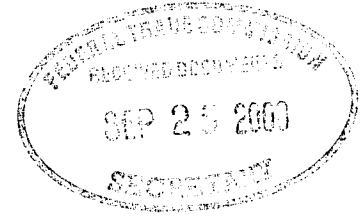


UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION



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

**RESPONDENT AVENTIS PHARMACEUTICALS, INC.'S  
FIRST SET OF INTERROGATORIES**

Pursuant to Rules 3.35 and 3.37 of the Federal Trade Commission's ("FTC") Rules of Practice for Adjudicative Proceedings ("Rules of Practice"), 16 C.F.R. §§ 3.35 & 3.37, and in accordance with the Court's Scheduling Order, dated April 26, 2000, Respondent Aventis Pharmaceuticals, Inc., formerly known as Hoechst Marion Roussel, Inc., by counsel, submits this First Set of Interrogatories to the FTC. The FTC is requested to respond, in writing, to the following Interrogatories within twenty (20) days after service hereof.

**DEFINITIONS**

1. As used herein, "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of these Interrogatories and document production any information that might otherwise be construed to be outside their scope. The term "each" includes "every," and vice versa. The terms "a," "an" and "any" include "all," and

“all” includes “a,” “an” and “any.” The singular form of a word shall be interpreted in the plural and vice versa whenever appropriate to bring within the scope of these Interrogatories any information that might otherwise be construed to be outside their scope.

2. As used herein, “ANDA” means an Abbreviated New Drug Application filed with the FDA pursuant to 21 U.S.C. § 355(j).

3. As used herein, “ANDA 74-752” means the Abbreviated New Drug Application filed with the FDA pursuant to 21 U.S.C. § 355(j) by Andrx for a generic bioequivalent version of Cardizem® CD.

4. As used herein, “Andrx” means Andrx Pharmaceuticals, Inc., its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf.

5. As used herein, “Biovail” shall refer to Biovail Corporation, its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf.

6. As used herein, “Cardizem® CD” means the diltiazem formulation sold under that trademark.

7. As used herein, “communication” means any written or verbal contact, formal or informal, at any time or place, and under any circumstance whatsoever, whereby information of any nature was to be transmitted or transferred, and includes without limitation

conversations, discussions, meetings, telephone conversations, letters, notes, memoranda, reports, and legal filings.

8. As used herein, the terms "document" or "documents" or "documentation" include these terms as defined by 16 C.F.R. § 3.34(b) and, in addition, the original or drafts or any kind of written, printed, recorded or graphic matter or sound reproduction, however produced or reproduced, whether sent or received or neither, and all copies thereof which are different in any way from the original (whether by notation, indication of copies sent or received or otherwise) regardless of whether designated "Confidential," "Privileged" or otherwise and including, but not limited to, any correspondence, paper, book, account, drawing, agreement, contract, e-mail, handwritten notes, invoice, memorandum, telegram, object, opinion, purchase order, report, records, transcript, summary, study, survey, recording of any telephone or other conversation, interviews or notes of any conference. The terms "document" or "documents" or "documentation" shall also include data stored, maintained or organized electronically or magnetically or through computer equipment, translated, if necessary, by you into reasonably usable form, and film impressions, magnetic tape and sound or mechanical productions of any kind or nature whatsoever.

9. As used herein, "Faulding" means Faulding Inc., its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf.

10. As used herein, "FDA" means the United States Food and Drug Administration, including without limitation its employees, scientists, technicians, agents, examiners and laboratories.

11. As used herein, “FTC,” “Complaint Counsel,” “you” or “your” means the United States Federal Trade Commission, including its employees, agents, attorneys, consultants, representatives, officers, and all other persons acting or purporting to act on its behalf.

12. As used herein, “HMR” means Hoechst Marion Roussel, Inc., its predecessors, including without limitations Hoechst AG and Marion Merrell Dow, Inc., and the officers, directors, employees, partners, subsidiaries, corporate parents, affiliates and divisions of each of the foregoing.

13. As used herein, “HMR/Andrx Stipulation and Agreement” means that agreement between Hoechst Marion Roussel, Inc., Carderm Capital, L.P. and Andrx Pharmaceuticals entered into on or about September 26, 1997.

