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,

OCT 25 2000
SECRETARY

and

ANDRX CORPORATION, a corporation.

DOCKET NO. 9293

RESPONDENT ANDRX'S MOTION TO COMPEL DEPOSITION TESTIMONY OR TO PRECLUDE

Pursuant to § 3.38 of the Federal Trade Commission's Rules of Practice, Respondent Andrx Corporation hereby moves for an Order: (1) compelling FTC staff members Bradley Albert, Geoffrey Oliver, Robin Moore, Daniel Kotchen and Elizabeth Mullin to testify concerning pre-complaint discussions they had with Andrx and that Complaint Counsel appears intent upon developing for use at trial in this matter or, alternatively, precluding Complaint Counsel from adducing evidence at trial concerning these discussions; and (2) granting such other and further relief as the Court deems just and proper.

The bases of this motion are set forth in the accompanying Memorandum of Law in Support of [Andrx's] Motion to Compel Deposition Testimony or to Preclude and the accompanying Declaration of Jonathan D. Lupkin, executed on October 24, 2000.

Dated: New York, New York October 24, 2000

Respectfully Submitted,

SOLOMON, ZADDERER, ELLENHORN, FRISCHER & SHARP

Louis M. Solomon Hal S. Shaftel

Jonathan D. Lupkin 45 Rockefeller Plaza

New York, New York 10111

(212) 956-3700

Counsel for Respondent Andrx Corporation

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

DECLARATION OF JONATHAN D. LUPKIN

JONATHAN D. LUPKIN, pursuant to 28 U.S.C. § 1746, declares as follows:

- 1. I am associated with Solomon, Zauderer, Ellenhorn, Frischer & Sharp, counsel for respondent Andrx Corporation ("Andrx"). I submit this declaration in support of Andrx Corporation's motion, pursuant to the FTC's Rule of Practice § 3.38, to compel FTC staff members Bradley Albert, Geoffrey Oliver, Robin Moore, Daniel Kotchen and Elizabeth Mullin to testify on the limited subject of pre-complaint discussions these staff members had with Andrx and that complaint counsel appears intent upon developing for use at trial in this matter.
- 2. Attached hereto collectively as Exhibit A are true copies of the letter, dated October 17, 2000, by Jonathan Lupkin to Markus Meier and the enclosed notice of deposition of the same date (the "Notice").

- 3. Attached hereto as Exhibit B is a true copy of the letter, dated October 17, 2000, from Markus Meier to Jonathan Lupkin refusing to tender witnesses in accordance with Andrx's Notice.
- 4. Attached hereto as Exhibit C a copy of Complaint Counsel's First Request for Admissions to Respondent Andrx Corporation, dated September 25, 2000.
- 5. Attached hereto as Exhibit D is an excerpt from the deposition of Edward Stratemeier.
- 6. Attached hereto as Exhibit E is an excerpt from the transcript of the August 3, 2000 hearing in this matter.
- 7. Attached hereto as Exhibit F is a copy of this Court's order, dated October 12, 2000.

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

Executed in New York, New York, on October 24, 2000.

JONATHAN D. LUPKIN

SOLOMON, ZAUDERER, ELLENHORN, FRISCHER & SHARP

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JOHN J. O'CONNELL OF COUNSEL

WRITER'S DIRECT DIAL (212) 424-0758

VIA FACSIMILE

Markus Meier, Esq. Federal Trade Commission 601 Pennsylvania Avenue, N.W., Room 3116 Washington, D.C. 20580

Re: In the Matter of Hoechst Marion Roussel, Inc., Carderm

Capital L.P., and Andrx Corporation, FTC Docket No. 9293

October 17, 2000

Dear Markus:

I enclose a notice of deposition, calling for the testimony of Bradley Albert, Jeffrey Oliver, Robin Moore, Daniel Kochen and Elizabeth Mullin. Please let us know whether you will take the position that subpoenas are required for these individuals and, if so, whether you will accept service on their behalf.

Ionathan Q. Lupkin

Enclosure

cc: All Counsel of Record

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

NOTICE OF DEPOSITION

PLEASE TAKE NOTICE that pursuant to Rule 3.33 of the Federal Trade Commission's Rules of Practice for Adjudicative Proceedings, Andrx Corp. will take the deposition of the following individuals at the dates, times and places set forth below:

Deponent	<u>Date</u>	<u>Time</u>	<u>Location</u>
Bradley Albert	October 25, 2000	10:00 a.m.	Solomon, Zauderer, Ellenhorn, Frischer & Sharp, 45 Rockefeller Plaza, New York, New York 10111
Jeffrey Oliver	October 25, 2000	2:00 p.m.	Solomon, Zauderer, Ellenhorn, Frischer & Sharp, 45 Rockefeller Plaza, New York, New York 10111

Robin Moore	October 26, 2000	10:00 a.m.	Solomon, Zauderer, Ellenhorn, Frischer & Sharp, 45 Rockefeller Plaza, New York, New York 10111
Daniel Kochen	October 26, 2000	2:00 p.m.	Solomon, Zauderer, Ellenhorn, Frischer & Sharp, 45 Rockefeller Plaza, New York, New York 10111
Elizabeth Mullin	October 27, 2000	10:00 a.m.	Solomon, Zauderer, Ellenhorn, Frischer & Sharp, 45 Rockefeller Plaza, New York, New York 10111

The aforementioned depositions will be conducted before some person authorized by law to administer oaths, and will continue from day to day until completed. The testimony will be recorded by stenographic means. You are invited to attend and cross-examine.

Dated: October 17, 2000

SOLOMON, ZAUDERBY, ELLENHORN FRISCHER & SHARP

By: Louis M: Solomon

Hal S. Shaftel Jonathan D. Lupkin 45 Rockefeller Plaza New York, New York 10111 212-956-3700

Attorneys for Respondent Andrx Pharmaceuticals, Inc.

212-956-4068 (Fax)

CERTIFICATE OF SERVICE

I, Jonathan D. Lupkin, hereby certify that on October 17 2000, I caused to be served upon the following persons by facsimile and by overnight mail, next business day delivery, the following document: Notice of Deposition:

Markus Meier, Esq. Federal Trade Commission Room 3114 601 Pennsylvania Ave., N.W. Washington, D.C. 20580

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

Peter O. Safir, Esq. Kleinfeld, Kaplan and Becker 1140 19th St., N.W. Washington, D.C. 20036

Dated: October 17, 2000

Jonathan D. Lupkin



FACSIMILE TRANSMISSION SHEET

FEDERAL TRADE COMMISSION Bureau of Competition Health Care Division 601 Pennsylvania Avenue, NW, S-3115 Washington, DC 20580

Phone: (202) 326-3759 Location: Solomon, Zauderer Fax: (202) 326-3384 Fax: (212) 956-4068 Phone: (212) 424-0710	FROM:	MARKUS H. MEIER	TO:	JONATHAN LUPKIN
Fax: (212) 956-4068	Phone:	(202) 326-3759	Location:	Solomon, Zauderer
Phone: (212) 424-0710	Fax:	(202) 326-3384	Fax:	(212) 956-4068
			Phone:	(212) 424-0710

Number of pages sent (including cover sheet): 2 Date: October 17, 2000

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Bureau of Competition

October 17, 2000

Via Facsimile

Jonathan D. Lupkin Solomon, Zauderer, Ellenhorn, Frischer, & Sharp 45 Rockefeller Plaza New York, New York 10111

Re:

In the Matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corporation, FTC Docket No. 9293

Dear Jonathan:

I have received your deposition notices of Bradley Albert, Geoffrey Oliver, Robin Moore, Daniel Kotchen, and Elizabeth Mullin. Your notice of deposition of these individuals is not only unprecedented but also wholly inappropriate for a variety of reasons. First, the cut-off date for discovery of this sort has long since passed. Second, as you are well aware, with the exception of Ms. Mullin, these individuals are Commission attorneys who worked on the investigation that led to the complaint and are currently serving as complaint counsel. Ms. Mullin, who was an honors paralegal during the investigative stage, is no longer with the Commission. Third, you have provided absolutely no basis for the depositions of these individuals, and you clearly have no legitimate basis for requesting their depositions.

Seeking to depose these individuals is yet another attempt by Andrx to divert attention from the relevant issues of the case, to delay the course of discovery, and to harass us. If you wish to pursue this matter further, you should file the appropriate motion with Administrative Law Judge Chappell.

Sincerely,

Marken Mun

Markus Meier

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 FIRST REQUESTS FOR ADMISSIONS TO RESPONDENT ANDRX CORPORATION

Pursuant to Federal Trade Commission ("FTC") Rules of Practice for Adjudicative Proceedings § 3.32, Complaint counsel submit these requests for admissions to respondent Andrx Corporation. Andrx is requested to respond, in writing, to the following requests for admissions within twenty (20) days after service hereof.

