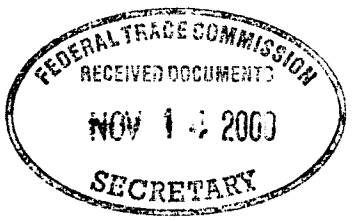
UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION



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

HOECHST MARION ROUSSEL, INC.'S MOTION TO COMPEL
RESPONSE TO INTERROGATORY NOS. 1, 11 AND 16

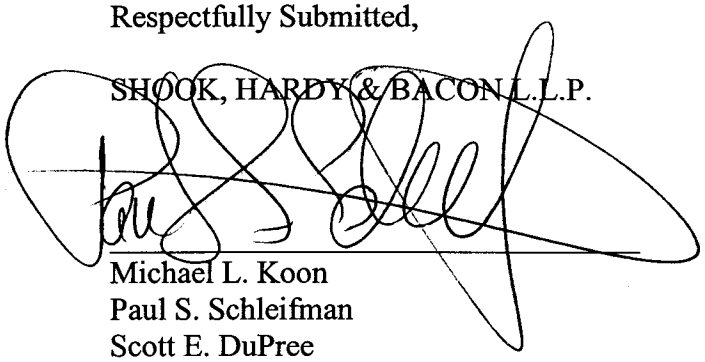
Pursuant to Rule 3.38(a) of the Federal Trade Commission's Rules of Practice, 16 C.F.R. § 3.38(a), Hoechst Marion Roussel, Inc. hereby moves for an Order compelling Complaint Counsel to respond to Interrogatory Nos. 1, 11 and 16 of Respondent's First Set of Interrogatories.

WHEREFORE, Respondent respectfully requests that this Court enter an Order compelling Complaint Counsel to respond to Interrogatory Nos. 1, 11 and 16 of Respondent's First Set of Interrogatories and further relief as the Court may deem just and proper.

Dated: November 13, 2000

Respectfully Submitted,

SHOOK, HARDY & BACON L.L.P.



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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

MEMORANDUM IN SUPPORT OF HOECHST MARION ROUSSEL, INC.'S MOTION TO COMPEL RESPONSE TO INTERROGATORY NOS. 1, 11 AND 16

Pursuant to Rule 3.38(a) of the Federal Trade Commission's ("FTC") Rules of Practice for Adjudicative Proceedings, 16 C.F.R. § 3.38(a), Respondent Aventis Pharmaceuticals, Inc., formerly known as Hoechst Marion Roussel, Inc. ("HMR"), submits this memorandum in support of its motion for an Order compelling Complaint Counsel to respond to Interrogatory Nos. 1, 11 and 16 of Respondent's First Set of Interrogatories.

In its Order of August 18, 2000, this Court reminded all parties "of their duty to seasonably amend prior responses to interrogatories, requests for production or requests for admission" and warned the parties "not [to] wait until the close of discovery to make supplemental responses." (Order on Respondent Andrx's Motion to Compel Complaint Counsel to Respond to Interrogatories (Aug. 18, 2000).) Unfortunately, these warnings do not appear to have moved Complaint Counsel to provide current and responsive answers to HMR's discovery requests.

BACKGROUND

HMR served Complaint Counsel with 16 contention interrogatories on September 25, 2000. These interrogatories were directed at five central issues to Complaint Counsel's case:

(1) the actual competitive effects, if any, that Complaint Counsel alleges to have resulted from the HMR/Andrx Stipulation and Agreement (Interrogatories Nos. 1-10);

(2) whether Complaint Counsel contend the patent litigation out of which the Stipulation and Agreement arose was a mere sham (Interrogatories Nos. 11-12);

(3) whether Complaint Counsel contends a patent infringer (as Andrx was alleged to be in the HMR/Andrx patent litigation) could be deemed to be an actual or potential competitor of a patent holder (Interrogatories Nos. 13-14);

(4) whether Complaint Counsel is of the view that patent settlement agreements in which an infringer agrees not to sell the infringing product constitute non-competition agreements under the antitrust laws (Interrogatory No. 15); and

(5) whether Complaint Counsel contends consumers are benefitted by the sale of infringing products (Interrogatory No. 16).

Complaint Counsel submitted objections and responses to HMR's contention interrogatories on October 16, 2000. Although the interrogatories were drafted to elicit "yes" or "no" responses, Complaint Counsel failed to answer a single question with either a "yes" or a "no." Only two of Complaint Counsel's answers fairly addressed the substance of the interrogatories. (Responses to Interrogatory Nos. 9 and 10.) As to the rest, rather than answer the interrogatories directly, Complaint Counsel offered incomplete and non-responsive narratives and summary objections.

By letter dated October 30, 2000, HMR advised Complaint Counsel of defects in their interrogatory responses and of the need to supplement and update their responses. In accordance with Rule 3.22(f) of the FTC's procedural rules, 16 C.F.R. § 3.22(f), HMR conferred with Complaint Counsel in good faith to resolve by agreement HMR's concerns with respect to Complaint Counsel's interrogatory responses on November 7, 2000. On Saturday, November 11, 2000, Complaint

Counsel sent, via facsimile, their Supplemental Objections and Responses to Respondent Hoechst Marion Roussel, Inc.'s First Set of Interrogatories ("Supplemental Responses").[1] While Complaint Counsel corrected many of the deficiencies contained in their original responses, there remain three interrogatories which Complaint counsel has refused to properly answer.