14. As used herein, “identify” means to specify in detail and to particularize the content of the answer to the question and not simply to state the reply in summary or outline fashion. In particular:

a. when used in reference to a document, “identify” means to (1) set forth (i) the name and address of the author of the document; (ii) the name and address of all recipients of a copy of the document; and (iii) the date of the document; and (2) identify and describe the content of the document in detail.

b. when used in reference to a natural person, “identify” means to set forth that person’s (i) name; (ii) present title or position and area of responsibility; (iii) present or last known business and home address; and (iv) present or last known employer. For any person identified, if any of the above information was different at the time with which a particular Interrogatory is concerned, supply both current information and such different information as applies to the time period in question. Once a person

has been identified properly, it shall be sufficient thereafter to identify the individual by name only.

c. when used in reference to a corporation or any other entity, “identify” means to set forth the address of its principal place of business. Once an entity has been identified properly, it shall be sufficient thereafter to identify the entity by name only.

d. when used in reference to a “communication,” “identify” means to state the (i) date of the communication; (ii) nature and substance of the communication; (iii) identity of each person who was present at or who participated in such communication; (iv) type of communication (*e.g.*, letter, memorandum, telegram, telephone conversation, etc.); and (v) identity of each document related in any way to such communication.

e. when used in reference to an event, “identify” means to state all relevant facts relating to that event.

15. As used herein, “initial formulation” means the original formulation of Andrx’s generic Cardizem® CD product that was the subject of Andrx’s ANDA 74-752, filed with the FDA on September 22, 1995, the patent certification dated December 30, 1995, and the Patent Infringement Litigation that ensued thereafter.

16. As used herein, “584 Patent” means U.S. Patent No. 5,470,584 issued by the U.S. Patent and Trademark Office on November 28, 1995.

17. As used herein, “patent certification” means the certification provided to the owner of the patent or holder of the application pursuant to 21 U.S.C. § 355(j)(2)(B).

18. As used herein, "Patent Infringement Litigation" means *Hoechst Marion Roussel, Inc. et al. v. Andrx Pharmaceuticals, Inc.*, Case No. 96-06121-Civ-Roettger (S.D. Fla.).

19. As used herein, "person" means any natural person, corporation, partnership, association, limited liability company, limited liability partnership, trust, government agency, or other entity or organization.

20. As used herein, "reformulated version" means the revised formulation of Andrx's generic Cardizem® CD product that was the subject of a Supplement to Andrx's ANDA 74-752, filed with the FDA on September 11, 1998, and of Andrx's supplemental patent certification dated February 3, 1999.

21. As used herein, "relate" or "relating to" means, by way of example only and not as a limitation, concerning, refers to, in connection with, in regard to, reflects upon, pertaining to, alludes to, responds to, is about, regards, discusses, shows, describes, records, evidences, sets forth, discloses, explains, summarizes, reflecting, analyzes or constitutes, or is in any way logically or factually connected with the matters discussed.

### **INSTRUCTIONS**

1. Each Interrogatory shall be answered fully in writing under oath.
2. Each Interrogatory shall be answered upon your entire knowledge from all sources, including all information in the possession, actual or constructive, of you or your attorneys, you and your investigators, or persons working on your or their behalf.
3. If, after exercising due diligence, you cannot answer the following Interrogatories, so state and answer to the extent possible, specifying your inability to answer the remainder. State whatever information or knowledge you have concerning the unanswered portion, and identify and describe in detail what you did in attempting to secure the unknown

information. Estimated dates could be given when, but only when, exact dates cannot be supplied. Any estimates should be identified as such. The sources and means of derivation of each estimate should be specifically set forth.

4. If you object to a portion or an aspect of any Interrogatory, state the grounds for your objection with specificity and answer the remainder of the Interrogatory. If any information called for by any Interrogatory is withheld because you claim that such information is protected by virtue of the attorney-client privilege, work product doctrine, or other privilege or doctrine, you are requested to so state, specifying for each such source of information (*i.e.*, document, communication, etc.) all applicable information required pursuant to Rule 3.38A of the FTC's Rules of Practice.

5. Each person who provides information in any answer to these Interrogatories will identify each answer for which he or she provided information and will furnish his or her name, address, and title. The answers are to be signed by the person(s) making them, and any objections are to be signed by the attorney making them.

6. These Interrogatories are continuing in nature. You are requested to supplement your responses when additional information responsive to these Interrogatories subsequently becomes available, whether directly or indirectly.

### **INTERROGATORIES**

1. Is it Complaint Counsel's contention that, but for the HMR/Andrx Stipulation and Agreement, Andrx would have entered the market with its initial formulation of generic Cardizem® CD prior to June 8, 1999? If your answer is "yes," please identify and describe the basis, if any, for this contention.