DEFINITIONS

- 1. "ANDA" means an Abbreviated New Drug Application filed with the FDA

 2. "ANDA 75 00 "
- 2. "ANDA 75-984" means the Abbreviated New Drug Application filed with the FDA by Faulding pursuant to 21 U.S.C. § 355(j) for a generic bioequivalent version of Cardizem CD.

- 3. "ANDA 75-1169" means the Abbreviated New Drug Application filed with the FDA by Biovail pursuant to 21 U.S.C. § 355(j) for a generic bioequivalent version of Cardizem CD.
- 4. "Andrx" means Andrx Pharmaceuticals, Inc., its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf.

 5. "Andry's Original Total Control of the Co
- 5. "Andrx's Original Formulation" means ANDA 74-752 filed by Andrx with the FDA pursuant to 21 U.S.C. § 355(j) on September 22, 1995 and amended on April 4, 1996, for a generic or bioequivalent version of Cardizem CD.

 6. "Andry's D. C. "Andry's D. "Andry's D.
- 6. "Andrx's Reformulated Product" means the formulation of Andrx's generic Cardizem CD product which was approved for sale by the FDA on or around June 8, 1999 pursuant to a supplement to ANDA 74-752 filed by Andrx on September 11, 1998.
 - 7. "API" means active pharmaceutical ingredient.
- 8. "Biovail" means Biovail Corporation, its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf.

 9. "Cardizon CD"

 - 10. "Cartia XT" means the diltiazem formulated sold by Andrx under that trademark.
- "District Court" means the U.S. District Court for the Southern District of

- 12. "Faulding" means Faulding Inc., its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees. agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants, or any person acting or purporting to act on its behalf.
- 13. "FDA" means the United States Food and Drug Administration, including without limitation its employees, scientists, technicians, agents, examiners and laboratories.
- 14. "Final Judgement" means a final and unappealable order or judgement as that phrase is defined in paragraph 8.A. of the HMR/Andrx Stipulation and Agreement.
- 15. "First Filer" means the applicant submitting the first substantially complete

 ANDA for a listed drug with a Paragraph IV certification to any patent in the Orange Book for
 the listed drug.
- 16. "Hatch-Waxman Amendments" means the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), adding section 505(j) to the Food Drug and Cosmetics Act (21 U.S.C. § 355(j)(5)).
- 17. "Hoechst" and "HMR" means Hoechst Marion Roussel, Inc., its predecessors, including without limitations Hoechst Inc. and Marion Merrell Dow Inc., and the officers, directors, employees, partners, subsidiaries, corporate parents, affiliates and divisions of each of the foregoing.
- 18. "HMR/Andrx Patent Infringement Litigation" means *Hoechst Marion Roussel*.

 Inc. et al. v. Andrx Pharmaceuticals, Inc., Case No. 96-06121-Civ-Roettger (S.D. Fla.).

- 19. "HMR/Andrx Stipulation and Agreement" means the agreement between Hoechst Marion Roussel, Inc., Carderm Capital, L.P. and Andrx Pharmaceuticals entered into on or about September 24, 1997.
- 20. "HMR/Andrx Stipulation and Order" means the agreement entered into between Hoechst and Andrx on or about June 8, 1999 which resolved the Patent Infringement Litigation and terminated the HMR/Andrx Stipulation and Agreement.
- 21. "Orange Book" means the FDA publication entitled Approved Drug Products with Therapeutical Equivalence Evaluations.
- 22. "Paragraph IV Certification" means the certification made to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).
- 23. "584 Patent" means U.S. Patent No. 5,470,584 issued by the U.S. Patent and Trademark Office on November 28, 1995.
- 24. "180-day Exclusivity Period" means the period of time established by section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j) et seq.).

REQUESTS FOR ADMISSIONS

Interstate Commerce

- Request No. 1: Admit that Andrx markets and sells pharmaceutical products, including Cartia XT in the United States.
- Request No. 2: Admit that Andrx's pharmaceutical products, including Cartia XT, are sold to consumers in states other than the state in which the products are manufactured.

Request No. 11: Admit that Andrx, as the First Filer for a generic version of Cardizem CD, was eligible for the 180-day Exclusivity Period.

The Patent Infringement Litigation

Request No. 12: Admit that on December 19, 1995, Andrx submitted to the FDA a certification stating that Andrx's Original Formulation did not infringe the patents listed in the Orange Book for Cardizem CD.

Request No. 13: Admit that Andrx sent Hoechst notification of its December 19.

1995 patent certification to the FDA stating that Andrx's Original Formulation did not infringe the patents listed in the Orange Book for Cardizem CD.

Request No. 14: Admit that on January 17, 1996, Andrx submitted to the FDA an amended certification stating that Andrx's Original Formulation did not infringe the patents listed in the Orange Book for Cardizem CD, including the '584 patent.

Request No. 15: Admit that Andrx sent Hoechst notification of its January 17, 1996 amended patent certification to the FDA stating that Original Formulation did not infringe the patents listed in the Orange Book for Cardizem CD, including the '584 patent.

Request No. 16: Admit that in the HMR/Andrx Patent Infringement Litigation,
Andrx took the position in papers filed with the District Court, including Andrx's Answer (dated
February 20, 1996) and Andrx's Motion for Summary Judgment on the Issue of NonInfringement and Memorandum in Support thereof (dated December 12, 1996) that Andrx's
Original Formulation did not infringe the patents listed in the Orange Book for Cardizem CD,
including the '584 patent.

Request No. 17: Admit that in the HMR/Andrx Patent Infringement Litigation.

Andrx never took the position in papers filed with the District Court that Andrx's Original

Formulation infringed the patents listed in the Orange Book for Cardizem CD, including the '584 patent.

Request No. 18: Admit that in the HMR/Andrx Patent Infringement Litigation,

Andrx took the position in its counterclaims filed with the District Court on February 20, 1996

that Hoechst's filing of the HMR/Andrx Patent Infringement Litigation would result in the delay in the FDA's approval of Andrx's Original Formulation.

Request No. 19: Admit that in the HMR/Andrx Patent Infringement Litigation,

Andrx took the position in its counterclaims filed with the District Court on February 20, 1996
that Hoechst's filing of the HMR/Andrx Patent Infringement Litigation would result in the delay
of the introduction of Andrx's Original Formulation.

Request No. 20: Admit that in the HMR/Andrx Patent Infringement Litigation,

Andrx took the position in its counterclaims filed with the District Court on February 20, 1996
that Hoechst's filing of the HMR/Andrx Patent Infringement Litigation would cause Andrx to
miss or be precluded from up to 30 months of sales of Andrx's Original Formulation.

Request No. 21: Admit that in the HMR/Andrx Patent Infringement Litigation,

Andrx never took the position that Andrx's Original Formulation infringed the '584 Patent.

Request No. 22: Admit that in the HMR/Andrx Patent Infringement Litigation,

Andrx never took the position that any of its generic versions of Cardizem CD infringed the '584

Patent.

Request No. 33: Admit that the District Court made no finding that Andrx's Original Formulation was substantially likely to infringe the '584 patent.

Request No. 34: Admit that no federal district court has found that Andrx's Original Formulation infringed the '584 patent.

Request No. 35: Admit that no federal district court has found that Andrx's Original Formulation was substantially likely to infringe the '584 patent.

Request No. 36: Admit that in the HMR/Andrx Patent Infringement Litigation, Andrx took the position in its counterclaims filed with the District Court on February 20, 1996, that diltiazem is the relevant product market for purposes of the antitrust laws of the United States

Request No. 37: Admit that in the HMR/Andrx Patent Infringement Litigation, Andrx took the position in its counterclaims filed with the District Court on February 20, 1996, that the sustained release (once-a day) form of diltiazem is a relevant product sub-market for purposes of the antitrust laws of the United States.

Request No. 38: Admit that in the HMR/Andrx Patent Infringement Litigation, Andrx took the position in its counterclaims filed with the District Court on February 20, 1996, that the United States is the relevant geographic market with respect to the relevant product market and relevant product sub-market for purposes of the antitrust laws of the United States.

HMR/Andrx Stipulation and Agreement

Request No. 39: Admit that in July 1997, representatives of Hoechst and Andrx met to discuss a possible agreement relating to the HMR/Andrx Patent Infringement Litigation.

Request No. 40: Admit that the first draft of the HMR/Andrx Stipulation and Agreement was prepared in July 1997.

Request No. 41: Admit that the HMR/Andrx Stipulation and Agreement was executed on September 24, 1997.

Request No. 42: Admit that the HMR/Andrx Stipulation and Agreement was negotiated over the course of nearly two months.

Request No. 43: Admit that during the negotiation of the HMR/Andrx Stipulation and Agreement, Hoechst and Andrx exchanged at least 40 drafts of the HMR/Andrx Stipulation and Agreement.

