UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

| | | |
|---|---|---|
| In the Matter of | ) | |
| HOECHST MARION ROUSSEL, INC., a corporation, | ) | |
| CARDERM CAPITAL, L.P., a limited partnership, | ) | Docket No. 9293 |
| and | ) | |
| ANDRX CORPORATION, a corporation. | ) | |

TO: The Honorable D. Michael Chappell
Administrative Law Judge

**SCHERING-PLOUGH CORPORATION'S MOTION TO QUASH**

Schering-Plough Corporation respectfully moves to quash subpoenas *duces tecum* and *ad testificandum* served on Key Pharmaceuticals, a division of Schering Corporation, by Respondent Andrx Corporation. As discussed in the Memorandum in Support submitted herewith, the subpoenas should be quashed for the following reasons:

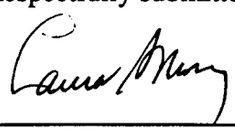
1. The information sought by the subpoenas is irrelevant to any material issue in this proceeding. Information relating to patent settlement agreements between Schering and any generic pharmaceutical company are not relevant to the claims and defenses here, which relate solely to an allegedly anticompetitive agreement between Hoechst and Andrx.

2. The information sought here is highly confidential and sensitive. Enforcement of the subpoenas thus would put into the hands of Schering's competitors highly confidential information about Schering's approach to dealing with its intellectual property disputes.

Moreover, nothing in the current protective order forecloses the possibility that parties in other ongoing proceedings could obtain access to the requested information.

3. Finally, the use in this proceeding of the information sought by the subpoenas will likely generate extensive, time consuming and distracting collateral litigation concerning, among other things, whether any settlement agreements by Schering and other companies are in fact "similar" to the Stipulation being challenged here, and whether such agreements are "common." Thus, even if "similar" patent settlements by other companies such as Schering had some conceivable relevance, the extraordinarily remote nature of any such relevance militates against permitting the discovery sought here.

Respectfully submitted,



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Attorneys for
Third Party Schering-Plough Corporation

Dated: August 24, 2000

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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| In the Matter of | ) | |
| HOECHST MARION ROUSSEL, INC., a corporation, | ) | |
| CARDERM CAPITAL, L.P., a limited partnership, | ) | Docket No. 9293 |
| and | ) | |
| ANDRX CORPORATION, a corporation. | ) | |

TO: The Honorable D. Michael Chappell
Administrative Law Judge

**ORDER GRANTING SCHERING-PLOUGH CORPORATION'S MOTION TO QUASH**

IT IS HEREBY ORDERED that Schering-Plough Corporation's Motion to Quash subpoenas issued to it by Andrx Corporation is hereby GRANTED; and those subpoenas are hereby quashed.

D. Michael Chappell
Administrative Law Judge

Date: _____, 2000

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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| In the Matter of | ) | |
| HOECHST MARION ROUSSEL, INC., a corporation, | ) | |
| CARDERM CAPITAL, L.P., a limited partnership, | ) | Docket No. 9293 |
| and | ) | |
| ANDRX CORPORATION, a corporation. | ) | |

TO: The Honorable D. Michael Chappell
Administrative Law Judge

**MEMORANDUM IN SUPPORT OF SCHERING-PLOUGH CORPORATION'S MOTION TO QUASH**

## I. INTRODUCTION

Schering-Plough Corporation, a third party to these proceedings, respectfully moves to quash the subpoenas served on it by Respondent Andrx Corporation.[1] The subpoenas seek from Schering a wide range of information relating to patent settlement agreements between Schering and any generic pharmaceutical company. This material is highly sensitive commercial information having no obvious relevance to these proceedings, which relate solely to a Stipulation among the Respondents in connection with litigation over Hoechst Marion Roussel, Inc.'s patent on extended-release diltiazem.

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[1] Copies of the subpoenas are attached as Exhibit A. The subpoenas are directed to Key Pharmaceuticals, which is a division of Schering Corporation. All are collectively referred to herein as "Schering."