ARGUMENT

Interrogatory No. 1.

Interrogatory No. 1 provides:

> 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 ro June 8, 1999. If your answer is "yes," please identify and describe the basis, if any, for this contention.

This interrogatory asks Complaint Counsel for a simple "yes" or "no" answer and, if the answer is "yes," asks Complaint Counsel to identify and describe the basis for its answer. Unfortunately, Complaint Counsel refuses to answer "yes" or "no." Instead Complaint Counsel responds generally that "at the time Andrx and Hoechst entered into the Stipulation and Agreement in September 1997, complaint counsel contend that there was substantial evidence that Andrx intended to bring to market its generic version of Cardizem CD upon FDA approval in July 1998." Complaint Counsel then recite some of the evidence which allegedly shows Andrx's intent.

The Interrogatory, however, does not ask Complaint Counsel if they contend there was evidence at the time the Stipulation and Agreement was entered that Andrx intended to market its initial formulation of a generic version of Cardizem CD upon FDA approval in July 1998. Instead, the interrogatory asks whether at the trial of this case Complaint Counsel will contend that but for the Stipulation and Agreement would have entered the market with its initial formulation prior to

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1. A copy of the Supplemental Responses is attached hereto as Exhibit A.

June 8, 1999. Complaint Counsel must be required to answer this question either "yes" or "no". A "no" answer will limit the issues to be tried and evidence presented in this case. A "yes" answer will help clarify to respondents the issues in the case and cause them to be ready to present evidence on this issue. Respondents should not be left at this late date guessing what legal or factual issues Complaint Counsel intend to present to this Court. For these reasons, Respondent Aventis Pharmaceuticals respectfully prays for an Order directing Complaint Counsel to answer Interrogatory No. 1.

Interrogatory No. 11.

Interrogatory No. 11 provides:

> Is it Complaint Counsel's contention that HMR's '584 Patent is or was invalid? If you answer is "yes," please identify and describe the basis, if any, for this contention.

In its Response, Complaint Counsel states:

> Andrx and Hoechst were engaged in a dispute in which the validity and enforceability of the '584 Patent was directly at issue. Andrx filed a Summary Judgment Motion on the Issue of Invalidity on February 14, 1997, in which it argued that the claim interpretation proposed by Hoechst placed claim 1 of the '584 patent within the dissolution ranges disclosed by the prior art, making claim 1 invalid. Andrx also filed a Motion for Summary Judgment and Sanctions for Fraud. Upon the U.S. Patent Office on November 24, 1998 in which it argued that the patentee misrepresented the scope of U.S. Patent No. 4,894,240 to the Patent Office. Andrx and Hoechst ultimately dismissed their patent litigation in the Sosuthern District of Florida before the court had ruled on the merits of this dispute. Accordingly, neither the court in the Southern District of Florida not any other court has found the '584 Patent to be not invalid.

Inasmuch as the Stipulation and Agreement is inextricably intertwined with the underlying patent litigation between Respondents, a crucial issue in this case is whether the Stipulation and Agreement was simply an attempt on Aventis' part to keep an infringing product off the market while the courts ruled on the merits of the litigation or whether, as Complaint Counsel contends, the Agreement was a market allocation agreement aimed at keeping Andrx's product off the market.

Interrogatory No. 11 goes to whether Complaint Counsel contends the Aventis patent at issue in the underlying case was valid or invalid. Either Complaint Counsel contends the '584 Patent is valid or it contends the '584 Patent was invalid. The mere listing of motions filed in the Florida patent infringement litigation does not answer the question or satisfy Complaint counsel's obligation to respond to this Interrogatory in a full and complete fashion.[2] It simply is no answer to such a "yes or no" question to provide neither a "yes" nor a "no," nor an explanation of why Complaint Counsel cannot answer "yes" or "no." Neither is it a response to offer, as Complaint Counsel does, irrelevant evidence and invite Respondents to attempt to ferret out answers by reading between the lines. For these reasons, Aventis Pharmaceuticals, Inc. respectfully prays that Complaint Counsel be ordered to properly answer Interrogatory No. 11.

Interrogatory No. 16.

Interrogatory No. 16 provides:

> 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.

Complaint Counsel submitted a lengthy response but failed to answer the question. The Interrogatory seeks Complaint counsel's position on whether consumers are benefitted by the sale of goods that infringe the valid patents of others. The relevance of this interrogatory is evident. Aventis claims Andrx's initial formulation infringed the '584 Patent. Aventis further claims that the

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2. It is fundamental that "[t]he answers to [contention] interrogatories must be responsive, full, complete and unevasive," and "[if the answering party lacks necessary information to make a full, fair and specific answer to an interrogatory, it should so state under oath and should set forth in detail the efforts made to obtain the information." *Continental Illinois Nat'l Bank & Trust Co. of Chicago v. Caton,* 136 F.R.D. 682, (D. Kan. 1991) (quoting *Miller v. Doctor's Gen. Hosp.,* 76 F.R.D. 136, 140 (W.D. Okla. 1977)).