Request No. 44: Admit that the language "other bioequivalent or generic versions of Cardizem CD" first appears in paragraph 2 of the HMR/Andrx Stipulation and Agreement in a August 15, 1997 draft, Bates stamped 1584-1600.

Request No. 45: Admit that Hoechst was responsible for inserting the language "other bioequivalent or generic versions of Cardizem CD" into paragraph 2 of the August 15, 1997 draft of the HMR/Andrx Stipulation and Agreement, Bates stamped 1584-1600.

Request No. 46: Admit that the language "other bioequivalent or generic versions of Cardizem CD" is crossed out in paragraph 2 of the August 26, 1997 draft of the HMR/Andrx Stipulation and Agreement, Bates stamped 1512-23.

Request No. 47: Admit that Andrx was responsible for crossing out the language "other bioequivalent or generic versions of Cardizem CD" from paragraph 2 of the August 26, 1997 draft of the HMR/Andrx Stipulation and Agreement, Bates stamped 1512-23.

Request No. 48: Admit that the language "other bioequivalent or generic versions of Cardizem CD" appears in paragraph 2 of the September 3, 1997 draft of the HMR Andrx Stipulation and Agreement, Bates stamped 1487-98.

Request No. 49: Admit that Hoechst was responsible for inserting the language "other bioequivalent or generic versions of Cardizem CD" into paragraph 2 of the September 3. 1997 draft of the HMR/Andrx Stipulation and Agreement, Bates stamped 1487-98.

Request No. 50: Admit that Andrx received FDA tentative approval for Andrx's Original Formulation on September 17, 1997.

Request No. 51: Admit that the HMR/Andrx Stipulation and Agreement was entered into eight days after Andrx received FDA tentative approval for Andrx's Original Formulation.

Request No. 52: Admit that Andrx could not receive final FDA approval to market Andrx's Original Formulation until after the termination of the 30-month Hatch-Waxman statutory injunction.

Request No. 53: Admit that the 30-month Hatch-Waxman statutory injunction for Andrx's Original Formulation expired in July 1998.

Request No. 54: Admit that Hoechst and Andrx entered into the HMR/Andrx Stipulation and Agreement more than 8 months before Andrx received final FDA approval to market Andrx's Original Formulation.

Request No. 55: Admit that under the HMR/Andrx Stipulation and Agreement, Andrx agreed not to commence the sale of any "bioequivalent or generic version of Cardizem CD in the United States directly or indirectly" until the earlier of: (1) the date that Final

Request No. 62: Admit that in the event Andrx commenced the sale of any "bioequivalent or generic version of Cardizem CD" in the United States while the HMR Andrx Stipulation and Agreement was in effect: (1) the HMR/Andrx Stipulation and Agreement would terminate; (2) Andrx would not receive any further \$10 million payments from Hoechst: and (3) Andrx would be required to repay to Hoechst all payments made to Andrx by Hoechst under the HMR/Andrx Stipulation and Agreement.

Request No. 63: Admit that under the HMR/Andrx Stipulation and Agreement, the phrase "bioequivalent or generic version of Cardizem CD" applied to products that infringed the '584 Patent.

Request No. 64: Admit that under the HMR/Andrx Stipulation and Agreement, the phrase "bioequivalent or generic version of Cardizem CD" applied to products that did not infringe the '584 Patent.

Request No. 65: Admit that under the HMR/Andrx Stipulation and Agreement, the phrase "bioequivalent or generic version of Cardizem CD" applied to Andrx's Reformulated Product.

Request No. 66: Admit that under the HMR/Andrx Stipulation and Agreement, Andrx agreed not to relinquish or otherwise compromise any rights accruing under its ANDA.

Request No. 67: Admit that under the HMR/Andrx Stipulation and Agreement, the phrase "any rights accruing under [Andrx's] ANDA" included any rights Andrx had to a 180-day Exclusivity Period.

Request No. 68: Admit that in the event Andrx relinquished or otherwise compromised any rights accruing under ANDA 74-752 while the HMR/Andrx Stipulation and

Agreement was in effect: (1) the HMR/Andrx Stipulation and Agreement would terminate: (2) Andrx would not receive any further \$10 million payments from Hoechst; and (3) Andrx would be required to repay to Hoechst all payments made to Andrx by Hoechst under the HMR/Andrx Stipulation and Agreement.

Request No. 69: Admit that in the event Andrx relinquished or otherwise compromised its 180-day Exclusivity Period while the HMR/Andrx Stipulation and Agreement was in effect: (1) the HMR/Andrx Stipulation and Agreement would terminate; (2) Andrx would not receive any further \$10 million payments from Hoechst; and (3) Andrx would be required to repay to Hoechst all payments made to Andrx by Hoechst under the HMR/Andrx Stipulation and Agreement.

Request No. 70: Admit that under the HMR/Andrx Stipulation and Agreement,
Hoechst granted Andrx an option to acquire a license to all intellectual property owned by
Hoechst that Andrx would need to sell, market, and distribute a generic formulation of Cardizem
CD in the United States ("Hoechst's Intellectual Property").

Request No. 71: Admit that under the HMR/Andrx Stipulation and Agreement, Andrx could not exercise its option to acquire a license to Hoechst's Intellectual Property until after either: (1) eighteen months after final FDA approval of Andrx's product – January 9, 2000; (2) 30 days after Hoechst provides notice to Andrx that it intended to license its intellectual property to another generic manufacturer or to market its version of generic Cardizem CD; or (3) if Andrx lost the HMR/Andrx Patent Infringement Litigation.

Request No. 72: Admit that under the HMR/Andrx Stipulation and Agreement, in the event that Andrx lost the HMR/Andrx Patent Infringement Litigation, Andrx could choose to exercise the option to acquire a license to Hoechst's Intellectual Property.

Request No. 73: Admit that under the HMR/Andrx Stipulation and Agreement, in the event that Andrx lost the HMR/Andrx Patent Infringement Suit, Andrx could choose not to exercise the option to acquire a license to Hoechst's Intellectual Property.

Request No. 74: Admit that under the HMR/Andrx Stipulation and Agreement, in the event that Andrx lost the HMR/Andrx Patent Infringement Suit and Andrx chose not to exercise the option to acquire a license to Hoechst's Intellectual Property, Andrx would keep all of the payments made to it by Hoechst.

Request No. 75: Admit that under Paragraph 4 of the HMR/Andrx Stipulation and Agreement, Hoechst agreed to pay Andrx \$10 million a quarter for the period from Andrx's receipt of final FDA approval for Andrx's Original Formulation through the duration of the HMR/Andrx Stipulation and Agreement.

Request No. 76:

Request No. 76: Admit that the quarterly payments from Hoechst to Andrx pursuant to Paragraph 4 of the HMR/Andrx Stipulation and Agreement began on the date Andrx received approval from the FDA to market Andrx's Original Formulation.

Request No. 77:

Request No. 77: Admit that Hoechst's payments to Andrx of \$10 million a quarter were to be made regardless of the outcome of the HMR/Andrx Patent Infringement Litigation.

Request No. 78: Admit that under the HMR/Andrx Stipulation and Agreement, Hoechst made a \$10 million payment to Andrx on July 9, 1998.

Request No. 79: Admit that under the HMR/Andrx Stipulation and Agreement.

Hoechst made a \$10 million payment to Andrx on October 1, 1998.

Request No. 80: Admit that under the HMR/Andrx Stipulation and Agreement, Hoechst made a \$10 million payment to Andrx on January 4, 1999.

Request No. 81: Admit that under the HMR/Andrx Stipulation and Agreement.

Hoechst made a \$10 million payment to Andrx on April 1, 1999.

Request No. 82: Admit that under the HMR/Andrx Stipulation and Agreement, in the event that Andrx lost the HMR/Andrx Patent Infringement Litigation, Andrx did not have to refund any of the \$10 million a quarter paid to it by Hoechst.

Request No. 83: Admit that under the HMR/Andrx Stipulation and Agreement, in the event that Andrx won the patent litigation, Hoechst would pay Andrx an additional \$60 million a year for the period from Andrx's receipt of final FDA approval for its Original Formulation through the duration of the HMR/Andrx Stipulation and Agreement.

Request No. 84: Admit that Hoechst did not file with the District Court a motion for a preliminary injunction in the HMR/Andrx Patent Infringement Action.

Request No. 85: Admit that the HMR/Andrx Stipulation and Agreement was not presented to the District Court for approval.

Request No. 86: Admit that the District Court did not approve the HMR/Andrx Stipulation and Agreement.

Request No. 87: Admit that the HMR/Andrx Stipulation and Agreement was not presented to any federal district court for approval.

Request No. 88: Admit that the HMR/Andrx Stipulation and Agreement was not approved by any federal district court.

Request No. 89: Admit that under the HMR/Andrx Stipulation and Agreement. Hoechst paid to Andrx approximately \$89.83 million.

