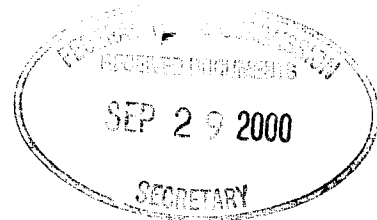


UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION



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
APPLICATION FOR *IN CAMERA* TREATMENT OF CERTAIN
CONFIDENTIAL DOCUMENTS**

Respondent Aventis Pharmaceuticals, Inc. ("Aventis"), formerly known as Hoechst Marion Roussel, Inc., hereby applies for *in camera* treatment of certain documents previously marked as "Confidential" or "Attorney Eyes Only" pursuant to Second Amended Protective Order Governing Discovery Material in this case. Stacy Ehrlich, counsel for Carderm Capital L.P., and Carolyn Dizon, counsel for Andrx Corporation, have consented to the application. A message was left for Bradley Albert, a Commission attorney serving as Complaint Counsel.

In support of this application, respondent respectfully refers the Court to the accompanying Memorandum and Declarations of Peter D. Bernstein, Esq. and Kay Noonan, Esq.

WHEREFORE, Respondent Aventis Pharmaceuticals, Inc. respectfully prays that this tribunal enter an Order granting *In Camera* treatment to the documents designated in the attached memorandum.

Dated: September 29, 2000

Respectfully Submitted,

A handwritten signature in black ink, appearing to read 'J.M. Spears', written over a horizontal line.

James M. Spears

Paul S. Schleifman

D. Edward Wilson, Jr.

Peter D. Bernstein

SHOOK HARDY & BACON, LLP

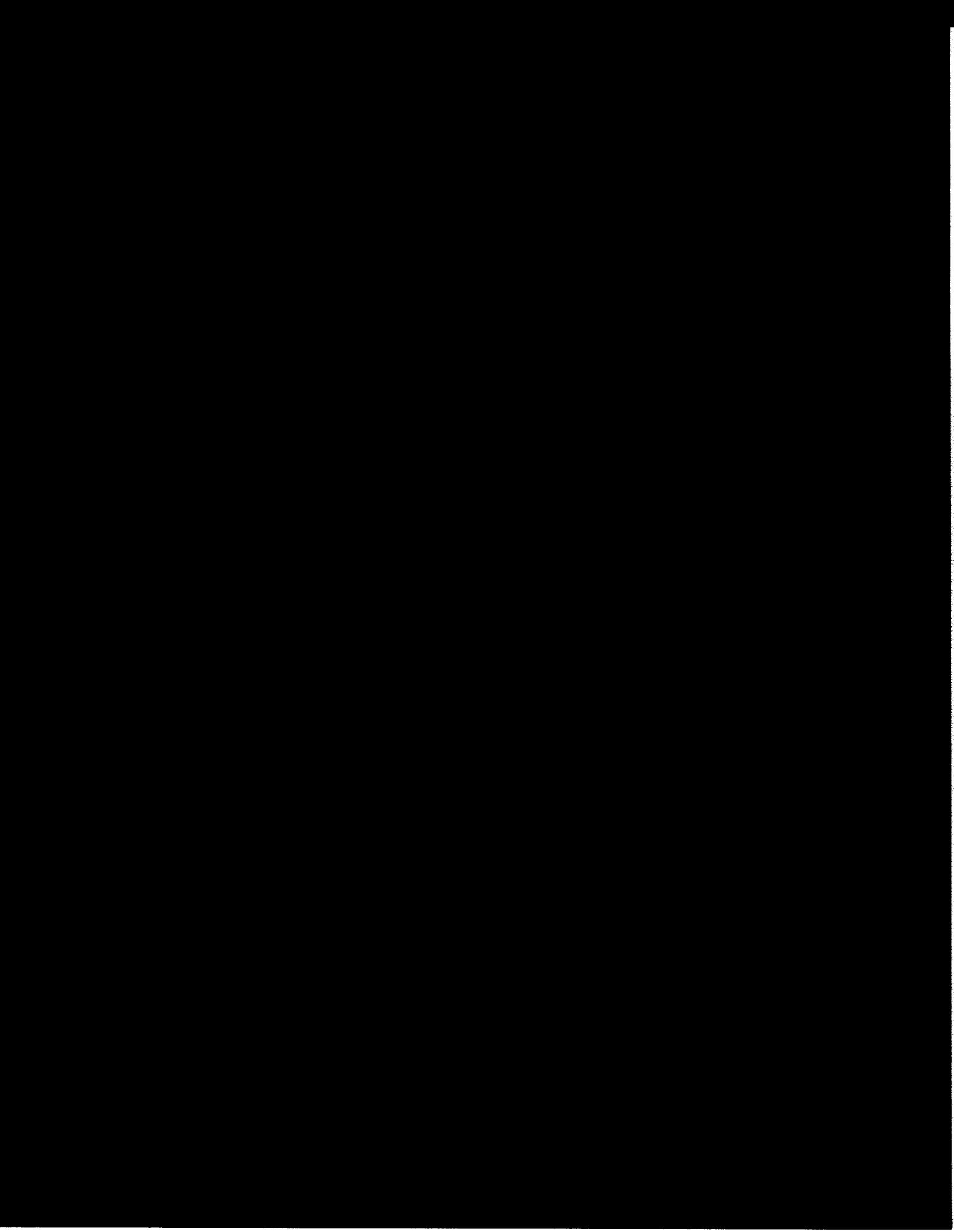
600 Fourteenth Street, N.W., Suite 800

Washington, D.C. 20005-2004

(202) 783-8400

Attorneys for Respondent

Aventis Pharmaceuticals, Inc.



**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

In the Matter of

HOECHST MARION ROUSSEL, INC.,
a corporation,

CARDERM CAPITAL L.P.,
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Docket No. 9293

**RESPONDENT AVENTIS PHARMACEUTICALS, INC.'S
MEMORANDUM IN SUPPORT OF APPLICATION FOR
IN CAMERA TREATMENT OF CERTAIN CONFIDENTIAL DOCUMENTS**

Pursuant to Rule 3.45 of the Federal Trade Commission's ("FTC") Rules of Practice, Respondent Aventis Pharmaceuticals Inc. ("Aventis") submits this Memorandum in Support of Application for *In Camera* Treatment of Certain Confidential Documents.

I. INTRODUCTION

On September 8, 2000, Complaint Counsel advised Aventis that it intended to include 386 documents (containing approximately 5000 pages) which Aventis designated "Confidential" pursuant to the Second Amended Protective Order Governing Discovery Materials "in a pleading, motion, exhibit, or other paper to be filed in this proceeding."¹ Aventis

-
1. See Complaint Counsel's List of Documents attached to the Declaration of Peter D. Bernstein in Support of Application for *In Camera* Treatment of Materials Marked Confidential Pursuant to Protective Order (the "Bernstein Declaration") as Exhibit A. Complaint Counsel's List of Documents also included a category of "Other" documents. This category includes deposition (continued...)

reviewed all 386 documents and believes that all or portions of approximately 215 documents meet the requirements for *in camera* treatment.² Accordingly, pursuant to the September 19, 2000 Order on Applications for *In Camera* Treatment and Modifying the Scheduling Order, the Protective Order³ and the FTC Rules of Practice,⁴ Aventis makes this application for *in camera* treatment of certain of the documents identified by Complaint Counsel.

II. LEGAL STANDARD GOVERNING *IN CAMERA* TREATMENT

The FTC's Rules of Practice provide for *in camera* treatment of confidential documents when "public disclosure will likely result in a clearly defined, serious injury to the . . . corporation requesting their *in camera* treatment."⁵ Proof of "serious injury" requires that "the information in question is secret and material to the applicant's business."⁶ In considering whether documents are entitled to *in camera* treatment, the Commission has identified the following factors:

(1) the extent to which the information is known outside of [the applicant's] business;

-
1. (...continued)
transcripts from various investigations and litigation, privilege logs and electronic data, all of which contain confidential information. In response to a September 26, 2000 letter to the Court, we were informed by Victoria Arthaud on September 27, 2000 that these "Other" materials need not be addressed in this application. Accordingly, any *in camera* application for these materials will be made when and if Complaint Counsel indicates its intention to utilize these materials or portions thereof.
 2. The remaining documents consist of either confidential documents which do not meet this Tribunal's stringent requirements for *in camera* treatment or documents which contain Andrx's confidential information. Aventis' position on Andrx' confidential information is set forth in Section III.E., *infra*. Aventis has requested *in camera* treatment for only those portions of documents meeting the requirements.
 3. Protective Order, ¶13.
 4. 16 C.F.R. § 3.45(b) (providing for *in camera* treatment of confidential documents).
 5. 16 C.F.R. § 3.45(b).
 6. *Bristol-Myers Co.*, 90 F.T.C. 455, 1977 FTC LEXIS 25 at 4 (1977); *General Foods Corp.*, 95 F.T.C. 352, 255 (1980).

- (2) the extent to which it is known by employees and others involved in [the applicant's] business;
- (3) the extent of measures taken by [the applicant] to guard the secrecy of the information;
- (4) the value of the information to [the applicant and its competitors];
- (5) the amount of effort or money expended by [the applicant] in developing the information;
- (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.⁷

Finally, Aventis respectfully requests that should the harmful nature of the release not be clear from the existing record, that the Court err on the side of designating the requested materials as *in camera*, with the understanding that this designation will be subject to further review as the case progresses. As the Commission stated in *Bristol-Myers*,

[I]t may be reasonable in some cases, as Commission Rule 3.45(a) allows, for the law judge to grant *in camera* treatment for information at the time it is offered into evidence subject to a later determination by the law judge or the Commission that the public disclosure is required in the interests of facilitating public understanding of their subsequent decisions.

Bristol-Myers Co., 90 F.T.C. 455, 1977 FTC LEXIS 25 at 6 (1977).

7. *Bristol-Myers Co.*, 90 F.T.C. 455, 1977 FTC LEXIS 25 at 5.