Stipulation and Agreement was an attempt to keep the infringing product off the market until the Courts ruled on whether the product infringed or not. Aventis is entitled to know whether Complaint Counsel contends that consumers would have been benefitted were they able to purchase Andrx's infringing product. This question goes to the heart of Complaint Counsel's case and Aventis is entitled to a proper response.

WHEREFORE, for the foregoing reasons, Respondent Hoechst Marion Roussel, Inc. respectfully prays that the Court grant this motion in its entirety and enter an Order requiring Complaint Counsel to amend, supplement and update its responses to Interrogatory N os. 1, 11 and 16 of HMR's First Set of Interrogatories, and for such further relief as the Court deems just and proper.

Dated: November 13, 2000

Respectfully Submitted,

SHOOK HARDY & BACON, LLP

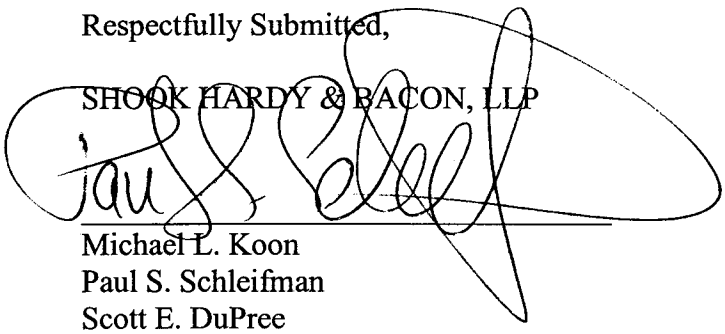

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EXHIBIT A

UNITED STATES OF AMERICA
BEFORE 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

COMPLAINT COUNSEL'S SUPPLEMENTAL OBJECTIONS AND RESPONSES TO RESPONDENT HOECHST MARION ROUSSEL, INC.'S FIRST SET OF INTERROGATORIES

Pursuant to section 3.35 of the Federal Trade Commission Rules of Practice for Adjudicatory Proceedings 16 C.F.R. § 3.35, complaint counsel hereby submit these Supplemental Objections and Responses to Respondent Hoechst Marion Roussel Inc's First Set of Interrogatories. The full text of each interrogatory is set out below, followed by our respective objections and responses.

GENERAL OBJECTIONS

The following general objections apply to each of Hoechst's Interrogatories:

1. Complaint counsel object to each interrogatory, instruction, or definition to the extent it seeks to impose obligations broader than those required or authorized by the Federal Trade Commission Rules of Practice for Adjudicatory Proceedings or any applicable order or rule of this Court.

2. Complaint counsel object to the each of the interrogatories as unreasonably cumulative and duplicative to the extent that the information sought already has been provided to respondents in response to previous discovery requests.

3. Complaint counsel object to each interrogatory to the extent it seeks information protected from disclosure by privilege, including, where applicable: (a) attorney-client privilege; (b) work-product privilege; (c) government deliberative-process privilege; (d) government informant privilege; and (e) any other applicable privilege.

4. Complaint counsel object to each interrogatory to the extent that it seeks information not reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defenses of any respondent.

5. Complaint counsel object to each interrogatory as excessively broad and unreasonably burdensome to the extent it seeks an exhaustive list of each fact or basis supporting complaint counsel's contentions. Complaint counsel has expended reasonable efforts to respond fully to each interrogatory. However, our response to each interrogatory is not intended to be exhaustive or to be admissions that other facts or bases are not supportive or relevant.

6. Complaint counsel's response to any particular interrogatory, notwithstanding any objections to any of the definitions, requests, or instructions, should not be construed as: (a) an admission that the information is relevant; (b) a waiver of the general or specific objections asserted herein; or (c) an agreement that requests for similar information will be treated in a similar manner. Complaint counsel specifically reserve all objections as to the competency,

relevancy, and admissibility of the information provided; all objections as to burden, vagueness, unintelligibility, over-breadth and ambiguity; and all rights to object to the use of the information in any other proceeding.

OBJECTIONS AND RESPONSES TO INTERROGATORIES

Interrogatory No. 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.

Subject to the general objections identified above, complaint counsel responds as follows: at the time Andrx and Hoechst entered into the Stipulation and Agreement in September 1997, complaint counsel contend that there was substantial evidence that Andrx intended to bring to market its generic version of Cardizem CD upon FDA approval in July 1998. Andrx had received two legal opinions that stated in "clear terms that they do not believe the Andrx product infringes the HMR patent." Andrx 9683-84. Andrx consistently maintained – both in statements to the FDA and to the federal district court in the patent infringement litigation – that its initial formulation of generic Cardizem CD (as amended in April 1996) did not infringe any valid patent listed in the Orange Book claiming Cardizem CD. For example, Andrx's President and Chief Scientist stated in a filed affidavit that "[i]f the FDA approves Andrx's ANDA for its once-a-day formulation . . . [the product] that will be sold will not infringe the [HMR] Patent." *See* HMRI S7 001599-607; *see also* HMRI S7 003129-3133; Andrx 2199-2200; Andrx 2068-77. Andrx made these same representations to its Board of Directors and to one of its primary

investors. Based on its apparent confidence in its legal position in the Florida patent action, Andrx represented to the federal district court during that action that it intended to "manufacture and sell its once-a-day diltiazem composition as soon as it receives FDA approval." *See* HMRI S7 002984-003000, at 2993.