Request No. 90: Admit that Andrx disclosed publicly in September 1997 that it had entered into the HMR/Andrx Stipulation and Agreement.

Request No. 91: Admit that Andrx did not disclose publicly in September 1997 the terms of the HMR/Andrx Stipulation and Agreement.

Request No. 92: Admit that Andrx did not disclose publicly in September 1997 the actual text of the HMR/Andrx Stipulation and Agreement.

Request No. 93: Admit that Andrx has never disclosed publicly the terms of the HMR/Andrx Stipulation and Agreement.

Request No. 94: Admit that Andrx has never disclosed publicly the actual text of the HMR/Andrx Stipulation and Agreement.

Request No. 95: Admit that during the time between the execution of the HMR/Andrx Stipulation and Agreement in September 1997, and the termination of the agreement in June 1999, Hoechst had net U.S. sales of roughly \$1.3 billion for Cardizem CD.

Request No. 96: Admit that at the time Andrx entered into the HMR/Andrx Stipulation and Agreement, Andrx believed that it would receive FDA approval for Andrx's Original Formulation upon expiration of the 30 month Hatch-Waxman waiting period in July 1998.

Request No. 97: Admit that at the time Andrx entered into the HMR/Andrx Stipulation and Agreement, Andrx believed that Faulding would receive tentative FDA approval of ANDA 75-984 prior to Final Judgement in the HMR/Andrx Patent Infringement Litigation.

Request No. 98: Admit that at the time Andrx entered into the HMR/Andrx Stipulation and Agreement, Andrx was uncertain as to whether or not Faulding would receive tentative FDA approval of ANDA 75-984 prior to Final Judgement in the HMR/Andrx Patent Infringement Litigation.

Request No. 99: Admit that at the time Andrx entered into the HMR/Andrx

Stipulation and Agreement, Andrx believed that Biovail would receive tentative FDA approval to market a generic version of Cardizem CD prior to Final Judgement in the HMR/Andrx Patent

Infringement Litigation.

Request No. 100: Admit that at the time Andrx entered into the HMR/Andrx Stipulation and Agreement, Andrx was uncertain as to whether or not Biovail would receive tentative FDA approval to market a generic version of Cardizem CD prior to Final Judgment in the HMR/Andrx Patent Infringement Litigation.

Request No. 101: Admit that Andrx took the position in its complaint in Andrx v. Friedman, Civ. No. 98-0099 (D.D.C.) that it was likely that the FDA would find Biovail's generic version of Cardizem CD approveable prior to Final Judgement in the HMR/Andrx Patent Infringement Litigation.

Andrx's Reformulated Product

Request No. 102: Admit that on June 8, 1999, Hoechst and Andrx entered into the HMR/Andrx Stipulation and Order.

Request No. 103: Admit that the HMR/Andrx Stipulation and Order terminated the HMR/Andrx Stipulation and Agreement.

Request No. 104: Admit that under the HMR/Andrx Stipulation and Order, Hoechst agreed that it would not institute or prosecute any action alleging patent infringement with respect to Andrx's Reformulated Product, so long as the Reformulated Product's SR2 beads release on average not less than 68% of the total amount of diltiazem after 18 hours when tested in the U.S. Pharmacopeia XXII Type 2 apparatus using 900 ml of 0.1 HCL at 37 degrees C and a paddle speed of 100 rpm.

Request No. 105: Admit that Hoechst has not initiated or prosecuted any action alleging patent infringement with respect to Andrx's Reformulated Product.

Request No. 106: Admit that Hoechst does not have a good faith basis for initiating or prosecuting a patent infringement action with respect to Andrx's Reformulated Product so long as Andrx's Reformulated Product's SR2 beads release on average not less than 68% of the total amount of diltiazem after 18 hours when tested in the U.S. Pharmacopeia XXII Type 2 apparatus using 900 ml of 0.1 HCL at 37 degrees C and a paddle speed of 100 rpm.

Request No. 107: Admit that in May 1999 Federal Trade Commission (FTC) staff discussed with Andrx an outline for a proposed consent order relating to the FTC's investigation of Hoechst and Andrx, FTC File No. 981-0368.

Request No. 108: Admit that Hoechst and Andrx reached an agreement in principle on the HMR/Andrx Stipulation and Order less than 3 weeks after the FTC staff discussed with Andrx an outline for a proposed consent order relating to the FTC's investigation of Hoechst and Andrx, FTC File No. 981-0368.

Request No. 109: Admit that the terms of the HMR/Andrx Stipulation and Order entered into by Hoechst and Andrx reflected at least some of the same terms proposed by the FTC's staff when the FTC staff discussed a proposed consent order relating to the FTC's investigation of Hoechst and Andrx, FTC File No. 981-0368.

Request No. 110: Admit that if Andrx and Hoechst had not entered into the HMR/Andrx Stipulation and Order, under the terms of the HMR/Andrx Stipulation and Agreement, Andrx would not have been permitted to commence the commercial sale of Andrx's Reformulated Product.

Request No. 111: Admit that if Andrx and Hoechst had not entered into the HMR/Andrx Stipulation and Order, under the terms of HMR/Andrx Stipulation and Agreement, Andrx would have had to repay Hoechst all amounts previously paid if it had commenced the commercial sale of Andrx's Reformulated Product.

Request No. 112: Admit that Hoechst's outside legal counsel James M. Spears believed that Hoechst and Andrx should enter into the HMR/Andrx Stipulation and Order because he understood that the FTC wanted the HMR/Andrx Stipulation and Agreement "ended in no uncertain terms."

Biovail

Request No. 113: Admit that Biovail filed ANDA 75-1169 for a generic version of Cardizem CD on April 21, 1997.

Request No. 114: Admit that as part of ANDA 75-1169, Biovail submitted to the FDA a Paragraph IV Certification stating that its generic Cardizem CD product did not infringe the patents listed in the Orange Book for Cardizem CD.

Request No. 115: Admit that Hoechst did not sue Biovail for patent infringement concerning the generic Cardizem CD product that was the subject of Biovail's ANDA 75-1169.

Faulding

Request No. 116: Admit that Faulding filed its application for a generic version of Cardizem CD, ANDA 75-984, on October 11, 1996.

Request No. 117: Admit that as part of ANDA 75-984, Faulding submitted to the FDA a Paragraph IV Certification stating that its generic Cardizem CD product did not infringe the patents listed in the Orange Book for Cardizem CD.

Request No. 118: Admit that on January 31, 1997, Hoechst filed a patent infringement action in the District of New Jersey, alleging that Faulding's generic product infringed U.S. Patent No. 5,439,689.

Request No. 119: Admit that the January 31, 1997 complaint filed by Hoechst against Faulding in the patent infringement action in the District of New Jersey did not allege that Faulding's generic product that is the subject of ANDA 75-984 infringed the '584 patent.

Request No. 120: Admit that Hoechst has not initiated or prosecuted a patent infringement claim alleging that Faulding's generic product that is the subject of ANDA 75-984 infringed the '584 patent.

Request No. 121:

Request No. 121: Admit that sales of Faulding's generic Cardizem CD product commenced on December 21, 1999.

Calcium Channel Blocker Products

Request No. 122: Admit that Cardizem CD was first sold in the United States in January 1992.

Request No. 123: Admit that Cardene SR was first sold in the United States in March 1992.

Request No. 124: Admit that Dilacor XR was first sold in the United States in June 1992.

Request No. 125: Admit that Norvasc was first sold in the United States in September 1992.

Request No. 126: Admit that Adalat CC was first sold in the United States in July 1993.

Request No. 127: Admit that Sular was first sold in the United States in January 1996.

Request No. 128: Admit that Tiazac was first sold in the United States in January

1996.

Request No. 129: Admit that Covera HS was first sold in the United States in May 1996.

Request No. 130: Admit that Dynacirc CR was first sold in the United States in December 1996.

Request No. 131: Admit that Verelan PM was first sold in the United States in March 1999.

Other

Request No. 132: Admit that on January 31, 1996, Hoechst and Carderm filed the HMR/Andrx Patent Infringement Litigation against Andrx in the Southern District of Florida.

Request No. 133: Admit that on April 4, 1996, Andrx filed with the FDA an amendment to its ANDA No. 74-752.

Request No. 134: Admit that Andrx's April 4, 1996 amendment to ANDA No. 74-752 added an additional dissolution specification for the SR2 beads which requires that each lot of the SR2 beads release not less than 55% of the total amount of diltiazem after 18 hours when tested in the U.S. Pharmacopeia XXII Type 2 apparatus using 900 ml of 0.1 HCL at 37 degrees C and a paddle speed of 100 rpm.

Request No. 135.

Request No. 135: Admit that on September 11, 1998, Andrx filed a supplement to its ANDA No. 74-752, which sought to add a small amount of a new ingredient to the SR2 bead coating and to change the dissoulution specification for the SR2 bead to "not less than 65% of the total diltiazem after 18 hours."