2. If your answer to Question No. 1 is “yes,” when, do you contend, would Andrx have entered the market with that formulation? Please identify and describe the basis, if any, for this contention.

3. Is it Complaint Counsel’s contention that, but for the HMR/Andrx Stipulation and Agreement, Andrx would have entered the market with its reformulated version of generic Cardizem® CD prior to June 8, 1999? If your answer is “yes,” please identify and describe the basis, if any, for this contention.

4. If your answer to Question No. 3 is “yes,” when, do you contend, would Andrx have entered the market with that formulation? Please identify and describe the basis, if any, for this contention.

5. Is it Complaint Counsel’s contention that, but for the HMR/Andrx Stipulation and Agreement, Faulding would have entered the market with its generic version of Cardizem® CD prior to June 8, 1999? If your answer is “yes,” please identify and describe the basis, if any, for this contention.

6. If your answer to Question No. 5 is “yes,” when, do you contend, would Faulding have entered the market with that formulation? Please identify and describe the basis, if any, for this contention.

7. Is it Complaint Counsel’s contention that, but for the HMR/Andrx Stipulation and Agreement, Biovail would have entered the market with its generic version of Cardizem® CD prior to June 8, 1999? If your answer is “yes,” please identify and describe the basis, if any, for this contention.



8. If your answer to Question No. 7 is “yes,” when, do you contend, would Biovail have entered the market with that formulation? Please identify and describe the basis, if any, for this contention.

9. Is it Complaint Counsel’s contention that, but for the HMR/Andrx Stipulation and Agreement, some other manufacturer would have entered the market with an FDA-approved generic version of Cardizem® CD prior to June 8, 1999? If your answer is “yes,” please identify and describe the basis, if any, for this contention, including, but not limited to, the identity of the manufacturer and the ANDA number of the product with which you contend it would have entered the market.

10. If your answer to Question No. 9 is “yes,” when, do you contend, would this other manufacturer have entered the market with that formulation? Please identify and describe the basis, if any, for this contention.

11. Is it Complaint Counsel’s contention that HMR’s ‘584 Patent is or was invalid? If your answer is “yes,” please identify and describe the basis, if any, for this contention.

12. Is it Complaint Counsel’s contention that Andrx’s initial formulation of its generic Cardizem® CD product did not infringe HMR’s patents? If your answer is “yes,” please identify and describe the basis, if any, for this contention.

13. Is it Complaint Counsel’s contention that the manufacturer of a product that infringes the patents held, licensed or otherwise controlled by another constitutes an “actual” or “potential competitor” of the person that holds, licenses or otherwise controls those patents? If your answer is “yes,” please identify and describe the basis, if any, for this contention.

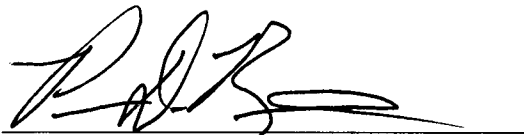
14. Where patent infringement litigation is brought in good faith and substantial evidence exists that a valid patent has been infringed, is it Complaint Counsel's contention that the disputants are "actual competitors" or "potential competitors" for the purposes of the antitrust laws? If your answer is "yes," please identify and describe the basis, if any, for this contention.

15. Is it Complaint Counsel's contention that the settlement of patent litigation, in which the accused infringer agrees not to sell the allegedly infringing product, constitutes an "agreement not to compete" under the antitrust laws? If your answer is "yes," please identify and describe the basis, if any, for this contention.

16. Is it Complaint Counsel's contention that consumers are benefitted by the sale of goods that infringe valid patents held, licensed or otherwise controlled by others? If your answer is "yes," please identify and describe the basis, if any, for this contention.

Dated: September 25, 2000

Respectfully Submitted,



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UNITED STATES OF AMERICA  
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 September 25, 2000, a copy of Aventis Pharmaceuticals, Inc.'s First Set of Interrogatories was served upon the following persons by hand delivery and/or Federal Express as follows:

Donald S. Clark, Secretary  
Federal Trade Commission  
Room 172  
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Washington, D.C. 20580

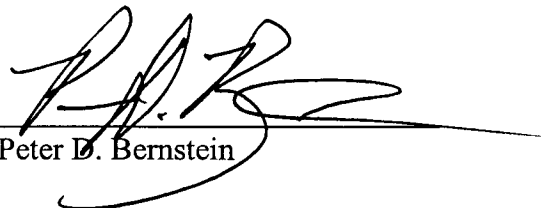
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