Andrx's financial documents and projections also anticipated a launch of its generic Cardizem CD product upon FDA approval. *See* Andrx 004668-71; 4515-33. Andrx had taken steps towards developing and manufacturing its generic Cardizem CD product in preparation for a launch upon FDA approval. In addition, Hoechst was concerned that Andrx was under enormous financial pressure to go to market and was willing to pay Andrx $10 million a quarter (and up to $100 million a year) to make it possible for Andrx to resist the financial pressure to enter.

Interrogatory No. 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.

Subject to the general objections identified above, complaint counsel responds as follows: in the absence of the HMR/Andrx Stipulation and Agreement, there is substantial evidence that Andrx would have entered the market with its initial formulation of generic Cardizem CD (as amended in April 1996) as early as July 9, 1998 – the date that Andrx received final FDA approval of that product. Complaint counsel refer Hoechst to our response to Interrogatory No. 1.

Interrogatory No. 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.

Subject to the general objections identified above, complaint counsel responds as follows: Because Andrx did not obtain final FDA approval for its reformulated version of generic Cardizem CD until June 8, 1999, complaint counsel does not contend that Andrx would have entered the market with its reformulated version of generic Cardizem CD prior to June 8, 1999. However, complaint counsel does contend that the HMR/Andrx Stipulation and Agreement had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition and consumers by preventing or discouraging the entry of generic versions of Cardizem CD into the relevant market, decreasing the output of generic Cardizem CD products, raising or stabilizing the prices of Cardizem CD, and eliminating or reducing consumer choice. Under the HMR/Andrx Stipulation and Agreement, Andrx agreed not to market the generic version of Cardizem CD that was subject to the patent infringement suit. In addition, Andrx agreed not to market any generic version of Cardizem CD (including Andrx's reformulated product) regardless of whether the product infringed any of Hoechst's patents. If Andrx failed to abide by any of these obligations, it would be required to repay all of the quarterly $10 million payments, forfeit any right to future quarterly $10 million payments, and forfeit any right to additional payments of up to $60 million per year (in the event Andrx prevailed in the Florida patent action). These penalty provisions created an incentive for Andrx to abide by its obligations under the HMR/Andrx Stipulation and Agreement and eliminated any incentive for

Andrx to market a generic version of Cardizem CD (including its non-infringing reformulated product) during the term of the agreement. Had the respondents not abandoned the HMR/Andrx Stipulation and Agreement under pressure from the Commission, Andrx likely would not have marketed its reformulated version of generic Cardizem CD upon FDA approval in June 1999.

Interrogatory No. 4:

If your answer to Question No. 3 is "yes," when, do you contend, would Andrx have entered the market with the reformulated version of generic Cardizem CD? Please identify and describe the basis, if any, for this contention.

Subject to the general objections identified above, complaint counsel refers Hoechst to our response to Interrogatory No. 3.

Interrogatory No. 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 you answer is "yes," please identify and describe the basis, if any, for this contention.

Subject to the general objections identified above, complaint counsel responds as follows: Complaint counsel contends that, had Andrx began commercial marketing of its initial generic Cardizem CD formulation in or around July 1998, Faulding could have entered the market with its generic version of Cardizem CD as of May 3, 2000 upon settling its patent infringement litigation with Hoechst.

At the time that respondents negotiated and entered into the HMR/Andrx Stipulation and Agreement, Faulding, which had filed an ANDA seeking approval for a generic version of Cardizem CD in December 1996, represented a potential competitive threat to HMR's lucrative

Cardizem CD franchise. The HMR/Andrx Stipulation and Agreement had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition and consumers by preventing or discouraging the entry of generic versions of Cardizem CD (including Faulding's version) into the relevant market, decreasing the output of generic Cardizem CD products, raising or stabilizing the prices of Cardizem CD, and eliminating or reducing consumer choice. Under the HMR/Andrx Stipulation and Agreement, Andrx agreed not to market any generic version of Cardizem CD, regardless of whether the product infringed any of HMR's patents. In addition, Andrx agreed not to relinquish or otherwise compromise its right to 180 days of market exclusivity. By prohibiting Andrx from commencing the commercial sale of not only the product subject to the patent infringement suit, but also of any bioequivalent or generic version of Cardizem CD during the term of the agreement, the HMR/Andrx Stipulation and Agreement had the purpose, as well as the intended or likely effect, of deterring Andrx from developing and selling any non-infringing or potentially non-infringing version of its generic Cardizem CD product. Had the respondents not abandoned their agreement under pressure from the Commission, Andrx likely would not have marketed its generic Cardizem CD product until January 2000 at the earliest, when it was eligible (but not required) to exercise a license. Had respondents not abandoned the HMR/Andrx Stipulation and Agreement under pressure from the Commission, Faulding would not have been able to market its product until after Andrx's 180-day exclusivity period had expired in July 2000 at the earliest (six months after Faulding actually began commercial sales of its generic Cardizem CD product).