Request No. 136: Admit that on October 7, 1998, Andrx notified Hoechst that it had filed a supplement to its approved ANDA No. 74-752.

Request No. 137: Admit that on January 8, 1999, Hoechst informed Andrx that FDA regulations required Andrx to provide Hoechst with a new Paragraph IV Certification that Andrx's Reformulated Product does not infringe the patents listed in the Orange Book for Cardizem CD.

Request No. 138: Admit that on January 19, 1999, Andrx informed Hoechst that it did not believe it was required to provide a new Paragraph IV Certification with respect to the Andrx's Reformulated Product.

Request No. 139: Admit that on January 15, 1999, Hoechst wrote to the FDA suggesting that Andrx was required to file a new Paragraph IV Certification for Andrx's Reformulated Product.

Request No. 140: Admit that on February 3, 1999, Andrx provided a Paragraph IV Certification to the FDA stating that Andrx's Reformulated Product did not infringe the patents listed in the Orange Book for Cardizem CD, including the '584 patent.

Request No. 141: Admit that Andrx purchases micronized diltiazem HCL API from Plantex USA, Inc.

Request No. 142: Admit that Andrx used micronized diltiazem HCL API in manufacturing Andrx's Original Formulation.

Request No. 143: Admit that Andrx uses micronized diltiazem HCL API in manufacturing Cartia XT.

Request No. 144: Admit that Andrx advertising and promotional materials for Cartia XT explicitly mention Cardizem CD.

Request No. 145: Admit that Andrx advertising and promotional materials for Cartia XT do not explicitly mention any prescription drug other than Cardizem CD.

Request No. 146: Admit that Andrx is a corporation within the meaning of Section 4 of the Federal Trade Commission Act.

Respectfully Submitted,

Markus W. Meier Bradley S. Albert Robin Moore

Counsel Supporting the Complaint

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

Dated: September 25, 2000

CERTIFICATE OF SERVICE

I, Bradley S. Albert, hereby certify that on September 25, 2000, I caused a copy of Complaint Counsel's First Requests for Admissions to Respondent Andrx Corporation to be served upon the following persons via facsimile and overnight delivery. Louis M. Solomon

Solomon, Zauderer, Ellenhorn, Frischer, & Sharp 45 Rockefeller Plaza New York, NY 10111

(via overnight delivery only)

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

Counsel Supporting the Complaint

In The Matter Of:

ANDRX CORPORATION AND HOECHST MARION ROUSSEL MATTER NO. 9810368

EDWARD H. STRATEMEIER Vol. 2, June 8, 1999

For The Record, Inc.

Court Reporting and Litigation Support
603 Post Office Road
Suite 309
Waldorf, MD USA 20602
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Original File 90608STR.ASC, 134 Pages Min-U-Script® File ID: 0934301743

Word Index included with this Min-U-Script®

- (1) been marked as Stratemeier Exhibit 30. It bears the caption the United States District [3] Court Southern District of Florida and is labeled [4] Stipulation and Order. The document is five pages Mr. Stratemeier, do you recognize this document? A: Yes, I do. Q: Could you please identify it for the record. 19: A: It's a stipulation and order entered into [10] [13] between Hoechst Marion Roussel, Inc. and Andrx 12 Pharmaceuticals, settling the patent litigation in [13] Florida Q: Exhibit 30 has not been signed. 1141 1151 Has this stipulation and order been signed? A: It is my understanding that both parties have 137 agreed to sign it. We have signed it. Our — as you [18] see, it's set up for outside counsel to sign as it's a (19) stipulation in a court. Our outside counsel has signed it. I have not (21) heard yet that their outside counsel has signed it, but we have been assured by counsel for Andrx that they will MR. SPEARS: It's in the process. It was in the process of being distributed to be signed this [1] afternoon when we left to come over here to the
 - [16] the litigation, and those are the discussions that led [18] questions. [19] BY MR. OLIVER: Q: Who represented Hoechst with respect to the [20] [21] negotiation of this document? A: I did and Mr. Spears. Q: Who represented Andrx with respect to the [23] [24] negotiation of this document? A: Mr. Lodin and Mr. Solomon. 1[25] Page 248 Q: When did the first negotiations of this document [2] take place? A: I believe two weeks ago today. MR. SPEARS: Is it two weeks ago? THE WITNESS: Yeah. Because a week ago today (6) was the 1st. We were trying to get everything finished 回 by the 1st, so we had — MR. SPEARS: That's right. THE WITNESS: So it was two weeks ago today, so [10] that would have been -MR. SPEARS: What's our date? May 25. [11] THE WITNESS: So May 25. [12] [13] BY MR. OLIVER: Q: Who first contacted whom with respect to [14] [15] proposing such an agreement? A: I think that was a conversation between outside [16] ।। त्र counsel, and I don't know who made the first contact. Q: Do you know approximately when that happened? A: No more than a week before that meeting. [19] Q: Around May 18? [20] A: Thereabouts. Q: In any event, was that after the first part of [23] your investigational hearing?

[16] this stipulation and order? A: In October of this year — of — excuse me — [18] of '98, we were notified by — I was notified by the [19] general counsel of Andrx that they had filed an ANDA [20] supplement for a new formulation which they believed [21] avoided our patent.

After some discussion on what happens next, we [23] Obtained samples of that product as well as some [24] information about the product in the filing they had

Page 247 MR. SPEARS: Excuse me. And the new Page 249 (2) certification. THE WITNESS: And they also - at our urging. (4) FDA required them to recertify as to whether or not this (5) product infringed the patent and notify us of the (6) certification, which they did. After our examination of their data and the (8) product, we determined that we would not assert our (9) patent against this product, provided that the product ing that they were actually going to manufacture was [19] substantially the same as the product that they had. ing filed on. Since that time, we have had some discussion [13] [14] about what that means in terms of the current litigation (15) in Florida, is the new product in the litigation, out of Page 250

[24] A: Yes, it was.

Q: I believe you testified that the actual

MATTER NO. 9810368 [1] negotiations began about May 25? Page 251 A: Yes. (1) knew what you wanted and that we - our position was Q: Can you please summarize generally those [3] [2] Crafted from the presentation that you all had made to [4] negotiations? (3) us and we did not discuss the specifics of any A: We met in Mr. Spears' office here in Washington, (4) conversations that we'd had with you all. (6) the four of us, Mr. Lodin, Mr. Sullivan, Mr. Spears and BY MR. OLIVER: Q: When did you first reach agreement in principle [6] We discussed how we might clarify the status of [8] | [7] with Andrx? (9) the litigation in Florida, which because they had a A: I believe we reached an agreement in principle product that was clearly within the litigation and : [8] [13] another product outside of the litigation, and we (9) on that day. (12) discussed the elements of the September of '97 Q: And that was approximately May 25? [13] stipulation and how that would apply to the new product, 1011 (14) what the circumstances would be. Q: Who then actually drafted the stipulation and [12] It was clear from their discussion that they :[13] Order? [15] A: I don't know who drafted it. (16) wanted to take their new product to market as quickly as 1141 Q: Since you were able to reach agreement on that [17] possible, and it was our point of view that we would not [15] [16] one day, why has it taken this long to get it signed? [18] assert a patent claim against it if it met certain — if [19] it was substantially the same as the information they A: I don't know how to best describe this. [18] We reached an agreement that there would be two [19] paragraphs in the stipulation and order. The first We got into a very lengthy discussion about what (20) paragraph would say they're not going to sell any (22) "substantially the same" means and were able to arrive product other than the new one when it gets approved. [23] at, after they apparently made several phone calls to (22) and the second one would say the lawsuit's dismissed [24] their manufacturing people, a limitation on what [23] and the effective date of termination of the [25] "substantially the same" meant. stipulation, the September 27 stipulation, was June 1. And we thought that that resolved all the And after that, the issue was how to craft a Page 252 23 settlement agreement that assumed that they would get [1] issues, that everything would be tied up, the lawsuit's [3] approval in the very near future but left some ability Page 254 (2) over, they're essentially fessing up to the fact that (4) on their part to take a license if they didn't get (3) their product infringes — their original product [5] approval of their new formulation in a reasonable period [4] infringes our patent, and we're saying that we won't [6] of time. And it took us two weeks to crash through [5] assert the patent against the reformulation. Since that time, we have been engaged with them [8] BY MR. OLIVER: in lengthy discussions about carve-backs and what-ifs Q: Did the stipulation and order result from a i (a) and just interminable proposal from one side or the other or was it mutual MR. SPEARS: You can't put that on the record. THE WITNESS: - nonsense of, well, we may not A: I believe it was mutual discussions. [12] [11] get this approved; well, we're going to get it approved Q: Did either party present a proposal at the [12] tomorrow; well, we may not get it approved. (14) beginning of the discussions? It has not been a pleasant experience, but A: The proposal that was more or less on the table (113) that's how — that's why it took two weeks to get from was the Commission's proposal for a consent order. (15) what I thought was a very simple, no-nonsense agreement Q: I assume when you say the proposal for a consent [16] to the document that's in front of you which, as I said, 8; order, you're referring to the discussions that (17) has carve-backs for the "in case we don't get it 9 Mr. Spears had with Mr. Albert and myself as well as a conversation that Mr. Solomon had by telephone with [18] approved." Mr. Albert and myself? [19] BY MR. OLIVER: Q: And when did you actually reach final agreement [20] A: That's correct. [21] with Andra? MR. SPEARS: I want to make clear on the record A: About nine o'clock this morning I think or that while we were - I was not aware that you in fact [23] ten o'clock maybe. had even had that discussion with Mr. Solomon, that I Q: If I could ask you to turn to page 2, and I'd like to direct your attention to paragraph 8 at the