III. CONFIDENTIAL DOCUMENTS FOR WHICH *IN CAMERA* TREATMENT IS SOUGHT

Due to the large number of documents identified by Complaint Counsel, for ease of review, Aventis has categorized the confidential documents into several groupings: Business Plans and Forecasts; Marketing, Sales and Contracting Documents; Corporate Minutes; Probuco Documents; Andrx Patent Litigation Documents; and Miscellaneous Documents. To further aid the Court, Aventis has identified each document for which *in camera* protection is sought in indexes and provided copies of the indexes and each document in binders corresponding to each category.⁸

Aventis respectfully advises the Court that in determining which documents should be afforded *in camera* treatment, Aventis has only designated those documents containing information the release of which would be harmful on a prospective as opposed to a retrospective basis. Aventis was also mindful not to request *in camera* treatment for dated materials the release of which would not cause serious injury. Moreover, all documents for which *in camera* treatment has been requested have continuously been treated as confidential by Aventis and have only been produced under protective orders in other related litigations marked “Confidential” or “Attorney Eyes Only.”⁹

8. In light of the highly confidential nature of these documents, the binders will be provided directly to chambers. Copies of the indexes are attached to the Bernstein Declaration as exhibit C.

9. See Bernstein Declaration, ¶ 5.

A. Business Plans and Forecasts

Complaint Counsel has identified a number of Aventis' business plans and forecasts that contain information on Cardizem® CD, which is an active, existing product line.¹⁰ While some of these plans are not for the current year, they contain strategic forecasting determinations made based upon internal analysis of market conditions. Included in the documents identified by Complaint Counsel are the internal business plans, quarterly forecasts, generic entry analyses, risk analyses, 5-Year forecasts, product lifecycle strategies, and strategic planning documents (collectively "Plans").

The Plans contain information on cost of sales, cost of goods, third party royalties, operating expenses, inter-company margins, cash discounts, revenues and rebates. While minor aspects of this information may later be used and aggregated to develop public financial statements, the Plans contain a plethora of information not publicly available.¹¹ Certain of the forecasting documents reflect proprietary modeling used to determine generic introduction and erosions scenarios.¹² Also contained in this category are studies conducted by outside vendors at significant cost to Aventis.¹³ In addition, some of the Plans contain information for products other than Cardizem® CD and others contain information for new products that are still in the

10. See Noonan Declaration, ¶ 3.

11. Should Complaint Counsel wish to identify particular aspects of the Plans for use, Aventis remains willing to work with them to provide information that may be made available to the public. Absent such an identification, Aventis is forced to request *in camera* treatment for these Plans and the information contained in them in their totality.

12. DUNC000222-223; DUNC000242-43; HMRI-000717-2; HMRI Spec 20 Stratemeier 000181-190.

13. See e.g., HMRI-006510-617; HMRI-007512-26; HMRI S18 000001-38.

FDA approval process.¹⁴ These documents reflect the thought processes and business judgement of Aventis employees. Granting competitors access to such confidential material would cause serious injury to Aventis.

Certain of the Plans also contain Aventis' internal analysis whether it should enter the hypertension market with a proprietary generic product.¹⁵ These documents include correspondence and a draft of an agreement reflecting discussions to sell a generic version of Cardizem® CD. This information is highly confidential, has been maintained as highly confidential, and since there remains the possibility that Aventis may enter into such an agreement, the release of this information would cause Aventis serious injury. Finally, certain of the Plans contain sales forecasts for a 360 mg formulation of Cardizem® CD which was recently launched by Aventis.¹⁶ The information in these Plans are clearly prospective and cover a product that was just introduced.

None of the Plans are widely circulated within the company and none have been shared with outside analysts or competitors. The Plans remain particularly sensitive given the current competition within the hypertension market. The effect of public disclosure could upset the competitive balance in the market and cause Aventis financial harm.

14. See e.g., BRAH00003-12; BRAH000021-46; HMRI S25 002162-74.

15. HMRI-001461-69; HMR001470-72; HMRI-001480-92; HMRI-001523-56; HMRI-007681; HMRI-007718-57; HMRI-007759-61; HMRI-007971; HMRI-008016-17; HMRI-013834-37; HMRI-00013849-51; HMRI-013852-54; HMRI-013855-56; HMRI-013863-64; HMRI-013865-67. It should be noted that some of these materials also contain information about products unrelated to Cardizem® CD.

16. HMRI-008369-74.

B. Marketing, Sales and Contracting Documents

Complaint Counsel has identified a number of documents that fall under the rubric of marketing and sales documents and contracting. This category includes strategy documents that concern competitive market positioning.¹⁷ While certain of these documents are more than three years old, the disclosure of these materials would place Aventis in a competitive disadvantage. These materials discuss product positioning against several of the key competitors on a prospective basis. This material should not be considered “stale” as there continues to be significant switching among hypertension products. Disclosure of these documents would provide clear signals to the competitors in the hypertension market, while seriously injury Aventis in terms of sales at the expense of these competitors. There are also materials within this category that contain information relating to products other than Cardizem® CD.¹⁸

A number of the documents in this category are reports conducted by outside vendors with internal company support. The reports include product positioning studies,¹⁹ a generic substitution study,²⁰ and a study of the hypertension market.²¹ These reports reflect efforts by outside consultants with internal Aventis support and are accomplished at significant time and expense.

The results of this research are relevant to marketing today and in the future, as Cardizem® CD remains a very active competitor in the hypertension marketplace. Competitors

17. See e.g., HMRI S19 011259-80; HMRI S19 0011281-90; HMRI S19 0011291-303.

18. See e.g., HMRI Spec 7 Doug Randall 000674-721; HMRI Spec 7 John Kelley 000895-933.

19. HMRI-006214-21; HMRI S19 005063-206.

20. HMRI-026859-904.

21. HMRI S19 003084-142.

would clearly find this information useful. These documents have not been shared outside of the company, were conducted at considerable time and expense, and would be difficult, if not impossible, for a competitor to duplicate. Release of this information would result in serious injury in terms of lost sales and would tempter future decisions in conducting such competitive studies all to the detriment of Aventis.

Complaint Counsel has also identified contracts Aventis has recently entered into with a number of third-party payors.²² The contracts contain highly sensitive information including rebate provisions that are only known by Aventis and its contract partners. Indeed, the third-party payors and other pharmaceutical companies who have contracted with Aventis generally consider the provisions in these contracts to be among the most competitively sensitive information in their possession.²³

Lastly, Complaint Counsel advises that it may include the Aventis 1999 Contract Training Manual in public filings.²⁴ This document reflects the company's current strategies for communicating with managed care providers and contains competitively sensitive information regarding products other than Cardizem® CD. Accordingly, disclosure of this document would negatively impact Aventis' ability to negotiate with third-party payors on a level playing field.

C. Corporate Minutes

Complaint Counsel also proposes to include minutes of internal company management meetings in its filings. These minutes reflect the internal discussions of the

22. See HMRI-029735-39; HMRI-029793-95; HMRI-029830-41; HMRI-029934-37; HMRI-029942-52; HMRI-030094-119; HMRI-030178-87; HMRI-030245; HMRI-030355-61; HMRI-030362-68; HMRI-030550-58.

23. See Bernstein Declaration, ¶ 6.

24. HMRI-026096-419.

management of the company and are generally the most tightly held and controlled documents within Aventis.²⁵

In addition, several sets of the minutes identified by Complaint Counsel contain information regarding products other than Cardizem® CD, including several products under development.²⁶ This information would enable competitors to anticipate sales promotions, strategies and product launches, causing serious injury to Aventis. Providing public access to such secretive internal thinking would chill the necessary and proper exercise of managerial governance and discretion.

D. Probucol Documents

Aventis recently provided access to its New Drug Application for Probucol to an unrelated third party pursuant to a written agreement.²⁷ That company is currently conducting the development work necessary to obtain approval for the marketing of this product.²⁸

Complaint Counsel has identified over 70 documents related to the development of an alternative indication for Probucol.

The documents contained in this category include Aventis' internal assessment regarding the development of Probucol;²⁹ detailed financial valuation forecasts;³⁰ confidential

25. See Noonan Declaration, ¶ 4.

26. HMRI-013834-37; HMRI-013849-51; HMRI-013852-54; HMRI-013855-56.

27. See Complaint, ¶ 21.

28. A number of the documents identified by Complaint Counsel originated with the unrelated third-party company. Complaint Counsel has mistakenly failed to list these documents as originating with that third-party. In order to protect this third party from the improper disclosure of its confidential information, Aventis applies for *in camera* of those materials at this time.

29. HMRI-008406-09.

30. HMRI-013214-33.

communications;³¹ minutes of meetings;³² a draft clinical study protocol;³³ and draft agreements.³⁴ As such, the documents contain the terms of the agreements between the parties, discussions of FDA feedback, and Aventis' internal process regarding product development and other details specifically related to this ongoing development project. As Probucol is still an ongoing project and the NDA continues to hold considerable financial value to Aventis, any public disclosure of these documents would cause serious harm to Aventis.

E. Andrx Patent Litigation

Complaint Counsel has identified a number of documents which Aventis produced from the patent infringement litigation filed by HMR against Andrx in the U.S. District Court for the Southern District of Florida.³⁵ A majority of these documents contain information that was provided by Andrx under the Protective Order entered by the Court in that action,³⁶ including some HMR documents that reference or specifically contain Andrx's confidential information.³⁷ Inasmuch as these documents contain Andrx' confidential information, Aventis has provided a copy of these materials to Andrx and Andrx has indicated that it will be filing an application with the Court for *in camera* protection of these materials.

31. HMRI-012477-83.

32. HMRI-008602-04.

33. HMRI-008641-80.

34. HMRI-009710-38.

35. *Hoechst Marion Roussel, Inc. et al. v. Andrx Corporation*, 96-CV-06121 (S.D. Fla.).

36. *See e.g.*, HMRI S5 000063-97 (containing Andrx's Hatch-Waxman patent certifications that are clearly marked on their face as confidential).

37. *See e.g.*, HMRI-000134-138.

There is, however, one document in this category for which Aventis makes an affirmative request for *in camera* treatment. The HMRI/Andrx Stipulation and Agreement³⁸ contains very specific licensing and royalty provisions, the release of which would cause serious harm to Aventis in negotiations with other pharmaceutical manufacturers. In order to address these concerns, Aventis has provided a redacted version of this document in the MDL action. Aventis proposes the use of the redacted version of the Stipulation and Agreement in this action for all public filings, with the unredacted portions receiving *in camera* treatment.³⁹

F. Miscellaneous Documents

The following documents listed by Complaint Counsel do not fit neatly into any one category and are addressed below.