Andrx apparently contends that patent settlements involving other pharmaceutical manufacturers such as Schering are relevant because they tend to show that agreements similar to the Stipulation at issue here are "common" in the industry, and Andrx is being unfairly and arbitrarily singled out by the Commission. *See* Answer of Andrx Corporation ("Andrx Ans.") ¶ 51. This "selective enforcement" defense has been rejected as legally baseless,[2] however and, discovery requests directed to proving this "defense" by demonstrating that other companies have engaged in similar conduct accordingly have been quashed as irrelevant. *See, e.g., In the Matter of Outdoor World Corp.,* Docket No. 9229, 1989 FTC LEXIS 142 (November 3, 1989).

The information sought by the subpoenas is highly confidential, and extremely sensitive. Given the extraordinarily remote relevance of the settlements to these proceedings, Schering should not be forced to turn them over to its competitors. Further, nothing in the protective order forecloses the possibility that discovery material, or information contained therein, will not be obtained by other third parties.

Finally, permitting Andrx to obtain discovery from other pharmaceutical manufacturers, such as Schering, in an effort to show they have entered agreements similar to the Stipulation would no doubt generate "mini-trials" in this proceeding over, among other things, whether each agreement is actually similar to the Stipulation in substance and in factual context, and whether agreements similar to the Stipulation are "common." Each of the Schering settlement agreements that would be responsive to the subpoena is significantly different from the Stipulation that is the subject of these proceedings. The terms and conditions of each stemmed from Schering's evaluation of the products at issue, the market involved, and the strength of the particular patent case. Given the extremely tenuous relevance of such agreements – even if "similar" – the Court should not permit Andrx to engage in third-party discovery that will mire this proceeding in time-consuming and distracting collateral litigation. Precedent exists for quashing subpoena

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2 *See In the Matter of Synchronal Corp.,* Docket No. 9251, 1992 FTC LEXIS 61 (March 5, 1992); *In the Matter of Rush-Hampton Indus., Inc.,* Docket No. 9167, 1984 FTC LEXIS 94 (April 8, 1984); *In the Matter of The Kroger Co.,* Docket No. 9102 C, 1977 FTC LEXIS 70 (October 18, 1977).

specifications under similar circumstances for precisely this reason. *In the Matter of Borg-Warner Corp.*, Docket No. 9120, 1979 FTC LEXIS 166 (October 19, 1979).

## II. FACTS

The subpoenas were served on Schering on August 8, 2000.[3] The original specifications of the subpoena *duces tecum* seek myriad documents relating to Schering's patent settlement agreements and license agreements involving payments to, or licensing agreements with, generic pharmaceutical manufacturers. *See* Exhibit A, specifications 1-5. The subpoena also seeks documents relating to any decision by Schering "to market or not market a pharmaceutical product in the context of an actual or threatened patent litigation." *Id.*, specification 6.

Counsel for Schering and Andrx had several conversations relating to Schering's objections to the production of the material sought by the subpoena. *See* Declaration of Jonathan Wasserman ("Wasserman Decl.") (Exhibit C) ¶ 4. Counsel for Andrx stated that the documents in which Andrx was chiefly interested in obtaining were agreements between Schering and generic pharmaceutical manufacturers in settlement of patent disputes involving Schering brand-name drugs.[4] (*Id.* ¶ 5.) Schering counsel expressed Schering's objections based on the highly sensitive and confidential nature of these agreements, and their lack of relevance to the proceedings involving Andrx and Hoechst. (*Id.* ¶ 6.) In particular, Schering counsel pointed out that each of the responsive agreements is substantially different from the Stipulation being challenged in this proceeding. (*Id.*) Despite the obvious differences among the agreements, Andrx has persisted in its demand that Schering produce the documents. (*Id.* ¶ 7.)

Andrx's counsel never proffered a satisfactory theory as to how the Schering agreements could possibly be relevant to the FTC's challenge to its agreement with Hoescht, even if they

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[3] Thus, under FTC Rules of Practice, Schering's motion to quash ordinarily would have been due on August 18, 2000. 16 C.F.R. § 3.34(c). However, Schering and Andrx stipulated to an extension of Schering's time to file a motion to quash until August 25, 2000. Letter from Hal S. Schaftel to Jonathon Wasserman, 8/14/00 (Exhibit B).