8.3.00	Pretrial Hearing Hoechst Marion, Cardenn & Andry C
Page 2	Page 4
UNITED STATES OF AMERIC	The state of the s
2 FEDERAL TRADE COMMISSION	
3	3 STACY L. EHRLICH, Attorney
4 In the Matter of:)	4 Kleinfeld, Kaplan and Becker
5 HOECHST MARION ROUSSEL, INC.,)	5 1140 19th Street, N.W., Suite 900
6 a corporation,) Docket No. 9293	6 Washington, D.C. 20036
7	
8 CARDERM CAPITAL L.P.,	() 222 3120
,	8
- F	9 ON BEHALF OF ANDRX:
, .	10 LOUIS M. SOLOMON, Attorney.
11 ANDRX CORPORATION.)	11 HAL S. SHAFTEL, Attorney
12 a corporation.	12 Solomon, Zauderer, Ellenhorn, Frischer & Shar
13)	13 45 Rockefeller Plaza
14 AUGUST 3, 2000	14 New York, New York 10111
15	15 (212) 956-3700
16 Room 532	16
17 Federal Trade Commission	17
18 6th Street and Pennsylvania	18
19 Ave., NW	19
20 Washington, D.C. 20580	
21 washington, D.C. 20380	20
	21
matter carrie on for	
23 prehearing conference, pursuant to notice, at	1:00 p.m. 23
24	24
25 THE HONORABLE JUDGE D.M. CHAPPE	ELL 25
Page 3	Page 5
1 APPEARANCES:	1 PROCEEDINGS
2	2
3 ON BEHALF OF THE FEDERAL TRADE COMN	IISSION: 3 JUDGE: Are the parties all present?
4 MARKUS H. MEIER, Attorney	For the record this is a hearing IN Docket
5 BRADLEY S. ALBERT, Attorney	
6 DANIEL A. KOTCHEN, Attorney	5 9293. Let's start with appearance of all the parties.
7 ROBIN L. MOORE. Attorney	6 starting with complainant counsel.
8 MICHAEL ANTALICS	7 MR. MEIER: Good afternoon, Your Honor, Markus
9 Federal Trade Commission	8 Meier on behalf of the Federal Trade Commission. With
	9 me today I have Don Kotchen, Brad Albert and Robin
Transfer and Transfer at the t	
1.1 1.1 (1.1 (1.1 (1.1 (1.1 (1.1 (1.1 (10 Moore. We also have Mike Antalics, deputy director of
12 (202) 628-4000	10 Moore. We also have Mike Antalics, deputy director of11 the bureau of competition here.
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12 (202) 628-4000 13 14 15 ON BEHALF OF HOECHST: 16 JAMES M. SPEARS, Attorney 17 PETER M. BERNSTEIN, Attorney 18 Shook, Hardy & Bacon, LLP 19 Hamilton Square, 600 14th Street, N.W., 20 Suite 800 21 Washington, D.C. 20005-2004	10 Moore. We also have Mike Antalics, deputy director of 11 the bureau of competition here. 12 MR. SPEARS: Your Honor, James Spears, Shook, 13 Hardy & Bacon for respondent Hoechst Pharmaceuticals. 14 With me is Peter Bernstein of my office. 15 MR. SAFIR: Your Honor, Peter Safir on behalf of 16 Carderm and with me is Stacy Ehrlick. 17 MR. SOLOMON: Good afternoon, Judge. Lou 18 Solomon with Solomon, Zauderer, Ellenhorn, Frischer & 19 Sharp on behalf of Andrx, and with me is my colleague 20 Mr. Shaftel and also Mr. Lasseril. 21 JUDGE: The order pretty much sets forth the 22 agenda of the issues we're going to hear today. I am

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around the privilege log issues is to try to deal with getting the factual information directly from the 3 third-parties and directly from the witnesses complaint counsel intends to rely on in five months.

JUDGE: Mr. Meier?

6 MR. MEIER: Thank you, Your Honor. A couple things. Again housekeeping to go back before I really get into it, apparently I was unaware that they've received any documents from third parties, and I would 10 like to ask on the record that they start producing them to us when they get them, and I would like Your Honor to 12 tell them that that's the proper way to do that. They 13 should send us those documents. 14

JUDGE: I'm not going to entertain discovery 15 requests on the record in a hearing. Those need to be 16 done under the rules. That goes for both sides also.

17 MR. MEIER: Thank you, Your Honor. And also I 18 have to take issue with this characterization that somehow we've been encouraging Biovail not to

20 cooperate. There's nothing to that. That's simply not

21 true, and the fact that we filed a motion on the Biovail 22 issue was they were trying to seek to preclude us far in

advance. It had nothing to do with the problems with

24 Biovail. It had to do with a witness, which Your Honor

25 has deferred ultimate judgment on if it comes up again

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Let's turn a little bit to the privilege log 2 First of all, this motion of a late privilege log

3 somehow waiving anything is rather ridiculous.

4 JUDGE: Let me be sure I'm correct here. We 5 have one privilege log issue to resolve but not the one

6 with Andrx; just so I'm correct?

MR. SHAFTEL: Correct, Judge.

8 MR. MEIER: Andrx has yet to produce any 9 privilege log to us with any documents from post

complaint discovery. The fact is we'll get into it in a 11 little while hopefully today.

12 JUDGE: Again as I alluded to, I'm not sure the 13 quid pro quo argument is very dispositive in this 14 Court. I understand that there are rules of good faith

15 and civility that need to be applied by the parties, but quid pro quo is not really a valid objection or response

17 to a legal issue.

18 MR. MEIER: I understand that, Your Honor, but 19 as both Mr. Spears and Mr. Shaftel have pointed out, our

20 rules do require production of privilege logs, and I'm merely pointing out they haven't produced a privilege

22 log to us, but it's not surprising since they haven't

produced a scalp of paper to us since this claim was

24 issued either. 25

Let's take a look -- I would like to have Your

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l later.

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JUDGE: Do you plan to use Biovail as a witness?

MR. MEIER: We hope, Your Honor. But we recognize the problem if Biovail doesn't show up and make itself available, that we may very well face preclusion at the end of the day.

JUDGE: You may very well, ves.

9 MR. MEIER: Yes. Your Honor. I've talked other 10 attorneys representing Biovail. I do understand, and it concerns us, but they're not a star witness. They're not the major part of the case, and they're not unimportant either. We would like to call them because 14 I think it would help inform Your Honor on the conduct 15 --

16 JUDGE: I've issued an opinion involving the 17 Canadian companies but a decision will be made if 18 necessary in a case where the government wants to -- one 19 side and the other side does not have a right to depose and cross examine the witness. That's going to be a decision that will be made if necessary. I'll advise 22 the parties of that.

23 MR. MEIER: I understand. We didn't take issue 24 with that. We took issue of precluding at this moment 25 before -- there's still three months left in discovery.

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Honor go back and take a look at our privilege log, and

as Your Honor takes a look at it, you'll find it's quite a detailed privilege log. It has the date, the title,

the author, the recipient, description of the document,

the privileges claimed and the basis of the claims.. It

goes on for page after page after page, 16, 17 pages.

7 Attached at the back of the appendix are lists of all the people who are mentioned in the earlier parts

of the privilege logs. The real question with this

privilege log. Your Honor, that Your Honor might want to

think about is. Does this privilege log provide

sufficient information to Your Honor to make an

assessment as to whether these privileges are properly

14 invoked

15 That's the real question about the privilege 16 log, and if Your Honor takes time to go back and look at

it. I think you'll find this is an extremely detailed

privilege log that provides all the types of information

19 that are required.

20 The one thing that I understand them to be

complaining about is the fact that we have a

categorization. In other words, for example, entry

number 1 we talk about internal E mail, and we say that

24 there's been approximately 200 internal E mails that

25 have gone back and forth by lawyers and economists

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

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In the Matter of) }	
HOECHST MARION ROUSSEL, INC., a corporation,)	
CARDERM CAPITAL L.P., a limited parmership,))) Docket No. 92	93
and)	
ANDRX CORPORATION, a corporation.)))	