1. Complaint Counsel advised that it may use in its public filings a current license agreement and research and development agreement Aventis entered with an unrelated third-party concerning development of diltiazem products and other sustained release technology.⁴⁰ These documents are particularly sensitive given that they reflect current licensing strategies and research and developments efforts related to a broader range of products than Cardizem® CD. Release of these documents would harm Aventis in future negotiations with third-parties regarding research and development.

38. HMRI S8 000012-23. A portion of the HMRI Stipulation and Agreement containing certain licensing information for which *in camera* treatment has been requested is also contained at HMRI-020029.

39. A copy of the redacted Stipulation and Agreement is attached to the Bernstein Declaration as Exhibit B.

40. HMRI-013865-67; HMRI-013865-67.

2. HMRI S12 001542-55 is a patent certification was provided to Aventis by Faulding under the Hatch-Waxman Act. Inasmuch as this document contains Faulding's confidential information, it would be up to Faulding, as a third-party, to apply for *in camera* protection for this document.

3. Complaint Counsel has indicated it intends to use a copy of a settlement agreement and correspondence related thereto in an unrelated patent infringement action.⁴¹ This patent infringement action involved a product other than Cardizem® CD. As this document contains third-party information and involves products other than Cardizem® CD, the release of this information could cause injury to Aventis.

4. HMRI Spec 20 Stratemeier 000283-291 is a privileged document that was inadvertently produced in a prior Commission investigation.⁴² The return of this document has been requested on numerous occasions. The document is clearly marked as privileged on its face. Complaint Counsel has recently moved for an Order declaring that Aventis waived the privileges attached to this document. Aventis will respond to the motion and vigorously assert all privileges that attach to this document.

Complaint Counsel has also identified correspondence with Commission staff regarding this document.⁴³ The listing of these letters is solely related to Complaint Counsel's attempts to wrongfully retain and utilize this document in this proceeding. Aventis again asserts that this document inadvertently produced, privileged document must be immediately returned.

41. HMRI S15 000003-10; HMRI S15 000059-62.

42. Given the disputed nature of this document, a copy has not been included.

43. FTC0004861-62, FTC0004863-65, FTC0004884-86, FTC0004896-97.

5. Complaint Counsel has identified selected correspondence with commission staff in the underlying investigation, including a white paper submitted to clarify the legal and factual issues surrounding this case and Aventis' response to a Civil Investigative Demand.⁴⁴

Confidential treatment was requested for these documents under Sections 6(f), 21(b) and 21(f) of the FTC Act, 15 U.S.C. §§ 46(f), 57b-2(b)&(f); Rule 4.10 of the Commission's Rules of Practice, 16 C.F.R. § 4.10; and any other applicable statutes or regulations.

The materials contained in these documents reflects the company's positions in negotiations before the Commission. The release of which could cause serious harm to Aventis in dealings with competitors. In addition, the Civil Investigative Demand response contains proprietary pricing and cost information that is unavailable to competitors. Release of this information would cause serious concern regarding the ability of companies such as Aventis to protect the release of confidential information provided to the Commission.

6. Complaint Counsel has listed a Long-Term Incentive Plan Overview was prepared and distributed only to relevant HMR personnel. The document contains proprietary human resource materials that, in the hands of a competitor, could be used to lure away staff. These are not the types of documents shared with competitors.

7. Finally, Complaint Counsel indicated that it may use "Hoechst Marion Roussel: The Pharmaceutical Company of Hoechst," a presentation dated January 15, 1999 that is clearly marked as a document produced in a recent merger investigation under the Hart-Scott-Rodino

44. FTC0001852-54, FTC0001861-68, FTC0002023-60 (Civil Investigative Demand Response).

Act.⁴⁵ This presentation contains internal company information, such as financial and structural information that is not available on a public basis.

IV. EXPIRATION DATE

Due to the peculiar regulatory and intellectual property aspects of the pharmaceutical industry, Aventis believes that the documents for which it seeks *in camera* treatment will retain their sensitive nature for some time. The majority of the products in the hypertension market with which Cardizem® CD competes retain patent exclusivity for the next 10 years, for example Procardia XL is protected until 2010 and Tiazac is protected until 2013.⁴⁶ Thus, unless otherwise specified, Aventis requests that the Court permit *in camera* treatment of certain of the identified documents until August 8, 2012, the date on which the last patent for Cardizem® CD expires.⁴⁷

45. The face of the item identifies it as a 4(c) document. This refers to item 4(c) on the Hart-Scott-Rodino (“HSR”) form. Materials submitted in a merger investigation are among the most closely held by the Commission’s own rules.

46. See Bernstein Declaration, ¶ 3.

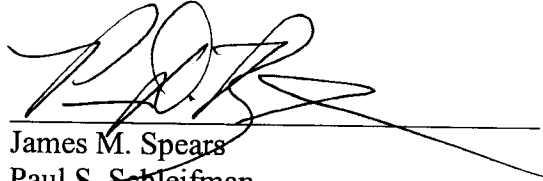
47. See *Id.*

V. CONCLUSION

For the above reasons, Aventis respectfully requests that this tribunal issue an *in camera* order for the documents listed in the indexes and binders produced to the Court.

Dated: September 29, 2000

Respectfully Submitted,



James M. Spears

Paul S. Schleifman

D. Edward Wilson, Jr.

Peter D. Bernstein

SHOOK HARDY & BACON, LLP

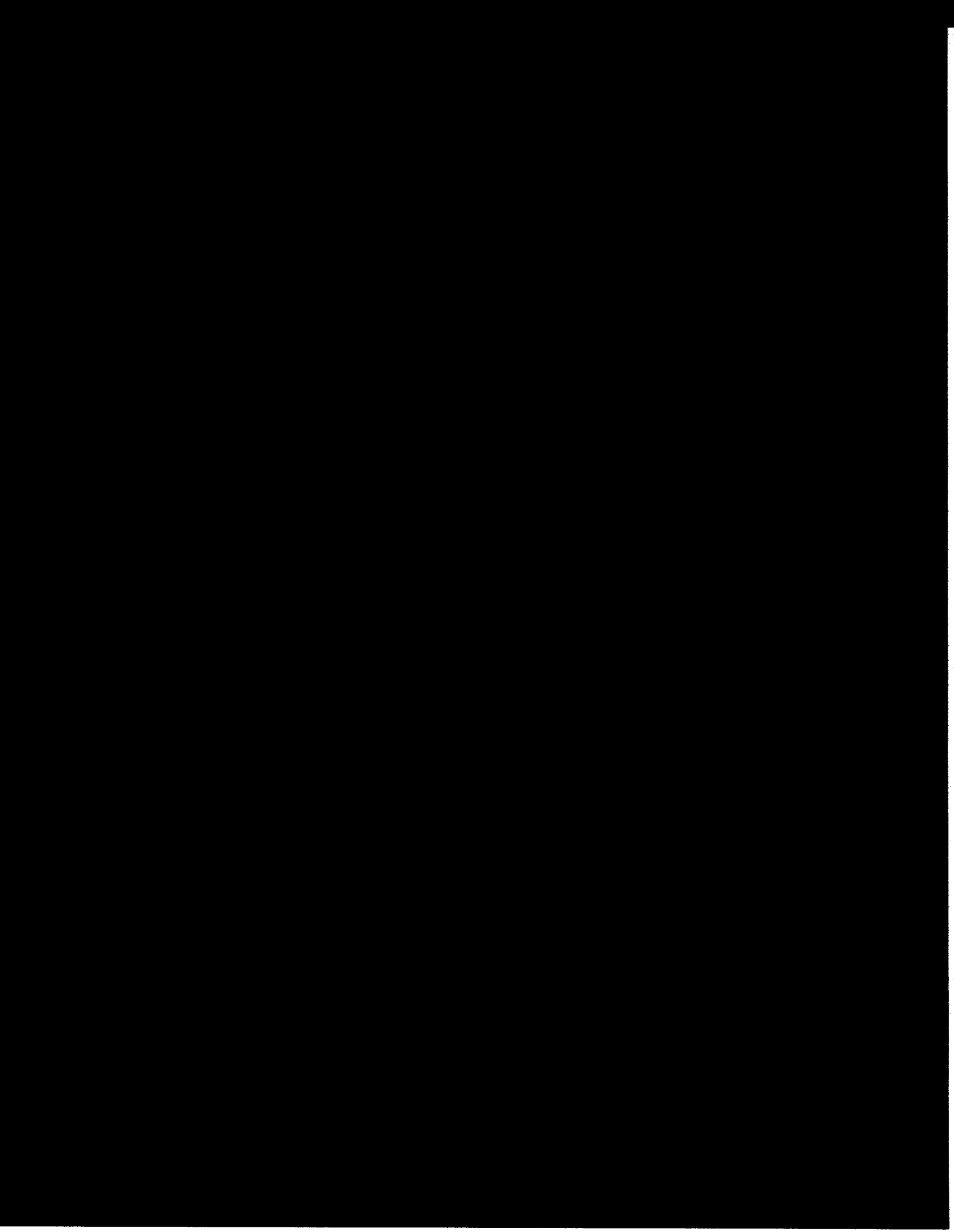
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Attorneys for Respondent

Aventis Pharmaceuticals, Inc.