By prohibiting Andrx from withdrawing its pending ANDA or relinquishing or otherwise compromising any right accruing under its ANDA, including its right to 180 days of generic

market exclusivity, until entry of final judgment in the respondents' patent action, the HMR/Andrx Stipulation and Agreement had the purpose, as well as the intended or likely effect, of deterring Andrx from relinquishing its eligibility for a 180-day period of exclusivity under Hatch-Waxman Act. Had the respondents not abandoned their agreement under pressure from the Commission, Andrx likely would not have relinquished its 180-exclusivity right. Accordingly, Faulding would not have been able to market its product until after Andrx's 180-day exclusivity period had expired in July 2000 at the earliest (six months after Faulding actually began commercial sales of its generic Cardizem CD product).

Interrogatory No. 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.

Subject to the general objections identified above, complaint counsel refers Hoechst to our response to Interrogatory No. 5.

Interrogatory No. 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.

Subject to the general objections identified above, complaint counsel responds as follows: Complaint counsel does not contend that Biovail would have entered the market with a generic version of Cardizem CD prior to June 8, 1999. However, at the time that respondents negotiated and entered into the HMR/Andrx Stipulation and Agreement, Biovail, which had filed an ANDA

seeking approval for a generic version of Cardizem CD in April 1997, represented a significant potential competitive threat to Hoechst's Cardizem CD franchise. Hoechst did not file a patent infringement suit against Biovail relating to its generic Cardizem CD application. Biovail was expected to receive FDA approval to market its generic version of Cardizem CD as early as April 1998. *See, e.g.*, HMRI S18 000001-33.

The HMR/Andrx Stipulation and Agreement had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition and consumers by preventing or discouraging the entry of generic versions of Cardizem CD (including Biovail's version) into the relevant market, decreasing the output of generic Cardizem CD products, raising or stabilizing the prices of Cardizem CD, and eliminating or reducing consumer choice. Under the HMR/Andrx Stipulation and Agreement, Andrx agreed not to market any generic version of Cardizem CD, regardless of whether the product infringed any of Hoechst's patents. In addition, Andrx agreed not to relinquish or otherwise compromise its right to 180 days of market exclusivity. By prohibiting Andrx from commencing the commercial sale of not only the product subject to the patent infringement suit, but also of any bioequivalent or generic version of Cardizem CD during the term of the agreement, the HMR/Andrx Stipulation and Agreement had the purpose, as well as the intended or likely effect, of deterring Andrx from developing and selling any non-infringing or potentially non-infringing version of its generic Cardizem CD product. Had the respondents not abandoned their agreement under pressure from the Commission, Andrx likely would not have marketed its generic Cardizem CD product until January 2000 at the earliest, when it was eligible (but not required) to exercise a license. Had respondents not abandoned the HMR/Andrx Stipulation and Agreement under pressure from the

Commission, Biovail would not have been able to market its product until after Andrx's 180-day exclusivity period expired in July 2000 at the earliest (six months after Biovail actually began commercial sales of its Cardizem CD product).

By prohibiting Andrx from withdrawing its pending ANDA or relinquishing or otherwise compromising any right accruing under its ANDA, including its right to 180 days of generic market exclusivity, until entry of final judgment in the respondents' patent action, the HMR/Andrx Stipulation and Agreement had the purpose, as well as the intended or likely effect, of deterring Andrx from relinquishing its eligibility for a 180-day period of exclusivity under Hatch-Waxman Act. Had the respondents not abandoned their agreement under pressure from the Commission, Andrx likely would not have relinquished its 180-exclusivity right. Accordingly, Biovail would not have been able to market its product until after Andrx's 180-day exclusivity period expired in July 2000 at the earliest (six months after Biovail actually began commercial sales of its generic Cardizem CD product

Interrogatory No. 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.

Subject to the general objections identified above, complaint counsel refers Hoechst to our response to Interrogatory No. 7.

Interrogatory No. 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.

Subject to the general objections identified above, complaint counsel responds as follows: complaint counsel does not contend that, but for the HMR/Andrx Stipulation and Agreement, some manufacturer other than Andrx, Biovail or Faulding would have entered the market with an FDA-approved generic version of Cardizem CD prior to June 8, 1999.

Interrogatory No. 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.

Subject to the general objections identified above, complaint counsel refers Hoechst to our response to Interrogatory No. 9.

Interrogatory No. 11:

Is it Complaint Counsel's contention that HMR's '584 Patent is or was invalid? If you answer is "yes," please identify and describe the basis, if any, for this contention.

Subject to the general objections identified above, complaint counsel responds as follows: Andrx and Hoechst were engaged in a dispute in which the validity and enforceability of the '584 Patent was directly at issue. Andrx filed a Summary Judgment Motion on the Issue of Invalidity on February 14, 1997, in which it argued that the claim interpretation proposed by Hoechst placed claim 1 of the '584 patent within the dissolution ranges disclosed by the prior art, making claim 1 invalid. Andrx also filed a Motion for Summary Judgment and Sanctions for Fraud Upon the U.S. Patent Office on November 24, 1998 in which it argued that the patentee

misrepresented the scope of U.S. Patent No. 4,894,240 to the Patent Office. Andrx and Hoechst ultimately dismissed their patent litigation in the Southern District of Florida before the court had ruled on the merits of this dispute. Accordingly, neither the court in the Southern District of Florida nor any other court has found the '584 Patent to be not invalid.

Interrogatory No. 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 you answer is "yes," please identify and describe the basis, if any, for this contention.