ORDER DENYING RESPONDENTS' MOTIONS FOR PROTECTIVE ORDERS

I.

Respondent Andrx Corporation ("Andrx"), on September 15, 2000, filed its motion for a protective order seeking to preclude Complaint Counsel from taking depositions of five Andrx employees or agents who had been examined by the FTC staff during the investigation which preceded this matter. Also on September 15, 2000, Respondent Aventis Pharmaceuticals, Inc. ("Aventis"), formerly known as Hoechst Marion Roussel, Inc. filed its motion for a protective order to preclude or limit further deposition of two of Aventis' attorneys ("Aventis Motion"). Complaint Counsel filed a consolidated opposition on September 27, 2000. Oral arguments of counsel were heard on October 5, 2000.

For the reasons set forth below, Respondents' motions are DENIED.

n.

Andrx and Aventis both assert that Complaint Counsel should be precluded from taking the depositions of these seven individuals because Complaint Counsel previously took their depositions during the investigatory phase of the Commission's case. In the alternative, Respondents assert, Complaint Counsel should be limited to questioning these individuals to "new" areas of testimony not previously known about during the previous questioning. In addition, Aventis asserts that Complaint Counsel should be precluded from taking the

depositions of Spears and Stratemeier because Spears is Aventis' lead outside counsel and Stratemeier is Aventis' General Counsel.

Complaint Counsel asserts that it needs to take the depositions of these individuals in order to develop and refine its case and to prepare a response to Respondents' defenses, regardless of the fact that these individuals were examined during the pre-complaint investigation. Complaint Counsel further asserts that limiting the subject matter of the proposed depositions to "new" topics is unwarranted and unworkable. In response to Aventis' argument that Spears and Stratemeier should not be deposed because they are counsel for Aventis, Complaint Counsel asserts that Spears and Stratemeier played a material role in the facts underlying the litigation and, thus, it is appropriate to take their depositions.

Ш.

Respondents rely on federal cases that hold that repeat depositions are disfavored, and where allowed, are limited to new areas. <u>E.g.</u>, Lobb v. United Air Lines, Inc., 1993 U.S. App. LEXIS 17495, *2-4 (9th Cir. 1993) (stating "[r]epeat depositions are disfavored" and precluding second round of questioning where party sought second deposition for alleged different purpose, for trial, after completion of earlier deposition, for settlement purposes); Tri-Star Pictures, Inc. v. Unger, 171 F.R.D. 94, 102-03 (S.D.N.Y. 1997) ("strictly confin[ing]" second deposition to new areas not covered in the first deposition and forbidding re-questioning on topics covered in previous testimony). Complaint Counsel counters that these cases are not analogous because they arise in context of repeat depositions in the same litigation and that here there is a significant difference between an examination during the investigatory phase of a matter and a deposition taken in the adjudicative phase of the matter

The Supreme Court, in Hamah et al. v. Larche et al., 363 U.S. 420, 446 (1960), noted that the rules of the Federal Trade Commission "draw a clear distinction between adjudicative proceedings and investigative proceedings." "The reason for these rules [regarding notice of investigation] is obvious. The Federal Trade Commission could not conduct an efficient investigation if persons being investigated were permitted to convert the investigation into a trial" Id. Also, in United States v. Morton Salt Co., 338 U.S. 632, 642 (1950), the Supreme Court distinguished the Commission's investigatory "power to get information from those who best can give it" and the judicial power to summon evidence in the course of litigation. The Commission "has a power of inquisition if one chooses to call it that, which is not derived from the judicial function. It is more analogous to the Grand Jury, which does not depend on a case or controversy for power to get evidence but can investigate merely on suspicion that the law is being violated, or even because it wants assurance that it is not." Id. See also Linde Thomson Langworthy Kohn & Van Dyke v. Resolution Trust Corp., 5 F.3d 1508, 1513 (D.C. Cir. 1993) ("Unlike a discovery procedure, an administrative investigation is a proceeding distinct from any litigation that may eventually flow from it.").

The Commission, in explaining differences between the scope of discovery under Part III of the Commission's Rules of Practice and an investigation under Part II, has stated:

[I]t should be manifest that the Commission's rules of practice are intended to and do provide for comprehensive pre-complaint investigation. The rules for adjudicatory proceedings are intended to embody the Commission's conviction that, to the fullest extent practicable, the strategy of surprise and the art of concealment will have no place in a Commission proceeding. Hence, we have also provided for thorough post complaint discovery procedures.

A subpoena, deposition, or order requiring access aimed at obtaining information not ordinarily obtainable before issuance of the complaint, additional details, or an extension of information as to disclosed transactions or events for which evidence is to be adduced in support of the complaint is manifestly within the bounds of proper pretrial discovery. There is no provision in the Commission's rules, nor is there any precedent which would, in effect, require complaint counsel to have all evidence that he will need prior to the issuance of the complaint.

The general rule still remains that an onerous burden would be placed not only on the investigator but upon the party or parties investigated if the preliminary investigation must encompass the gathering of all of the details for each and every transaction which may eventually become an evidentiary item in a subsequent complaint. Many Federal Trade Commission proceedings present factual and conceptual complexities. In such cases, complaint counsel may properly find, particularly after the issues are refined in a prehearing conference, that some additional documentation may be required to round out, extend, or supply further details for the particular transactions to be pursued.

All-State Indus., et al., 72 F.T.C. 1020, 1023-24, 1967 FTC LEXIS 159, *6-10 (Nov. 13, 1967) (emphasis in original).

In re Chain Pharmacy Ass'n, Inc., et al., 1990 FTC LEXIS 193 (June 20, 1990) presents a situation similar to the instant conflict. There, an agent of respondent refused to answer questions in a deposition in Part III adjudication on the grounds that complaint counsel had asked him the same questions during an investigational hearing. Noting that the Rules of Practice adopt a liberal approach to discovery and that the discovery sought need only be relevant and holding that "the Rules do not prohibit repetitive questioning[,]" the Administrative Law Judge ordered respondents to submit to depositions and to answer the questions. Id. at *2-4.

Simply because the agents of Respondents were examined during the pre-complaint investigation does not preclude Complaint Counsel from taking the depositions of these individuals in accordance with Part III of the Commission's Rules of Practice. Although the Administrative Law Judge retains the discretion to limit discovery if it is unreasonably

cumulative or duplicative, and may enter a protective order to deny discovery to protect a party from annoyance, oppression or undue burden, or to prevent undue delay in the proceeding, 16 C.F.R. § § 3.31(c), 3.31(d), those circumstances are not present here.

IV.

Aventis' motion for a protective order seeks to preclude Complaint Counsel from taking the depositions of Spears and Stratemeier on the additional grounds that depositions of opposing counsel are disfavored and may be allowed only under limited circumstances. Complaint Counsel asserts that the Commission and federal courts have found it appropriate to allow depositions of opposing counsel where counsel played a material role in the facts underlying the litigation.

Judicial decisions and precedents under the Federal Rules of Civil Procedure concerning discovery motions, though not controlling, provide helpful guidance for resolving discovery disputes in Commission proceedings. L.G. Balfour Co., et al., 61 F.T.C. 1491, 1492, 1962 FTC LEXIS 367, *4 (Oct. 5, 1962), In re Int'l Ass'n of Conference Interpreters, 1995 FTC LEXIS 21, *17 (Jan. 24, 1995). Federal courts determining whether to permit the deposition of opposing counsel apply conflicting standards. See generally Sparton Corp. v. United States, 44 Fed. Cl. 557, 560 (Ct. Cl. 1999) (discussing conflicting cases). Compare Shelton v. American Motors Corp., 805 F.2d 1323, 1327 (8th Cir. 1986) (allowing the deposition of opposing counsel only "where the party seeking to take the deposition has shown that (1) no other means exist to obtain the information than to depose opposing counsel ...; (2) the information sought is relevant and nonprivileged; and (3) the information is crucial to the preparation of the case") with Johnston Dev. Group, Inc., et al. v. Carpenters Local Union No. 1578, et al., 130 F.R.D. 348, 353 (D.N.J. 1990) (blocking the deposition of opposing counsel only where the party opposing the deposition "establishes undue burden or oppression measured by (1) the relative quality of information in the attorney's knowledge, that is whether the deposition would be disproportional to the discovering party's needs, (2) the availability of the information from other sources that are less intrusive into the adversarial process; and (3) the harm to the party's representational rights of its

Regardless of which standard is used, nearly all courts recognize that the deposition of a party's attorney may be both necessary and appropriate when the attorney is a fact witness, such as an actor or a viewer. American Casualty Co. v. Krieger, et al., 160 F.R.D. 582, 588 (S.D. Cal 1995); N.F.A. Corp. v. Riverview Narrow Fabrics, Inc., 117 F.R.D. 83, 85-86 n.2 (M.D.N.C. 1987). "In cases where the attorney's conduct itself is the basis of a claim or defense, there is little doubt that the attorney may be examined as any other witness." Johnston Dev. Group, 130 F.R.D. at 352 (citing Jamison v. Miracle Mile Rambler, Inc., 536 F.2d 560 (3d Cir. 1976); Kalmanovitz v. G. Heileman Brewing Co., Inc., 610 F. Supp. 1319 (D. Del. 1985), aff'd. 769 F.2d also In re Tutu Water Wells Contamination Litig., 184 F.R.D. 598 (D. Del. 1973)). See protective order will not issue where the attorney's conduct is the basis for the claim or defense

or where the attorney observed or participated in the underlying transaction or occurrence giving rise to the cause of action."); Rainbow Investors Group, Inc. v. Fuji Trucolor, 168 F.R.D. 34, 38 (W.D. La. 1996) (denying motion for protective order where attorney played "key role" in negotiating the transaction at the heart of the underlying dispute).