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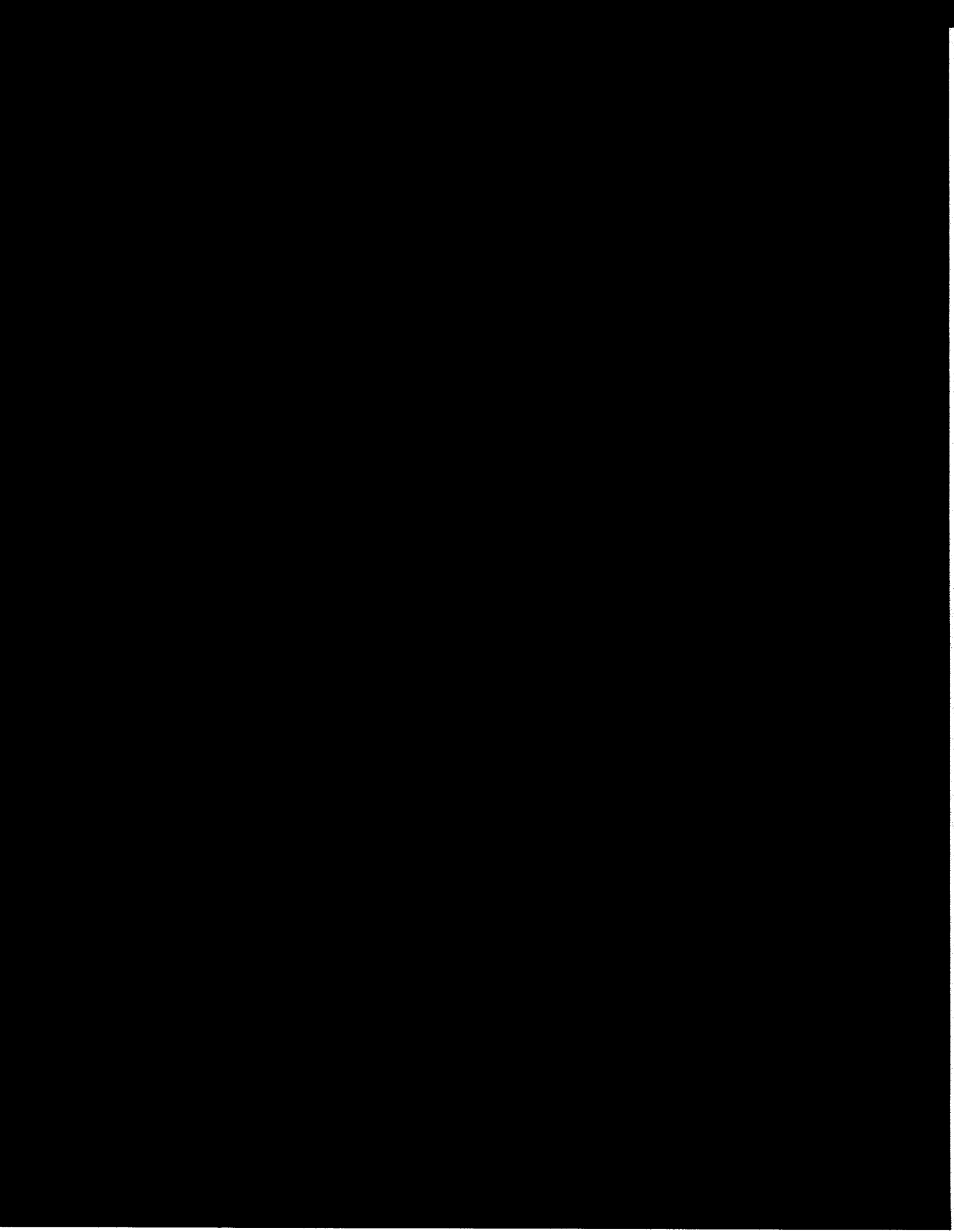
**ORDER GRANTING RESPONDENT AVENTIS PHARMACEUTICALS,
INC.'S APPLICATION FOR *IN CAMERA* TREATMENT OF CERTAIN
CONFIDENTIAL DOCUMENTS**

On September 29, 2000, Respondent Aventis Pharmaceuticals, Inc. filed an application for *in camera* treatment of certain confidential documents. Respondent's motion is GRANTED.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Date: October __, 2000



**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

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Docket No. 9293

**DECLARATION OF PETER D. BERNSTEIN IN SUPPORT
OF RESPONDENT AVENTIS PHARMACEUTICALS, INC.'S
APPLICATION FOR *IN CAMERA* TREATMENT OF
CERTAIN CONFIDENTIAL DOCUMENTS**

I, Peter D. Bernstein, pursuant to 28 U.S.C. § 1746, declare as follows,:

1. I am associated with the firm of Shook Hardy & Bacon LLP, counsel for respondent Aventis Pharmaceuticals, Inc. ("Aventis").
2. Stacy Ehrlich, counsel for Carderm Capital L.P., and Carolyn Dizon, counsel for Andrx Corporation, have consented to the application. A message was left for Bradley Albert, a Commission attorney serving as Complaint Counsel.
3. According to the U.S. Food and Drug Administration Center for Drug Evaluation and Research Approved Drug Products with Therapeutic Equivalence Evaluations, Patent and Exclusivity Information Addendum B (commonly known as the "Orange Book")(June 8, 2000) <<http://www.fda.gov/cder/orange/adp.htm>>, the last patent for Cardizem® CD expires on August 8, 2012, the last patent for Procardia XL expires on November 23, 2010, and the last patent for Tiazac expires on June 25, 2013.
4. The documents for which *in camera* treatment is requested have been reviewed with Aventis corporate counsel. See Declaration of Kay Noonan in Support of Application for *In Camera* Treatment of Materials Marked Confidential Pursuant to Protective Order.

5. As the Court knows, there are numerous private actions around the country that are factually related. A large number of these documents have been produced under the protective orders governing discovery in two of those actions, *Biovail Corporation v. Hoechst AG, et al.*, Civil Action No. 98-1434(D.N.J.) and *In Re Cardizem CD Antitrust Litigation*, MDL Docket No. 1278 (E.D. Mich.). All of documents produced in these litigations that are identified by this application for *in camera* treatment have been produced either as “Confidential” or “Attorney Eyes Only” in the other litigations.

6. During the discovery process in this proceeding many pharmaceuticals companies and third-party payors objected to the production of this information. They were concerned that such information would cause them serious harm if individuals from the respondent companies were to have access. This ultimately led to the “attorney eyes only” modification to the protective order.

7. Annexed hereto as Exhibit A is a copy of Complaint Counsel’s List of Documents, dated September 8, 2000.

8. Annexed hereto as Exhibit B is a copy of the HMRI/Andrx Stipulation and Agreement as redacted in *In Re Cardizem CD Antitrust Litigation*, MDL Docket No. 1278 (E.D. Mich.).


9. Annexed hereto as Exhibit C is a copy of the indexes of the documents for which *in camera* treatment has been requested.

10. Binders labeled Business Plans and Forecasts; Marketing, Sales and Contracting Documents; Corporate Minutes; Probucol Documents; Andrx Patent Litigation Documents; and Miscellaneous Documents have been provided directly to chambers. These binders contain indexes and the documents for which *in camera* treatment is sought.

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

Executed in Washington, D.C., on September 29, 2000

Respectfully Submitted,



Peter D. Bernstein

EXHIBIT A

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

In the Matter of

HOECHST MARION ROUSSEL, INC.,
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Docket No. 9293

COMPLAINT COUNSEL'S LIST OF DOCUMENTS

Pursuant to the Court's scheduling order, complaint counsel hereby identifies those documents or other materials that have been designated as confidential that we reasonably expect to include in a pleading, motion, exhibit, or other paper to be filed in this proceeding. Since discovery is ongoing and we expect to receive additional documents from respondents as well as third parties, we reserve the right to supplement this list as circumstances may warrant. We also reserve the right to use in a future submission or as an exhibit any document, information, or materials identified by respondents on their lists. Finally, we reserve the right not to include any document, information, or materials identified on the attached lists in a future submission or as an exhibit.

Subject to these reservations of rights, our list of documents is as follows:

Andrx

000001-24	000663	01678-79
000003-21	000664-668	01680-84
000020-22	000699-701	001684-1705
000023-26	000700-703	01685
000025-80	000702	01686
000027-64	000703-04	01689-90
000069-70	000704-05	01694
000074-120	000705-710	01695-98
000125-77	000706-08	01699-1709
000180-291	000883-889	01710-42
000218-219	000905-06	001726-46
000221-224	000907-17	01848-50
000225-273	000921-982	01851-53
000345-387	000986-87	2004-17
000395-402	000992-993	2018-41
000440-443	01231-67	2052-67
000444	01385-95	002370-75
000445	01396-97	002377-79
000446	01398-409	002533-36
000469-472	01410-21	002687-2810
000473	01422-35	003092-122
000504-05	01437-49	003361
000506-09	01450-62	003805-37
000562-563	01463-75	003871
000564-566	01476-86	004019-20
000588-610	01487-98	004291-300
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1. FTC0002102-69 (Andrx CID response)
2. FTC0002234-36 (2/11/00 letter from C. Underwood to B. Albert)
3. FTC0002266-70 (6/21/00 letter from L. Solomon to J. Bulow)
4. FTC0002323-30 (2/28/00 letter from L. Solomon to J. Bulow)

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1. Warburg Dillon Read "Specialty Pharmaceuticals Industry" report, 11/10/98
2. 8/10/97 Fax from J. Spears to L. Solomon, "Discussion Draft"

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BRAH000003-12	HMRI 000140-41	HMRI-008406-09
BRAH000021-46	HMRI 000142	HMRI-008410-14
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HMRI Spec 20 Stratemeier

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1. FTC0001852-54 (5/10/99 letter from J. Spears to B. Albert)
2. FTC0001861-68 (7/12/99 letter from J. Spears to B. Albert)
3. FTC0002023-60 (HMRI CID response and accompanying letter)
4. FTC0004861-62 (12/16/97 letter from J. Eiszner to D. Inglefield)
5. FTC0004863-65 (12/19/97 letter from J. Eiszner to D. Inglefield)
6. FTC0004884-86 (3/16/98 letter from D. Inglefield to J. Eiszner)
7. FTC0004896-97 (2/10/98 letter from J. Eiszner to D. Inglefield)

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1. "Settlement Discussion Agreement" in Hoechst Marion Roussel, Inc. v. Andrx Pharmaceuticals, Inc., Civil Action 96-06121-CV-Roettger
2. 6/8/99 letter from L. Solomon to J. Spears
3. Hoechst organizational charts, all of which are dated in 1997
4. "Long-Term Incentive Plan Overview" for Hoechst Marion Roussel, Inc.
5. "Hoechst Marion Roussel: The Pharmaceutical Company of Hoechst" presentation, 1/15/99

Carderm

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0000065-77
0000124-33
0000218-31

0000279-81
0000298-99
0000300-04
0000308-16

0000317-22
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0000732-64

Third Parties

Amerinet

Amerinet 00492-503
 Amerinet 00593-649
 Amerinet 00895-908
 Amerinet 01072-75

Astra

AP 000158-323
 AP 000326-421
 AP 000648-726
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Bayer