Subject to the general objections identified above, complaint counsel responds as follows: Andrx and Hoechst were engaged in a dispute concerning whether Andrx's initial formulation of its generic Cardizem CD product (as amended in April 1996) infringed the '584 Patent. Andrx had received two legal opinions that stated in "clear terms that they do not believe the Andrx product infringes the HMR patent." Andrx 9683-84. Andrx consistently maintained – both in statements to the FDA and to the court in the patent infringement suit – that its initial formulation of generic Cardizem CD did not infringe any valid patent listed in the Orange Book claiming Cardizem CD. For example, Andrx's President and Chief Scientist stated in an affidavit that "[i]f the FDA approves Andrx's ANDA for its once-a-day formulation . . . [the product] that will be sold will not infringe the [HMR] Patent." *See* HMRI S7 001599-607; *see also* HMRI S7 003129-3133; Andrx 2199-2200; Andrx 2068-77. Andrx made these same representations – that its product did not infringe HMR's patents – to its Board of Directors and to one of its primary investors. It is more likely than not that the district court would have granted Andrx's Motion for Summary Judgment on the Issue of Non-infringement. Based on its apparent confidence in its

legal position in the Florida patent action, Andrx represented to the federal district court during that action that it intended to "manufacture and sell its once-a-day diltiazem composition as soon as it receives FDA approval." *See* HMRI S7 002984-003000, at 2993. Andrx and HMR ultimately dismissed their patent litigation before the Southern District of Florida court had ruled on the merits of this dispute. Accordingly, neither the court in the Southern District of Florida nor any other court has found that Andrx's initial formulation of generic Cardizem CD (as amended in April 1996) infringed any of Hoechst's patents, including the '584 patent.

Interrogatory No. 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.

In addition to the general objections identified above, complaint counsel objects to Interrogatory No. 13 to the extent it seeks a response to a hypothetical not related to the facts of this proceeding. Subject to these objections, complaint counsel responds as follows: at the time Andrx and Hoechst entered into the HMR/Andrx Stipulation and Agreement, they were potential competitors in the relevant market for once-a-day diltiazem products. First, Andrx already had developed, and received tentative FDA approval for, a generic version of Cardizem CD. In submitting its application to the FDA, Andrx had filed a Paragraph IV certification stating that its product did not infringe any valid patents listed in the Orange Book for Cardizem CD. Andrx consistently maintained – both in statements to the FDA and to the court in the patent infringement suit – that its initial formulation of generic Cardizem CD did not infringe any valid

patent listed in the Orange Book claiming Cardizem CD. For example, Andrx's President and Chief Scientist stated in an affidavit that "[i]f the FDA approves Andrx's ANDA for its once-a-day formulation . . . [the product] that will be sold will not infringe the [HMR] Patent." *See* HMRI S7 001599-607; see also HMRI S7 003129-3133; Andrx 2199-2200; Andrx 2068-77. During the patent infringement dispute, Andrx represented to the federal district court that it intended to "manufacture and sell its once-a-day diltiazem composition as soon as it receives FDA approval." See HMRI S7 002984-003000, at 2993.

Second, at the time Andrx and Hoechst entered into the HMR/Andrx Stipulation and Agreement, Andrx was positioned to develop within a reasonable period of time a reformulated version of generic Cardizem CD that also would not infringe any of Hoechst's patents. Indeed, Andrx's subsequent actions prove that Andrx was capable of developing such a non-infringing product. In September 1998, less than one year after entering into the HMR/Andrx Stipulation and Agreement, Andrx filed with the FDA a Prior Approval Supplement to its ANDA, which reflected a modified version of its generic Cardizem CD product. Hoechst agreed that Andrx's reformulated product did not infringe any patent listed in the Orange Book claiming Cardizem CD, including the '584 patent, and Andrx began commercial sales of the reformulated product in June 1999.

Third, at the time Andrx and Hoechst entered into the HMR/Andrx Stipulation and Agreement, Andrx was positioned to enter the market within a reasonable period of time by selling another company's non-infringing generic version of Cardizem CD.

Finally, in October 1997, just one month after entering into the HMR/Andrx Stipulation and Agreement, Andrx began competing against Hoechst in the relevant market with sales of

Diltia XT, a generic version of another once-a-day diltiazem product.

Interrogatory No. 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.

In addition to the general objections identified above, complaint counsel objects to Interrogatory No. 14 to the extent it seeks a response to a hypothetical not related to the facts of this proceeding. Subject to these objections, complaint counsel responds as follows: at the time Andrx and Hoechst entered into the HMR/Andrx Stipulation and Agreement, they were potential competitors in the relevant market for once-a-day diltiazem products. First, Andrx already had developed, and received tentative FDA approval for, a generic version of Cardizem CD. In submitting its application to the FDA, Andrx had filed a Paragraph IV certification stating that its product did not infringe any valid patents listed in the Orange Book for Cardizem CD. Andrx consistently maintained – both in statements to the FDA and to the court in the patent infringement suit – that its initial formulation of generic Cardizem CD did not infringe any valid patent listed in the Orange Book claiming Cardizem CD. For example, Andrx's President and Chief Scientist stated in an affidavit that "[i]f the FDA approves Andrx's ANDA for its once-a-day formulation . . . [the product] that will be sold will not infringe the [HMR] Patent." *See* HMRI S7 001599-607; see also HMRI S7 003129-3133; Andrx 2199-2200; Andrx 2068-77. During the patent infringement dispute, Andrx represented to the federal district court that it intended to "manufacture and sell its once-a-day diltiazem composition as soon as it receives FDA approval." See HMRI S7 002984-003000, at 2993.