In the present case, Aventis admits that "Stratemeier and Spears were involved, on behalf of Aventis, in the negotiation and drafting of the Stipulation and Agreement alleged in the Complaint as anticompetitive." Aventis Motion at 3. As actors or participants in the negotiation and drafting of the Stipulation and Agreement at issue, Spears and Stratemeier may be deposed. Inquiry shall be limited to relevant, non-privileged information.

It is hereby ORDERED that Respondents' motions for protective orders are denied.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Date: October 12, 2000





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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

RESPONDENT ANDRX'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO COMPEL DEPOSITION TESTIMONY OR TO PRECLUDE

Pursuant to § 3.38 of the Federal Trade Commission's Procedures and Rules of Practice, respondent Andrx Corporation ("Andrx") submits this memorandum in support of its motion for an order compelling the depositions of the specific FTC staff members who participated in discussions that Complaint Counsel has put into issue in this action. Alternatively, Complaint Counsel should be precluded from adducing evidence at trial concerning the subject matter of these discussions.

Preliminary Statement

Complaint Counsel has put in issue and has sought discovery on particular discussions between the FTC staff and Andrx's attorneys. Regardless, it has resisted providing reciprocal discovery on these very same discussions. Complaint Counsel's resistance is striking; in response to interrogatories propounded by Andrx at the inception of this proceeding, which sought, in essence, the details concerning Complaint Counsel's case, it never identified these discussions, and the time to supplement its responses has now passed. Andrx believes that delving into these

discussions is inappropriate. However, fundamental fairness dictates that if Andrx is required to provide discovery on these discussions, then Complaint Counsel should be similarly obliged. Alternatively, if Complaint Counsel does not provide this discovery, then they should be precluded at trial, as a matter of rudimentary due process, from offering evidence on this subject matter.

BACKGROUND

A. Complaint Counsel's Effort to Take <u>Discovery on it Pre-Complaint Discussions with Andrx</u>

In around May or June of 1999, the FTC staff initiated a telephone conference with counsel for Andrx. It is undisputed that FTC staff members Bradley Albert, Geoffrey Oliver, Robin Moore, Daniel Kotchen and Elizabeth Mullin were on the call. During that conversation, issues concerning the investigation were discussed. Complaint Counsel appears to be indicating that these discussions somehow had an impact on the then-ongoing negotiations between Andrx and HMR to settle the Florida Patent Action.

Complaint Counsel's intention to put these pre-complaint discussions into issue became evident when it propounded its first request for admissions just one month ago, on the last day to serve written discovery in this proceeding. Among the 146 separate requests, Complaint Counsel interposed several that directly relate to the May, 1999 discussion:

"Request No. 107: Admit that in May 1999 Federal Trade Commission (FTC) staff discussed with Andrx an outline for a proposed consent order relating to the FTC's investigation of Hoechst and Andrx, FTC file no. 981-0368.

Request No. 108: Admit that Hoechst and Andrx reached an agreement in principle on the HMR/Andrx Stipulation and Order

less than three weeks after the FTC staff discussed with Andrx an outline for a proposed consent order relating to the FTC's investigation of Hoechst and Andrx, FTC file no. 981-0368.

Request No. 109: Admit that the terms of the HMR/Andrx Stipulation and Order entered into by Hoechst and Andrx reflected at least some of the same terms proposed by the FTC staff when the FTC staff discussed their proposed consent order relating to the FTC's investigation of Hoechst and Andrx, FTC file no. 981-0368.

Request No. 112: Admit that Hoechst's outside legal counsel James M. Spiers believed that Hoechst and Andrx should enter into the HMR/Andrx stipulation and order because he understood that the FTC wanted the HMR/Andrx stipulation and agreement "ended in no uncertain terms."

(<u>See</u> Declaration of Jonathan D. Lupkin, dated October 24, 2000 ("Lupkin Decl."), Exhibit C at 19-20)

In addition, Complaint Counsel questioned Edward Stratemeier, HMR's General Counsel, concerning these same topics at his deposition. (Lupkin Decl., Exhibit D at 249-53.)

B. Andrx's Futile Attempt to Obtain Reciprocal Discovery

In light of Complaint Counsel's inquiries into these discussions, Andrx served a notice of deposition on Complaint Counsel, calling for the depositions of Bradley Albert, Geoffrey Oliver, Robin Moore, Daniel Kotchen and Elizabeth Mullin, the other participants in the conversation occurring in May or June of 1999. (Lupkin Decl., Exhibit. A). Andrx believes that the FTC may attempt to distort these discussions, arguing that they somehow affected the resolution of the underlying Florida Patent Action between HMR and Andrx. If fully developed, however, the record will be to the contrary, as evidence from the FTC staff who participated in the discussions will corroborate. Andrx wishes to make clear, though, that its depositions of these

individuals would be limited to questioning concerning the subject matter of these precomplaint discussions.

In response, Complaint Counsel summarily rejected Andrx's attempt to get bilateral discovery on this issue, wrapping itself once again in the "I am the government" defense -- a defense that Complaint Counsel apparently views as without limitation.

See Lupkin Decl., Exhibit B (letter from Complaint Counsel condemning the notice of deposition as "unprecedented" and "inappropriate" because "with the exception of Ms. Mullin, these individuals are Commission attorneys who worked on the investigation that led to the complaint and are currently serving as Complaint Counsel.")

ARGUMENT

I. THE FTC'S RULES OF PRACTICE CONTEMPLATE DISCOVERY OF COMPLAINT COUNSEL

Nothing in the FTC's Rules of Practice immunize Complaint Counsel from providing discovery. To the contrary, the rules explicitly contemplate discovery -- including depositions -- from Commission employees. See FTC Rule of Practice § 3.33(g)(ii)(permitting the use of a deposition, at trial, of "an official or employee . . . of the Commission by "an adverse party for any purpose"). Deposition discovery is particularly appropriate in circumstances such as this, where the Commission employees were participants in discussions that Complaint Counsel itself has put at issue.

II. COMPLAINT COUNSEL'S ATTEMPT TO TAKE DISCOVERY ON THE PRE-COMPLAINT DISCUSSIONS ENTITLES ANDRX TO RECIPROCAL DISCOVERY FROM COMPLAINT COUNSEL.

Complaint Counsel's refusal to provide the requested deposition is unfair and violates Andrx's right to due process. This is particularly so given that it was Complaint Counsel that first sought discovery concerning these discussions. Moreover, in its October 12, 2000 order, this Court has already ordered Louis Solomon, Scott Lodin, Andrx's General Counsel, Edward Stratemeirer, and James Spears to sit for depositions in this proceeding. (Lupkin Decl., Exhibit F). Presumably, Complaint Counsel will inquire of these witnesses concerning these pre-complaint discussions. But if Complaint Counsel insists upon this discovery and is permitted to pursue it by the Court, then fundamental fairness requires that Andrx be permitted to depose those FTC staff members who participated in these very discussions. Accord Wardius v. Oregon, 412 U.S. 470, 475 (1973) (discovery must be a "two-way street").

Alternatively, if Complaint Counsel refuses to tender these witnesses for deposition, then they should be precluded from offering evidence concerning these discussions at trial. In other contexts, this Court has recognized – and Complaint Counsel has acknowledged – that it will be precluded from offering testimony in areas that it has blocked deposition discovery. See Lupkin Decl., Exhibit E at 127 (Complaint Counsel "recogniz[ing] the problem if [the Biovail witness(es)] doesn't show up and make itself available, that we may very well face preclusion at the end of the day"). The same rationale in favor of preclusion applies equally here – indeed, more so since the witnesses whose testimony is sought are FTC employees.

CONCLUSION

For the foregoing reasons, Andrx respectfully requests that its motion be granted in its entirety.

Dated:New York, New York October 24, 2000

Respectfully Submitted,

SOLOMON, ZAUDERER, ELLENHORN,

FRISCHER & SHARP

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