[4] Counsel for Andrx reserved Andrx's rights to pursue its requests for the other specified materials (Wasserman Decl. ¶ 5); and while Schering's motion addresses the settlement agreements themselves, its does not waive its rights to challenge any future efforts to obtain the remaining materials.

were to contain "similar" provisions. The only explanations given by Andrx counsel in conversations with Schering's counsel were that Andrx wants the agreements to prove that provisions similar to those in the Stipulation are common in the industry and that they are somehow relevant to a rule of reason analysis. (*Id.* ¶ 7.) Andrx's counsel presumably was hoping to obtain evidence to support the Twelfth Defense set forth in Andrx's answer. That defense alleges that restraints such as those found in the Stipulation are "typically found in agreements" between brand and generic companies, and thus the "FTC is acting unlawfully and arbitrarily in attempting to single out Andrx for challenge with respect to these commonplace provisions." (Andrx Ans. ¶ 51.)

This supposed "defense" by Andrx is currently subject to a fully-briefed and argued motion to strike filed by Complaint Counsel. Further, Complaint Counsel, in response to a similar request, has refused to produce documents relating to its investigations of other patent settlements between brand name and generic manufacturers on the ground that these documents are completely irrelevant to this proceeding. *See* Complaint Counsel's Opposition to Respondent's Motion to Compel, 6/23/00 (Exhibit D), at 21 ("The existence of, as well as the internal FTC analysis of, other patent settlements is irrelevant to whether Andrx and Hoechst violated the antitrust laws . . .").

In light of the irrelevance, confidentiality and sensitivity of Schering's patent settlement agreements, Schering has refused to produce them, and asks that the subpoena seeking them, as well as the subpoena for testimony related to them, be quashed.

## III. ARGUMENT

### A. The Subpoenas Seek Irrelevant Information

Parties are permitted to seek discovery in FTC proceedings only "to the extent that it may be reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defenses of any respondent." 16 C.F.R. § 3.31(c)(1). Thus, an FTC subpoena will be enforced only to the extent that the information sought is "reasonably relevant"

to the charges asserted in the complaint, or defenses thereto. *FTC v. Anderson,* 631 F.2d 741, 745-46 (D.C. Cir. 1979); *FTC v. Gibson Prods. of San Antonio,* 569 F.2d 900, 906 (5th Cir. 1978); *FTC v. Adams,* 296 F.2d 861, 866-67 (8th Cir. 1961) (in determining relevance of information sought by subpoena, "we must lay the specifications alongside the complaints"). The information Andrx seeks from Schering bears no reasonable relevance to any material issue in this proceeding.

Patent settlement agreements between Schering and generic pharmaceutical manufacturers, when viewed in the context of the allegations of the Complaint, have no relevance to the charges brought by the FTC. This proceeding involves a Stipulation between Hoechst and Andrx, entered into in during patent litigation regarding Hoechst's Cardizem CD and Andrx's generic extended-release diltiazem. (Complaint ¶¶ 17-18, 22-26.) The Complaint alleges that this agreement harmed competition in the market for once-a-day diltiazem, a calcium channel blocker medication for the treatment of hypertension and angina. (*Id.*)

None of the requested patent settlement agreements with generic manufacturers involves products in the relevant market. These agreements accordingly have no bearing on the effects the Hoechst-Andrx agreement may have had on competition in any potentially relevant market. These settlements involve different products, different patents, different markets, different competitors and potential competitors and different terms.

Nor is the material requested by Andrx reasonably relevant to any possible defense by Andrx. Andrx counsel has told counsel for Schering that it is seeking Schering's patent settlements with generic manufacturers as part of a strategy to demonstrate that provisions such as those in the Stipulation are "common" in the industry. (Wasserman Decl. ¶ 7.) And Andrx asserts as a defense in its Answer that the Stipulation's terms are "typically found in agreements" between brand-name and generic manufacturers and thus the "FTC is acting unlawfully and arbitrarily in attempting to single out Andrx for challenge with respect to these commonplace provisions." (Andrx Ans. ¶ 51 (Twelfth Defense).)

