevent the sale of infringing goods in order to prevent potential secondary effects from arising in the market due to the operation of the Hatch-Waxman Amendments to the Food Drug and Cosmetics Act.

EIGHTH ADDITIONAL DEFENSE

HMRI does not have a monopoly, is not likely to obtain a monopoly and has never attempted to obtain a monopoly in any relevant market nor was there any dangerous probability of achieving a monopoly in any relevant market.

NINTH ADDITIONAL DEFENSE

HMRI had legitimate business justifications for all conduct at issue in this matter.

TENTH ADDITIONAL DEFENSE

HMRI's conduct was not intended to have, did not have and was not likely to have had any adverse effects on competition in any relevant market.

TWELFTH ADDITIONAL DEFENSE

The procompetitive efficiencies contained in the Stipulation and Agreement outweighed any actual or potential anticompetitive effects that could properly be ascribed to the Stipulation and Agreement.

THIRTEENTH ADDITIONAL DEFENSE

The relief sought by the Complaint is contrary to public policy and not in the public interest in that it limits, interferes with and otherwise hampers the orderly maintenance, prosecution and settlement of patent infringement litigation, thereby raising the cost of patent enforcement, reducing the value of patents, and deterring innovation and dynamic efficiencies.

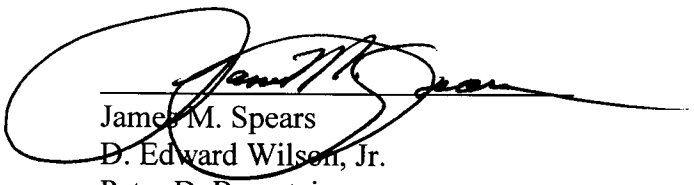
FOURTEENTH ADDITIONAL DEFENSE

The relief sought by the Complaint is inconsistent with and preempted by the Hatch-Waxman Amendments to the Food Drug and Cosmetics Act and the regulations issued by the FDA implementing same.

WHEREFORE, answering respondent demands judgment dismissing the Complaint with prejudice and with costs and such other relief as is deemed just and proper.

Dated: April 10, 2000

Respectfully Submitted,



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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of **Hoechst Marion Roussel, Inc., et al.,** **Respondents**	Docket No. 9293

CERTIFICATE OF SERVICE

I, Peter D. Bernstein, hereby certify that on April 10, 2000, a copy of the Answer of Respondent Aventis Pharmaceuticals, Inc., formerly known as Hoechst Marion Roussel, Inc., was served upon the following persons by hand delivery and/or Federal Express as follows:

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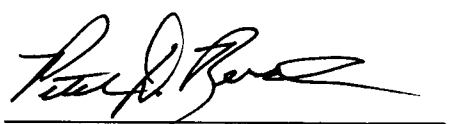

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