Second, at the time Andrx and Hoechst entered into the HMR/Andrx Stipulation and Agreement, Andrx was positioned to develop within a reasonable period of time a reformulated version of generic Cardizem CD that would not infringe any of Hoechst's patents. Indeed, Andrx's subsequent actions prove that Andrx was capable of developing such a non-infringing product. In September 1998, less than one year after entering into the HMR/Andrx Stipulation and Agreement, Andrx filed with the FDA a Prior Approval Supplement to its ANDA, which reflected a modified version of its generic Cardizem CD product. Hoechst agreed that Andrx's reformulated product did not infringe any patent listed in the Orange Book claiming Cardizem CD, including the '584 patent, and Andrx began commercial sales of the reformulated product in June 1999.

Third, at the time Andrx and Hoechst entered into the HMR/Andrx Stipulation and Agreement, Andrx was positioned to enter the market within a reasonable period of time by selling another company's non-infringing generic version of Cardizem CD.

Finally, in October 1997, just one month after entering into the HMR/Andrx Stipulation and Agreement, Andrx began competing against Hoechst in the relevant market with sales of Diltia XT, a generic version of another once-a-day diltiazem product.

Interrogatory No. 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.

In addition to the general objections identified above, complaint counsel objects to Interrogatory No. 15 to the extent it seeks a response to a hypothetical not related to the facts of

this proceeding. Subject to these objections, complaint counsel responds as follows: the HMR/Andrx Stipulation and Agreement constitutes an "agreement not to compete" under the antitrust laws. It is a written agreement between competitors or potential competitors in which one party is paid by the other not to compete in the United States. Specifically, under the HMR/Andrx Stipulation and Agreement, Andrx agreed not to market the generic version of Cardizem CD that was subject of the patent infringement action; not to market any generic version of Cardizem CD, regardless of whether the product infringed any of Hoechst's patents; and not to relinquish or otherwise compromise its right to 180 days of market exclusivity. By prohibiting Andrx from commencing the commercial sale of not only the product subject to the patent infringement suit, but also of any bioequivalent or generic version of Cardizem CD during the term of the agreement, the HMR/Andrx Stipulation and Agreement had the purpose, as well as the intended or likely effect, of deterring Andrx from developing and selling any non-infringing or potentially non-infringing version of its generic Cardizem CD product. By prohibiting Andrx from withdrawing its pending ANDA or relinquishing or otherwise compromising any right accruing under its ANDA, including its right to 180 days of generic market exclusivity, until entry of final judgment in the respondents' patent action, the HMR/Andrx Stipulation and Agreement had the purpose, as well as the intended or likely effect, of deterring Andrx from relinquishing its eligibility for a 180-day period of exclusivity under Hatch-Waxman Act and thus keeping out other competitors.

Interrogatory No. 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.

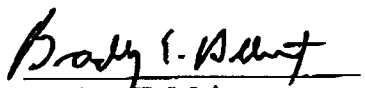
In addition to the general objections identified above, complaint counsel objects to Interrogatory No. 16 to the extent it seeks a response to a hypothetical not related to the facts of this proceeding. Subject to these objections, complaint counsel responds as follows: consumers are benefitted by the sale of goods in a competitive marketplace. The HMR/Andrx Stipulation and Agreement interfered with this competitive marketplace by restricting entry of those companies that could potentially compete with Hoechst's lucrative Cardizem CD product. Under the HMR/Andrx Stipulation and Agreement, Andrx agreed not to market the generic version of Cardizem CD that was subject of the patent infringement action. In addition, Andrx agreed not to market any generic version of Cardizem CD, regardless of whether the product infringed any of Hoechst's patents. Finally, Andrx agreed not to relinquish or otherwise compromise its right to 180 days of market exclusivity. By prohibiting Andrx from commencing the commercial sale of not only the product subject to the patent infringement suit, but also of any bioequivalent or generic version of Cardizem CD during the term of the agreement, the HMR/Andrx Stipulation and Agreement had the purpose, as well as the intended or likely effect, of deterring Andrx from developing and selling any non-infringing or potentially non-infringing version of its generic Cardizem CD product. By prohibiting Andrx from withdrawing its pending ANDA or relinquishing or otherwise compromising any right accruing under its ANDA, including its right to 180 days of generic market exclusivity, until entry of final judgment in the respondents' patent

action, the HMR/Andrx Stipulation and Agreement had the purpose, as well as the intended or likely effect, of deterring Andrx from relinquishing its eligibility for a 180-day period of exclusivity under Hatch-Waxman Act.