BAYER 00019-49
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 BVSupp 0052-61
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*(Memo from M. Levy to
 K. Cancellera re: CID;
 12/14/98)*
 FTC0002957-58
*(Letter and attachment
 from D. Beddow to D.
 Pender; 1/18/00)*
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 KH001410-12
*(Ex. 66 to K.
 Cancellera's deposition;
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Blue Cross/Blue Shield

1000293-301
1000302-305
1000306-39

Caremark

0040-43
0044-57
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Elan

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Faulding

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F 1408628-59
F 1410534-48
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(Faulding's CID
response)

Forest

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Foundation Health System

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Merck

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DIL 0278-80
FTC0002170-74
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FOIA Confidential 0704-18
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Novartis

NOV000115-21
NOV000144-83

PCS

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PCS-00028-35
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PCS-00044-57
PCS-00070-74
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PCS-00225-32
PCS-00249-52
PCS-00291-93

Pfizer

000359-362
000363-70
000371-77
000385-443
000444-476
000509-615
000616-83
000684-809
000810-56
001034-61
001062-86
001087-105
001152-79
003662-947
004863-71
PFE 169-84
PFE 185-202
PFE 203-21
PFE 317-18
FTC0003004-05
(Fax from M. Brotman to
K. Bokat; 2/14/00)

PhRMA

PhRMA 0356-413
PhRMA 2461-521

Rhone-Poulenc Rorer

RPR 000005-61
RPR 000388-407
RPR 001029-44
RPR 001065-111

Searle

FTC0002011-22
(Searle's CID response)

Watson

FTC0002206-13
(Letter and attachment
from R. Reinish to B.
Albert; 12/17/98)
FTC0004803-05
(Minutes of meeting at
RPR on 4/4/97; 4/9/97)
FTC0004834-35
(Memo from K. Clarke to
A. Chao and F.
Wilkinson; 3/18/97)
WPI 0046-52
WPI 0144-45
WPI 0212-13
WPI 0224-25
WPI 0266-69
WPI 0270
WPI 0275-78
WPI 0282-83
WPI 0284-86
WPI 0378-424
WPI 0427-32
WPI 0440-56
WPI 0625
WPI 0641-43
WPI 0721-23
WPI 0760-63
WPI 1233-34
WPI 1252-57
WPI 1287-96
WPI 1374-80
WPI 1404-06
WPI 1423-24
WPI 1583-84
WPI 1589-98
WPI 1614
WPI 1643-44
WPI 1647-48
WPI 1723-1811
WPI 1985-86
WPI 1996

WPI 2269-76
WPI 2277-81
WPI 2282-86
WPI 2287-90
WPI 2291-99
WPI 2300-2303
WPI 2304-07
WPI 2310-11
WPI 2312-13

WPI 2314
WPI 2315-18
WPI 2319-21
WPI 2322-23
WPI 2324-25
WPI 2330-31
WPI 2332
WPI 2340-59
WPI 2360-69

Wilkerson Group

IBM 00001-3
IBM 00004-6
IBM 00007-10
IBM 00011-12
IBM 00013-55
IBM 00056-74

Third-Party Documents with No Bates Numbers

Quatro Scientific

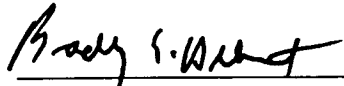
1. Notes of Dr. G. Cote, 7/16-9/11/97 (36 pp.) (Ex 1 to Cote's 1/15/00 personal statement)
2. Letter from Dr. J-C. Tardif to M.Canton, 7/2/99

*These documents contain bates numbers only on the first page.

Other

1. The transcripts of investigational hearings taken during FTC File No. 981-0368.
2. The transcripts of investigational hearings taken during FTC File No. 981-0006
3. The transcripts of depositions taken during Biovail Corporation Int'l vs. Hoechst Marion Roussel, Inc. et al., Civ. No. 98-1434 (D.N.J.)
4. Privilege logs submitted by respondents and third parties during FTC File No. 981-0368 and *In the Matter of Hoechst Marion Roussel et al.*, Dkt. No. 9293
5. Data submitted in electronic form by respondents during FTC File No. 981-0368 and *In the Matter of Hoechst Marion Roussel et al.*, Dkt. No. 9293.

Respectfully Submitted,



Markus H. Meier
Bradley S. Albert
Daniel A. Kotchen

Counsel Supporting the Complaint

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

Dated: September 8, 2000

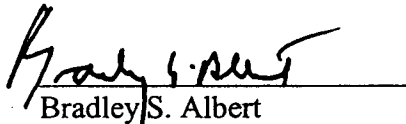
CERTIFICATE OF SERVICE

I, Bradley S. Albert, hereby certify that on September 8, 2000, I caused a copy of the Complaint Counsel's List of Documents to be served upon the following persons via federal express.

James M. Spears, Esq.
Shook, Hardy & Bacon, L.L.P
600 14th Street, N.W.
Suite 800
Washington, DC 20005-2004

Peter O. Safir, Esq.
Kleinfeld, Kaplan, and Becker
1140 19th Street, N.W.
9th Floor
Washington, DC 20036

Louis M. Solomon, Esq.
Solomon, Zauderer, Ellenhorn,
Frischer, & Sharp
45 Rockefeller Plaza
New York, NY 10111



Bradley S. Albert
Counsel Supporting the Complaint

EXHIBIT B

STIPULATION AND AGREEMENT

Stipulation and Agreement, dated September 24, 1997, between Hoechst Marion Roussel, Inc. and Carderm Capital L.P. (collectively, HMRI) and Andrx Pharmaceuticals, Inc. (Andrx);

WHEREAS, HMRI is the holder of United States patent No. 5,470,584 ('584 Patent), which patent HMRI asserts covers the controlled release diltiazem hydrochloride formulation which is marketed in the United States under the trademark 'Cardizem® CD; and

WHEREAS, Andrx has developed a controlled release diltiazem hydrochloride formulation which it asserts is bioequivalent to Cardizem® CD and, pursuant to 21 U.S.C. § 355(j), has submitted and amended an abbreviated new drug application (ANDA) to the United States Food and Drug Administration (FDA) in order to obtain the right to sell that product (the Andrx Product) in the United States; and

WHEREAS, HMRI has filed a Complaint against Andrx in the United States District Court claiming that the Andrx Product infringes the '584 patent, which case is pending in the Southern District of Florida as Case Number 96-06121 (the Patent Infringement Action); and

WHEREAS, both parties recognize that until the issues of whether the Andrx Product infringes the '584 patent and whether the '584 patent is valid and enforceable are resolved in a final and unappealable order or judgment (Final Judgment) each party could take actions during the pendency of the Patent Infringement Action which could have significant financial repercussions; and

WHEREAS, HMRI believes that the market for diltiazem hydrochloride and the consumers of diltiazem hydrochloride could be harmed in the event that an infringing or non-bioequivalent product were brought to market; and

WHEREAS, HMRI has asserted that it intends to seek an injunction barring the marketing, distribution or sale of the Andrx Product prior to the entry of Final Judgment on HMRI's claims in the Patent Infringement Action; and

WHEREAS, HMRI has also asserted that it intends to seek substantial damages and trebled damages for any marketing of the Andrx Product before the entry of Final Judgment; and

WHEREAS, Andrx recognizes that it could lose a substantial investment were it to move forward to market the Andrx Product following the date on which the FDA's approval of the Andrx Product under 21 U.S.C. §355(j) becomes effective (FDA Approval) but before the entry of Final Judgment and were HMRI successful in obtaining an injunction blocking the distribution and sale of the product; and

WHEREAS, Andrx also recognizes that the damages could be potentially ruinous were Andrx to bring the Andrx Product to market and were HMRI to prevail in the Patent Infringement Action; and

WHEREAS, Andrx also believes that if it were to refrain from selling the Andrx Product until after Final Judgment is rendered in the Patent Infringement Action and it prevails in the Patent Infringement Action, then it will have lost substantial revenues from the Andrx Product; and

WHEREAS, Andrx is desirous of bringing a bioequivalent or generic form of Cardizem® CD to the market; and

WHEREAS, the parties intend to fully and vigorously litigate the infringement and validity issues underlying the Patent Infringement Action, but wish to reduce the risks and losses which could result from an adverse decision with respect to damages.

NOW THEREFORE, in consideration of the foregoing and for other good and valuable consideration, and the mutual covenants set forth herein, the parties agree as follows:

1. Effect of Recitals:

The recitals set forth above are true and correct and are incorporated herein by reference.

2. Obligation to Maintain Status Quo:

(A). Pending the entry of Final Judgment, the parties agree to maintain the status quo with respect to the commercial sale of the Andrx Product in the United States. Andrx agrees not to commence the commercial sale of the Andrx Product or other bioequivalent or generic version of Cardizem® CD in the United States directly or indirectly until the entry of Final Judgment, or until it obtains a license from HMRI pursuant to paragraphs 5, 6, and 7 of this Stipulation and Agreement, or until Andrx receives the notice required by Paragraph 5 of this Stipulation and Agreement, whichever is the first to occur. Andrx further agrees that during the pendency of the Patent Infringement Action, it will diligently prosecute the ANDA for the Andrx Product and will not relinquish or otherwise compromise any right accruing thereunder or pertaining thereto.

(B). HMRI agrees not to seek further preliminary injunctive relief against Andrx in this litigation or otherwise until the entry of Final Judgment. HMRI further agrees that for the period beginning on April 1, 1998 and ending upon the termination of this Stipulation and Agreement or the termination of any licensing agreement entered hereunder, whichever is later, HMRI will provide Andrx with a copy of any changes it proposes to the FDA with respect to the package insert and the immediate container label for Cardizem® CD within 10 days of the date upon which such proposed changes are transmitted to the FDA. HMRI further agrees that it will notify Andrx of any proposed changes which may be pending before the FDA as of April 1, 1998.

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HMRI further agrees to notify Andrx in writing of any labeling change which is approved by the FDA with respect to Cardizem® CD within 10 days of receiving notification of such approval.

(C). Andrx agrees that it will dismiss, without prejudice, its antitrust and unfair competition counterclaims in the Patent Infringement Action (including but not limited to counts III through VI and counts XI through XV of said counterclaim) within 30 days of the execution of this Stipulation and Agreement. Andrx further agrees that as between the parties to this Stipulation and Agreement, such dismissal shall be with prejudice as of the date that Final Judgment becomes effective, provided that HMRI has fully complied with the terms of this Stipulation and Agreement.