First, the Schering agreements would only be germane to such a "selective enforcement" defense if they in fact contained terms similar to those contained in the Hoechst-Andrx Stipulation. But even if any similarity existed, the "selective enforcement" defense has been stricken repeatedly in Commission proceedings as legally insufficient. *See In the Matter of Synchronal Corp.*, Docket No. 9251, 1992 FTC LEXIS 61 (March 5, 1992) ("That other competitors engaged in the same practices alleged in the Complaint is not a defense"); *In the Matter of Rush-Hampton Indus., Inc.*, Docket No. 9167, 1984 FTC LEXIS 94 (April 6, 1984) (striking selective enforcement defense because "[t]he fact that others engage or engaged in the same practices as alleged in the complaint is not a defense"); *In the Matter of The Kroger Co.*, Docket No. 9102 C, 1977 FTC LEXIS 70 (October 18, 1977) (striking selective enforcement defense because it "is insufficient as a matter of law").

Thus, the ALJ in *In the Matter of Outdoor World Corp.*, Docket No. 9229, 1989 FTC LEXIS 142 (November 3, 1989), quashed a subpoena in circumstances very similar to those present here. There, the respondent subpoenaed documents from the Commission's files relating to the operations of the respondent's competitors "in order to prove its affirmative defenses that it has been unfairly singled out from an industry where the practice alleged in the complaint is rampant." *Id.* The ALJ quashed the subpoena on relevance grounds, explaining as follows:

> This demand is irrelevant. Absent a patent abuse of discretion, the Commission may proceed against one party without acting against others similarly situated.

*Id.* (citing *FTC v. Universal-Rundle Corp.*, 387 U.S. 244, 250 (1967)).

Andrx's subpoenas demand equally irrelevant information. Even assuming any similarity in the terms of the agreements, the information would be irrelevant to any reasonably sustainable defense.

### B. The Highly Confidential And Sensitive Nature Of The Information Sought Weighs Against Its Production In This Proceeding

Each of the settlement agreements that would be responsive to the document subpoena is highly confidential. The terms upon which Schering has settled patent disputes with generic manufacturers is extremely sensitive information, which Schering would never voluntarily disclose outside the company, particularly to its competitors or to their lawyers.

Moreover, nothing in the protective order here would prevent Schering's patent settlement documents, as a result of having been turned over to Respondents, from being produced in other parallel proceedings pursuant to document requests there. The protective order only provides that if a party in possession of confidential documents is requested to produce such documents in another court proceeding, that party must notify the party that produced the confidential documents of the request. (Protective Order, 5/8/00, at ¶ 11.) Then the only recourse for the owner of the confidential documents is to attempt to block enforcement, within a relatively short time frame, of the document request in the proceeding in which it has been issued. (*Id.*)

The risks and burdens associated with disclosure of Schering's patent settlement documents far outweigh any conceivable relevance of such documents to this proceeding. If the subpoena is enforced, Schering's competitors will obtain highly sensitive competitive information regarding Schering's analysis and resolution of disputes involving its intellectual property. Moreover, there is a significant chance that the documents produced here will be the subject of discovery requests in other proceedings. In light of the (at most) marginal relevance of the information sought, the Court should decline to order Schering to subject itself to these risks.

### C. The Discovery Sought Would Generate Complicated And Distracting "Mini-Trials" With Little Or No Benefit

Even if the discovery Andrx seeks had some relevance to this case, any such relevance would be extraordinarily remote. To extract anything at all relevant from patent settlements

between other brand name and generic manufacturers, Andrx would first have to demonstrate that the agreements at issue are "similar" to the Stipulation in substance and factual context. This would require extensive, time consuming and distracting litigation concerning each settlement agreement Andrx wishes to use, which necessarily would focus on the terms of the agreement, the nature of the suit sought to be settled, the relative merits of the case, and the nature of the products and the relevant markets involved.[5] Andrx's "selective enforcement" theory would further require litigation concerning the propriety of the FTC's decision whether or not to proceed against each brand-generic settlement agreement. Thus, if permitted, the discovery sought by Andrx would open the floodgates to an exponential multiplication of these proceedings. In light of the (at most) extremely tenuous relevance of other settlement agreements to the issues here – even if those agreements were shown to be "similar" – this expansion of the proceedings is not justified.