The fact that Hoechst had asserted that Andrx's product infringed a particular patent claiming Cardizem CD does not provide a legitimate justification for respondents' agreement not to compete; nor does it justify depriving consumers the benefits of a competitive marketplace. Andrx and Hoechst were engaged in a dispute concerning whether Andrx's generic version of Cardizem CD product infringed any valid patent listed in the Orange Book claiming Cardizem CD. Andrx had received two legal opinions that stated in "clear terms that they do not believe the Andrx product infringes the HMR patent." Andrx 9683-84. Andrx consistently maintained – both in statements to the FDA and to the court in the patent infringement suit – that its initial formulation of generic Cardizem CD (as amended in April 1996) did not infringe any valid patent listed in the Orange Book claiming Cardizem CD. For example, Andrx's President and Chief Scientist stated in an affidavit that "[i]f the FDA approves Andrx's ANDA for its once-a-day formulation . . . [the product] that will be sold will not infringe the [HMR] Patent." *See* HMRI S7 001599-607; *see also* HMRI S7 003129-3133; Andrx 2199-2200; Andrx 2068-77. Andrx made these same representations – that its product did not infringe Hoechst's patents -- to its Board of Directors and to one of its primary investors. It is more likely than not that the district court would have granted Andrx's Motion for Summary Judgment on the Issue of Non-infringement. Based on its apparent confidence in its legal position in the Florida patent action, Andrx represented to federal district court during that action that it intended to "manufacture and sell its once-a-day diltiazem composition as soon as it receives FDA approval." *See* HMRI S7

002984-003000, at 2993. Andrx and Hoechst ultimately dismissed their patent litigation before the Southern District of Florida court had ruled on the merits of this dispute. Accordingly, neither the court in the Southern District of Florida nor any other court has found that Andrx's initial formulation of generic Cardizem CD (as amended in April 1996) infringed any of Hoechst's patents, including the '584 patent. Until a court ruled either that Andrx's generic Cardizem CD product infringed one of Hoechst's patents, or that Hoechst had made a showing sufficient to obtain a preliminary injunction, Andrx had the legal right to market its generic version of Cardizem CD as soon as it received final FDA approval in July 1998.

Respectfully Submitted,



Markus H. Meier
Bradley S. Albert

Counsel Supporting the Complaint

Bureau of Competition
Federal Trade Commission
Washington, D.C. 20580

Dated: November 11, 2000

CERTIFICATE OF SERVICE

I, Bradley S. Albert, hereby certify that on November 11, 2000, I caused a copy of the Complaint Counsel's Supplemental Objections and Responses to Respondent Hoechst Marion Roussel, Inc.'s First Set of Interrogatories and Complaint Counsel's Supplemental Objections and Responses to Respondent Hoechst Marion Roussel, Inc.'s First Request for Admissions to be served upon the following persons via facsimile and/or first class mail.

Michael Koon, Esq.
Shook, Hardy & Bacon, L.L.P
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New York, NY 10111

Bradley S. Albert

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

DECLARATION OF PAUL S. SCHLEIFMAN IN SUPPORT OF HOECHST MARION ROUSSEL, INC.'S MOTION TO COMPEL DISCOVERY

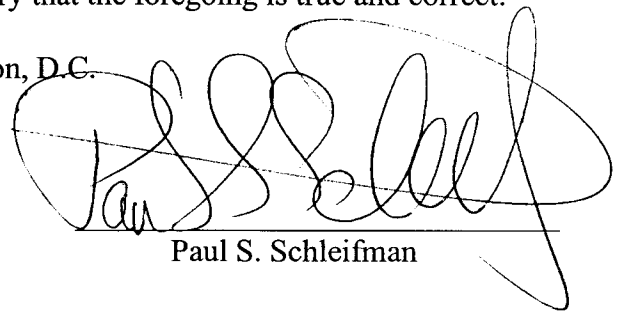
Paul S. Schleifman, pursuant to 28 U.S.C. § 1746, declares as follows:

1. I represent Aventis Pharmaceuticals, Inc., formerly known as Hoechst Marion Roussel, Inc. ("HMR") in these proceedings. I submit this declaration pursuant 16 C.F.R. § 3.22(f) in support of HMR's Motion to Compel Discovery.

2. On November 13, 2000, I conferred with Bradley Albert of the FTC, in a good faith effort to resolve by agreement the issues raised in the Motion to Compel. Unfortunately the parties were unable to reach agreement.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on November 13, 2000 in Washington, D.C.



Paul S. Schleifman

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

ORDER GRANTING HOECHST MARION ROUSSEL, INC.'S MOTION TO COMPEL RESPONSE TO INTERROGATORY NOS. 1, 11 AND 16

IT IS HEREBY ORDERED that Hoechst Marion Roussel, Inc.'s Motion to Compel Response to Interrogatory Nos. 1, 11 and 16 is hereby GRANTED.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Date: November __, 2000

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, Scott E. DuPree, hereby certify that on November 14, 2000, a copy of Hoechst Marion Roussel, Inc.'s Motion to Compel Response to Interrogatory Nos. 1, 11 and 16 and Memorandum in support thereof was served upon the following persons by hand delivery and/or Federal Express as follows:

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

Markus Meier
Federal Trade Commission
Room 3017
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Hon. D. Michael Chappell
Administrative Law Judge
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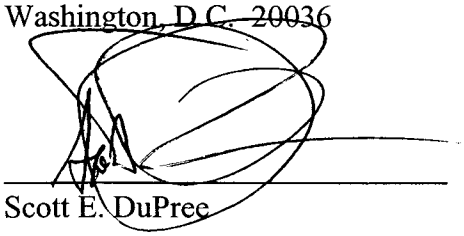

Scott E. DuPree