(D). Both parties agree that neither will apply to the court in the Patent Infringement Action for an order increasing or decreasing the thirty (30) month period provided for by 21 U.S.C. §355(j)(4)(B)(iii).

3. Lost Profit Payments:

(A). For the purposes of this Stipulation and Agreement, the parties stipulate that the profits that Andrx would have realized from the sale of the Andrx Product would be [REDACTED] per year after FDA Approval.

(B). If Final Judgment determines that the '584 patent is invalid or unenforceable or that the Andrx Product does not infringe said patent, HMRI shall pay Andrx an amount, calculated at the stipulated rate of [REDACTED] and prorated for fractions of a year, for the period beginning upon FDA Approval and ending on the date that Final Judgment becomes effective. (For the purposes of this Stipulation and Agreement, the Effective Date of Final Judgment shall mean the later of the date of final disposition in respect of said Final Judgment (or order, as the case may be) or the expiration of the period to appeal or seek review of said disposition, order or Final Judgment.) Said amount shall be reduced solely by an amount equal to the amounts actually paid to Andrx by HMRI pursuant to Paragraph 4(A) below.

(C). In the event that HMRI provides Andrx with notice pursuant to Paragraph 5(B) of this Stipulation and Agreement, the end of the period described in Paragraph 3(B) above shall be the earlier of: (1) the date Andrx effects its first commercial sale of the Andrx Product; or (2) the date HMRI or its licensee effects its first commercial sale of a generic or bioequivalent form of Cardizem® CD, provided that the first such sale by HMRI or its licensee occurs after the expiration of the notice period described in Paragraph 5(B).

(D). In the event that Andrx exercises its option to acquire a license pursuant to Paragraph 6 (A)(ii) of this Stipulation and Agreement, the end of the period described in Paragraph 3(B) above shall be the date upon which said license agreement becomes effective.

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(E). Andrx shall prepare and forward an invoice for the amount due from HMRI pursuant to this Paragraph and that invoice shall be payable and paid to Andrx within 30 days of the date of the invoice.

4. Interim Payments:

(A). For the period beginning upon FDA Approval and ending on the Effective Date of Final Judgment, Andrx shall be entitled to receive nonrefundable interim payments from HMRI of \$40 million per year, payable quarterly. Within 10 days after FDA Approval, HMRI shall pay to Andrx a prorated amount for the period between that effective date and the end of that calendar quarter. On the first day of each calendar quarter after that effective date, HMRI shall pay to Andrx the full \$10 million quarterly payment due to Andrx under this Paragraph.

(B). In the event that HMRI provides Andrx with notice pursuant to Paragraph 5(B) of this Stipulation and Agreement, the end of the period described in Paragraph 4(A) shall be the date upon which the applicable written notice period described in Paragraph 5(B) expires or the date Andrx effects its first commercial sale of the Andrx Product, whichever is earlier.

(C). In the event that Andrx exercises its option to acquire a license pursuant to Paragraph 6 (A)(ii) of this Stipulation and Agreement, the end of the period described in Paragraph 4(A) above shall be the date upon which said license agreement becomes effective.

5. License:

HMRI hereby grants, and warrants it has the right to grant, to Andrx an irrevocable option to acquire a license (or sublicense as the case may be) to all intellectual property which HMRI owns or controls that Andrx may need to sell, market and distribute the Andrx Product in the United States, its territories and possessions, including the Commonwealth of Puerto Rico. (HMRI agrees that it shall not sell, assign or otherwise voluntarily divest itself of said intellectual property during the term of this Stipulation and Agreement in a way which would interfere with or otherwise frustrate Andrx's right to acquire a license under either Paragraphs 5 or 6 of this Stipulation and Agreement.) Such license shall be non-exclusive.

(A). In the event that Andrx previously has taken a license under Paragraphs 6(A)(i) or 6(A)(ii) of this Stipulation and Agreement, HMRI shall have no obligation to notify Andrx of HMRI's intention to either license said intellectual property to any other party (either directly or indirectly, including, but not limited to, an agreement not to enforce said intellectual property against the other party) for the purposes of selling a bioequivalent or generic version of Cardizem® CD or utilize said intellectual property (directly or through a subsidiary) for the purpose of selling its own bioequivalent or generic version of Cardizem® CD in its own right.

(B). In the event that Andrx has not taken a license under Paragraphs 6(A)(i) or 6(A)(ii) of this Stipulation and Agreement and HMRI elects to either license said intellectual property to

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any other party (either directly or indirectly, including, but not limited to, an agreement not to enforce said intellectual property against the other party) for the purposes of selling a bioequivalent or generic version of Cardizem® CD or utilize said intellectual property (directly or indirectly through a subsidiary or any other entity) for the purpose of selling its own bioequivalent or generic version of Cardizem® CD in its own right, then HMRI shall give Andrx written notice prior to the date upon which the third party licensee is authorized to make its first commercial sale or the date of HMRI's first commercial sale as required in the following schedule:

(i). If the date upon which the third party licensee is authorized to make its first commercial sale or HMRI's first planned sale arises on or before [REDACTED] notice is required.

(ii). If the date upon which the third party licensee is authorized to make its first commercial sale or HMRI's first planned sale arises after [REDACTED] and on or before [REDACTED] notice is required.

(iii). If the date upon which the third party licensee is authorized to make its first commercial sale or HMRI's first planned sale arises on or after [REDACTED] and on or before [REDACTED] prior written notice is required.

(iv). If the date upon which the third party licensee is authorized to make its first commercial sale or HMRI's first planned sale arises on or after [REDACTED] and on or before [REDACTED] prior written notice is required.

(v). If the date upon which the third party licensee is authorized to make its first commercial sale or HMRI's first planned sale arises after [REDACTED] prior written notice is required.

(C). The notice provided in Paragraph 5(B) above shall identify, by name, the third party licensee or the HMRI entity authorized to sell a bioequivalent or generic version of Cardizem® CD and shall specify the date upon which the third party licensee is authorized to make its first commercial sale or the date HMRI's first commercial sale is contemplated.

(D). Except as expressly provided in this Stipulation and Agreement, HMRI expressly retains all rights under said intellectual property.

6. Time to Exercise Option to Obtain License:

(A). The option referred to in Paragraph 5 above must be exercised, if at all, at one of the three opportunities set forth below.

(i) By no later than the period beginning on [REDACTED] and ending [REDACTED]

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(ii) In the event that [REDACTED]

(a) [REDACTED] or,

(b) [REDACTED]

Andrx may exercise said option at any time beginning on the earlier of these dates and ending [REDACTED]

(iii) In the event that HMRI notifies Andrx of its intent to license said intellectual property to any other party for the purposes of selling a bioequivalent or generic version of Cardizem® CD, or of its intent to use said intellectual property (directly or indirectly through a subsidiary or any other entity) for the purpose of selling its own bioequivalent or generic version of Cardizem® CD, Andrx may exercise said option [REDACTED]

(B). Except as regards the license fees and royalty rates set forth below, the terms of the license shall be negotiated in good faith by the parties and shall allow Andrx to sell the Andrx Product as a bioequivalent or generic version of Cardizem® CD. Andrx shall be authorized to sell the Andrx Product during such negotiations and prior to the execution of a formal license agreement.

7. License Fee and Royalties:

As set forth below, Andrx agrees to pay HMRI a license fee at the time it acquires a license pursuant to this Stipulation and Agreement as well as royalties based upon [REDACTED] For the purpose of this Stipulation and Agreement and of any license entered into by the parties pursuant to this Stipulation and Agreement, the term [REDACTED]

(A). In the event that Andrx acquires the license pursuant to [REDACTED]

(B). In the event that Andrx acquires the license pursuant to [REDACTED]

(i). [REDACTED]

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[REDACTED]

(ii).

[REDACTED]

8. Final Judgment and Termination:

(A). In the event that HMRI dismisses the Patent Infringement Action prior to the Effective Date of Final Judgment, such dismissal shall be deemed to be as between the parties to this Stipulation and Agreement, a Final Judgment that the '584 patent is invalid or unenforceable or that the Andrx Product does not infringe said patent and said Final Judgment will be deemed to be effective on the date [REDACTED]

[REDACTED]

(B). It is understood by the parties that in addition to the specific obligations set forth in Paragraph 2 of this Stipulation and Agreement, Andrx agrees that it may not transfer, sell or assign any right to obtain a license pursuant to Paragraphs 5 and 6 of this Stipulation and Agreement or any rights granted to Andrx pursuant to a license issued under said paragraphs to any other party without the express written consent of HMRI (a change in the ownership or control of Andrx's stock shall not require HMRI's consent), and, subject to subparagraph (iv) below, Andrx may not, prior to the Effective Date of Final Judgment, withdraw the ANDA that it has submitted to the FDA for the Andrx Product.

(i). In the event that Andrx violates its obligations under Paragraph 2; transfers, sells or assigns any rights granted to Andrx by HMRI pursuant to Paragraphs 5 and 6 of this Stipulation and Agreement or pursuant to any license issued under said paragraphs to any other party without the express written consent of HMRI (a change in the ownership or control of Andrx's stock shall not require HMRI's consent), or, prior to the Effective Date of Final Judgment, withdraws the ANDA that it has submitted for the Andrx Product, then Andrx sha [REDACTED]

[REDACTED]

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(ii). Before HMRI may seek termination of this Stipulation and Agreement and the return of monies paid to Andrx pursuant to this Subparagraph 8(B)(i), HMRI shall provide express written notice to Andrx specifying the obligation which, in HMRI's opinion, Andrx has not fulfilled, the specific manner in which each such obligation has not been fulfilled, and the specific conduct by Andrx that, in HMRI's opinion, will cure the asserted default. In the event that Andrx cures the alleged non-fulfillment identified by HMRI within 30 days of receiving such notice (or such other longer period as HMRI in writing expressly consents), such cure will be deemed full compliance (retroactive to the date of the first asserted default) and this Stipulation and Agreement will remain in full force and effect.

(iii). If Andrx has taken a license under either [REDACTED] of this Stipulation and Agreement, termination of this Stipulation and Agreement as contemplated under Paragraph 8(B)(i) shall not terminate any license previously granted to Andrx pursuant to Paragraph 5 and, with respect to license fees and royalty payments, [REDACTED]

(iv). Nothing in this Stipulation and Agreement shall be construed as prohibiting or limiting Andrx's right to amend or modify the ANDA that it has filed with respect to the Andrx Product so long as such amendment or modification shall not require the withdrawal of the existing ANDA and/or submission of a new ANDA and shall otherwise be consistent with Andrx's obligation to diligently prosecute its ANDA before the FDA as set forth in Paragraph 2 of this Stipulation and Agreement. For all purposes of this Stipulation and Agreement, the term "Andrx Product" shall mean the product Andrx intends to sell pursuant to the ANDA on file with the FDA and as said ANDA may be amended consistent with this subparagraph.

(C). Notwithstanding any other provision of this Stipulation and Agreement, in the event that there is a final unappealable determination in the Patent Infringement Action that does not determine either (1) that the '584 Patent is valid and enforceable and the Andrx Product infringes said patent; or (2) that the '584 patent is invalid or unenforceable and/or that the Andrx Product does not infringe said patent, such determination shall be deemed to constitute, for all purposes in this Stipulation and Agreement, a Final Judgment that the '584 patent is invalid or unenforceable or that the Andrx Product does not infringe said patent unless HMRI notifies Andrx in writing within 30 days of the date of such determination that it continues to believe that the Andrx Product infringes the '584 Patent and that it will seek to enforce the '584 patent by refiling its action at an appropriate time in an appropriate forum and refiles its action no later than 30 days following the later of either: (1) FDA Approval; or, (2) the date upon which the final unappealable determination referenced above in this Paragraph is entered. Andrx agrees that it will not seek to block or otherwise frustrate HMRI's efforts to refile its action in this manner in a timely fashion provided that nothing herein shall be deemed to constitute a waiver by Andrx of any defenses, including the defense of preclusion, that it may have available in such refiled action. In the event HMRI provides the notice set forth above and refiles its action within the time frames herein

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established, such renewed action shall constitute the Patent Infringement Action for the purposes of the Stipulation and Agreement and the parties' respective obligations and rights under this Stipulation and Agreement shall continue uninterrupted and unimpaired as though no final, unappealable determination had been entered. In the event HMRI does not provide the notice set forth above or does not refile its action within the time frames herein established, Final Judgment shall be deemed to have been entered on the expiration of the period for HMRI to issue such notice, if it has not done so, or the expiration of the period in which it was required to refile such action if notice was provided, and for the purposes of this Stipulation and Agreement, such date shall be deemed as the Effective Date of Final Judgment. In the event that Final Judgment is deemed entered pursuant to this paragraph, it shall, as between the parties to this Stipulation and Agreement, constitute a final conclusive and unappealable determination that the '584 patent is invalid or unenforceable or that the Andrx Product does not infringe said patent.

(D). Notwithstanding any other provision of this Stipulation and Agreement, in the event that prior to a Court determining the issues of the validity of the '584 patent and whether the Andrx Product infringes that patent, Andrx in writing stipulates or, in open court and on the record, concedes that the '584 patent is valid and that the Andrx Product infringes said patent, Andrx shall repay to HMRI an amount equal to the amount of all payments that have been paid to Andrx pursuant to this Stipulation and Agreement, and this Stipulation and Agreement shall be terminated.

9. Use of Agreement:

Except as otherwise required by law or as otherwise may be requested by the court in the Patent Infringement Action, the terms and existence of this Stipulation and Agreement shall be kept confidential. This Stipulation and Agreement and any drafts thereof or any documents or records pertaining thereto or information derived therefrom shall not be introduced into evidence in the Patent Infringement Action or any other litigation for any purpose.

10. Effect of Agreement:

The parties represent and warrant that this Stipulation and Agreement constitutes their valid and legally binding obligations and shall be binding upon and inure to the benefit of the parties hereto and their successors and assigns. Except as otherwise provided in Paragraph 8(B), this Stipulation and Agreement may not be assigned without the express written consent of the other party. However, nothing in this Paragraph or this Stipulation and Agreement shall restrict Andrx's right to assign its right to receive income under this Stipulation and Agreement.

11. Applicable Law - Consent to Jurisdiction:

The parties hereto expressly agree that all the terms and provisions hereof shall be construed under the laws of the State of Florida as now adopted or as may be hereafter amended, without giving effect to any conflict of law or choice of law provision or rule. In the event of a

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dispute between the parties as to the interpretation, application or effect of this Stipulation and Agreement, the parties agree that any litigation arising out of such dispute shall be filed and venue shall be conclusively laid in the United States District Court for the Southern District of Florida, and both parties expressly consent to personal jurisdiction in that forum for the purposes of resolving said dispute.

12. Entire Agreement:

This Stipulation and Agreement constitutes the entire agreement of the parties hereto with respect to the matters set forth herein and supersedes any prior understanding or agreement, oral or written, with respect thereto.

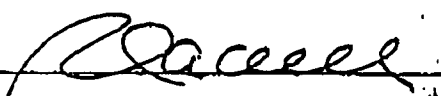
13. Nonpayment:

Any amounts not paid when due shall thereafter bear interest at 18% per annum and all costs and expenses, including reasonable attorneys' fees, incurred in connection with the enforcement of this Stipulation and Agreement shall be paid to the prevailing party by the non-prevailing party, upon demand.

IN WITNESS WHEREOF, the parties hereto have caused this Stipulation and Agreement to be executed by their duly authorized representatives on the date first written above.

Hoechst Marion Roussel, Inc.

Andrx Pharmaceuticals, Inc.

By 

By 

Name Peter W. Ladell

Name Chih-Ming J. Chen, Ph.D.

Title Chief Operating Officer

Title President

Carderm Capital L.P.

By 

Name Dirk Kruse

Title Authorized Representative

EXHIBIT C

Business

Plans/Forecasting

BRAH000001-2
BRAH000003-12
BRAH000021-46
BRAH000047-70
BRAH000071-81
BRAH000102-38
BRAH000139-65
BRAH000166-88
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HMRI-000924-28
HMRI-001440-60
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HMRI S17 001200-25
HMRI S18 000001-38

Business

Plans/Forecasting

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BRAH000102-38
BRAH000139-65
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HMRI SPEC 20

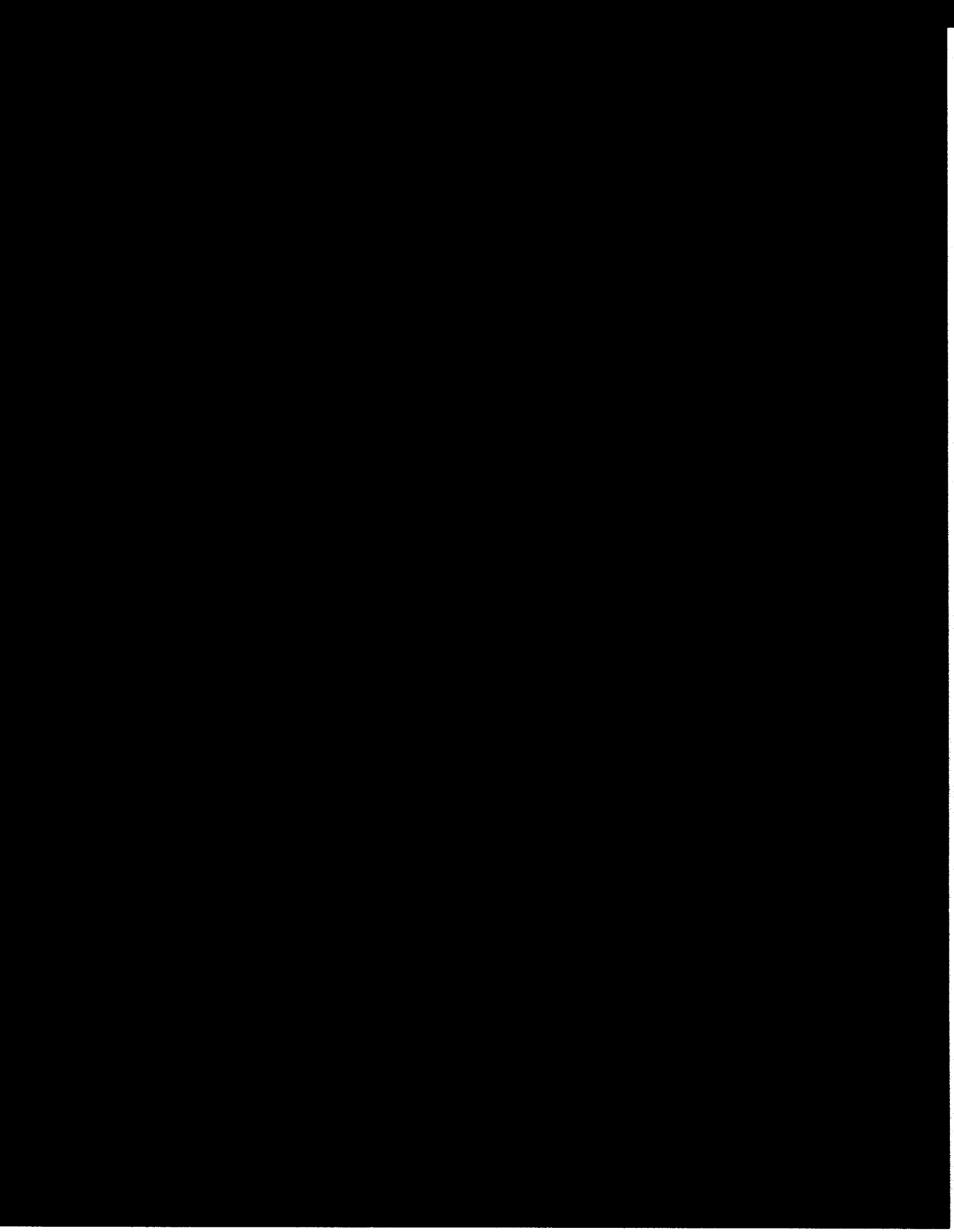
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Settlement Discussion
Agreement

6/8/99 letter from L.

Solomon to J. Spears

HMRI-020029



Miscellaneous

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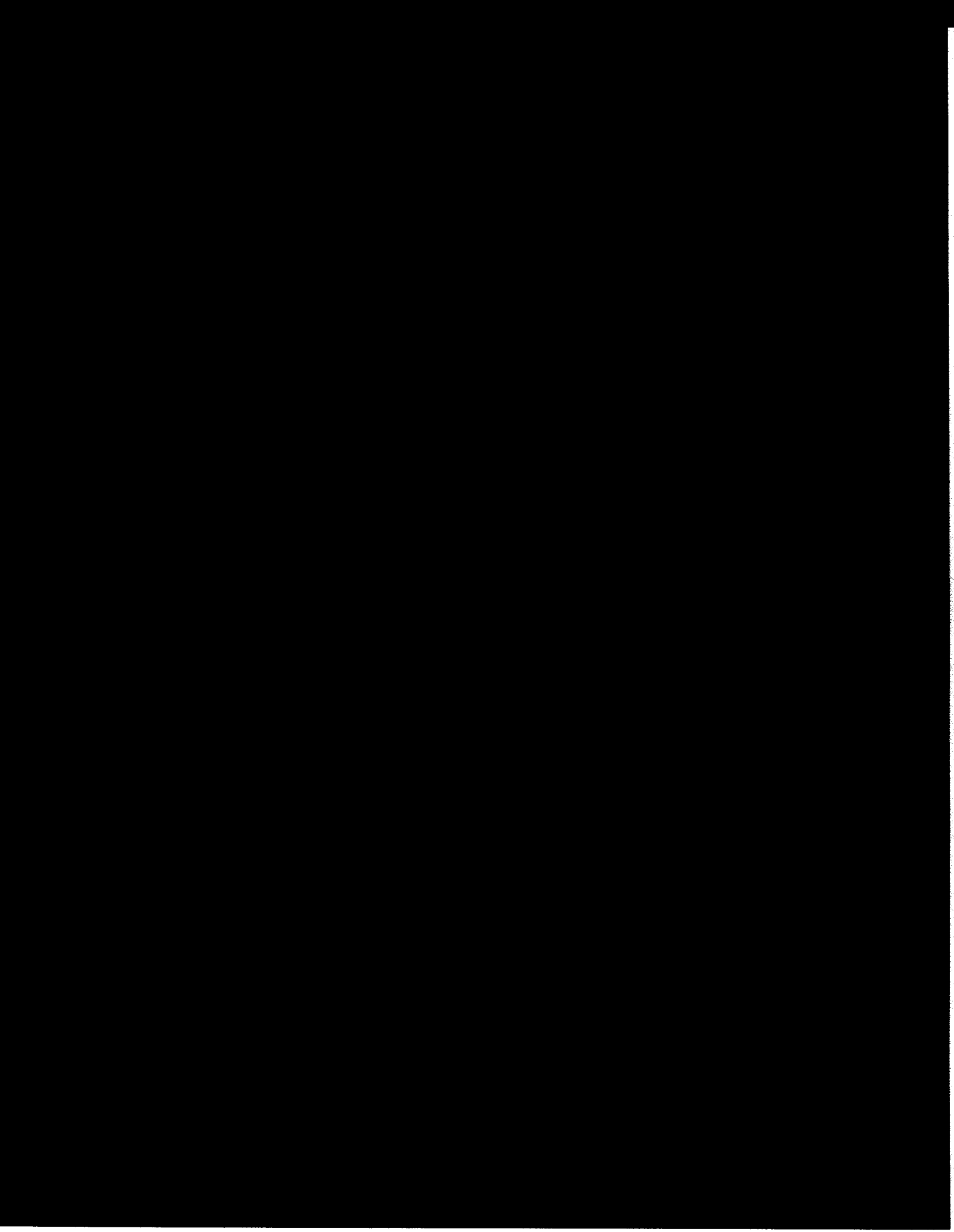
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"Long Terms Incentive
Plan Overview" for
Hoechst Marion
Roussel, Inc.

"Hoechst Marion
Roussel: The
Pharmaceutical
Company of Hoechst"
presentation, 1/15/99



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 KAY NOONAN IN SUPPORT OF
RESPONDENT AVENTIS PHARMACEUTICALS, INC.'S
APPLICATION FOR *IN CAMERA* TREATMENT OF
CERTAIN CONFIDENTIAL DOCUMENTS

I, Kay Noonan, pursuant to 28 U.S.C. § 1746, declare as follows,:

1. I am in-house counsel for respondent Aventis Pharmaceuticals, Inc. ("Aventis").
2. I have discussed and reviewed with Peter Bernstein, outside counsel for Aventis, the documents for which *in camera* treatment has been requested.
3. Aventis, and its predecessors, have sold Cardizem® CD since 1993 and continue to do so in 2000. Cardizem® CD is indicated for the treatment of hypertension and angina and competes with numerous other pharmaceutical products.
4. Our review of these documents revealed that the identified information is closely held and is not widely circulated within the company. Typically, information is only disseminated within the company to those with a necessary interest. A good example of this is internal company minutes, that are typically only distributed to attendees and anyone with specific reasons for possessing such information. Information such as minutes, business plans, and marketing studies are valuable to the company as it provides the necessary facts with which prudent business decisions are made. This sort of information would be valuable in the hands of any competitor. Due to the proprietary nature

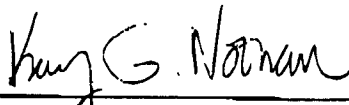
of the identified information, it would not be available to a competitor and it would be difficult, if not impossible, for a competitor to acquire or duplicate this information. The Business Plans and Forecasts, Marketing, Sales and Contracting Documents; and Corporate Minutes reflect the thought processes and business judgement of Aventis employees. Granting competitors access to such confidential materials would cause serious injury to Aventis.

5. Release of this information contained in this application would cause serious injury in that the information for which *in camera* treatment has been requested would provide competitors with access to proprietary information including cost of sales, cost of goods, third party royalties, operating expenses, inter-company margins, cash discounts, revenues and rebates. Such access would undermine Aventis' competitive position in the hypertension market and jeopardize its negotiating positions with third-party payors.

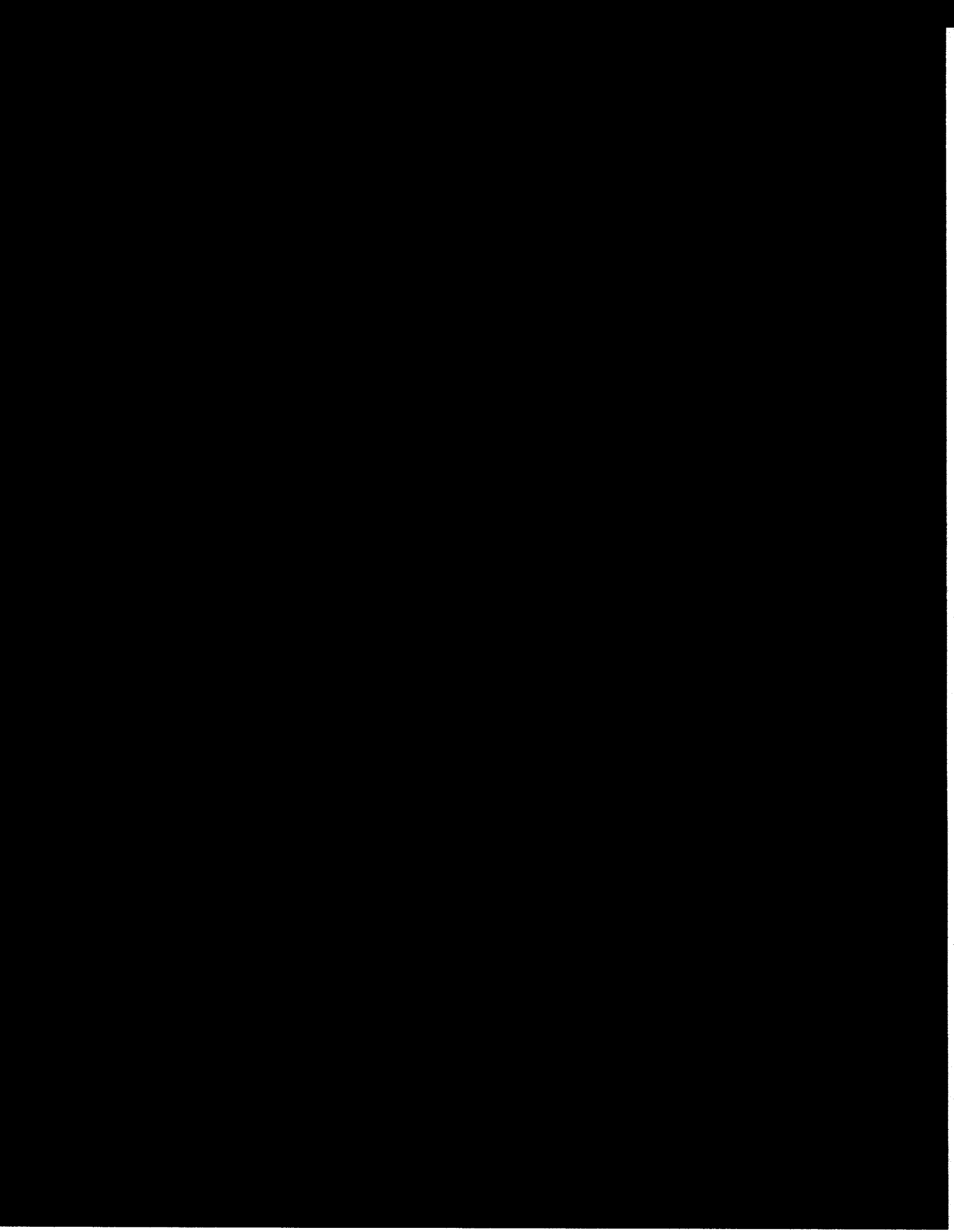
I declare under penalty of perjury that the foregoing is true and correct.

Executed in Kansas City, MO, on September 29, 2000

Respectfully Submitted,



Kay Noonan



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 29, 2000, a copy of Aventis Pharmaceuticals, Inc.'s Application for *In Camera* Treatment of Certain Confidential Documents was served upon the following persons by hand delivery and/or Federal Express as follows:

Donald S. Clark, Secretary
Federal Trade Commission
Room 172
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

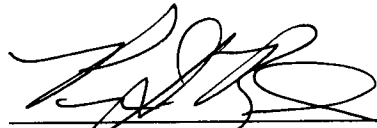
Richard Feinstein
Federal Trade Commission
Room 3114
601 Pennsylvania Ave., N.W.
Washington, D.C. 20580

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

Markus Meier
Federal Trade Commission
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Peter D. Bernstein