An ALJ has, in quashing similar discovery requests, relied on concerns that discovery on tangentially-relevant issues would unreasonably multiply proceedings. *See, e.g., In the Matter of Borg-Warner Corp.*, Docket No. 9120, 1979 FTC LEXIS 166 (October 19, 1979). In *Borg-Warner*, the respondent had served a subpoena with a specification calling for certain information that was "at best marginally relevant." *Id.* at *7. The ALJ quashed the specification, finding that litigating the issue on which discovery was sought "would generate a number of collateral issues unduly delaying the proceeding." *Id.* Another set of specifications was found to "have at best peripheral relevance," and was quashed because "additional discovery on this point might well inject collateral issues into the proceeding prolonging the trial itself." *Id.* at *9.

The same problem is presented here. The relevance, if any, of the information Andrx seeks is remote, at best. The potential expansion of the proceedings that will result if Andrx is permitted to go down this path is substantial. The subpoenas accordingly should be quashed.

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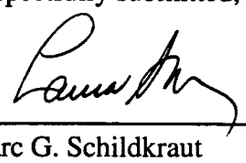
[5] Indeed, the determination whether agreements similar to the Stipulation are "common" would require virtually industry-wide discovery of pharmaceutical manufacturers. It would not be enough simply to demonstrate that one or two companies have entered similar arrangements.

## CONCLUSION

For the foregoing reasons, Schering respectfully requests that the subpoenas be quashed.

Respectfully submitted,



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(202) 783-0800

Attorneys for
Third Party Schering-Plough Corporation

Dated: August 24, 2000

## CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing Schering Plough Corporation's Motion to Quash, the Memorandum in Support thereof, and a Proposed Order, were served by Federal Express, this 24th day of August, 2000 upon each of the parties listed below:

Louis M. Solomon, Esq.
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Solomon, Zauderer, Ellenhorn,
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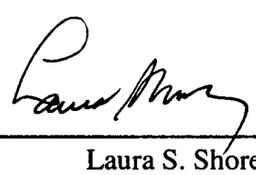


Laura S. Shores

# SUBPOENA DUCES TECUM

## Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

Key Pharmaceuticals
By one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf concerning the subject matter of this action and/or of the subject matter of the documents described in Exhibit A.
2000 Galloping Hill Rd.
Kenilworth, NJ 07033

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION

SOLOMON, ZAUDERER, ELLENHORN,
FRISCHER & SHARP
45 Rockefeller Plaza
New York, NY 10111
or at such other location as is mutually agreed upon.

4. MATERIAL WILL BE PRODUCED TO Notary Public (at the request of Respondent Andrx Corporation)

5. DATE AND TIME OF PRODUCTION OR INSPECTION

**Aug. 29, 2000 at 10:30 a.m.**

6. SUBJECT OF PROCEEDING

In the matter of Hoechst Marion Roussel, Inc., et al.

7. MATERIAL TO BE PRODUCED

**See Exhibit A**

8. ADMINISTRATIVE LAW JUDGE

The Honorable D. Michael Chappell

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

SOLOMON, ZAUDERER, ELLENHORN,
FRISCHER & SHARP
45 Rockefeller Plaza, 7th Floor
New York, NY 10111

Attorneys for Respondent Andrx Corporation

DATE ISSUED

26 JUN 2000

SECRETARY'S SIGNATURE

Donald S. Clark

## GENERAL INSTRUCTIONS

### APPEARANCE

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

### MOTION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any motion to limit or quash this subpoena be filed within the earlier of 10 days after service or the time for compliance. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission, accompanied by an affidavit of service of the document upon counsel listed in Item 9, and upon all other parties prescribed by the Rules of Practice.

### TRAVEL EXPENSES

The Commission's Rules of Practice require that fees and mileage be paid by the party that requested your appearance. You should present your claim to counsel listed in Item 9 for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from counsel listed in Item 9.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

**EXHIBIT A**

1. All documents sufficient to identify each settlement or partial settlement of patent litigation, concerning which your Company is aware, involving an innovator or brand name pharmaceutical company, and a generic company, that involved any form of:

(a) payment from the brand name company to the generic company; or

(b) licensing and/or royalty arrangement between the brand name company and the generic company.

2. All operative agreements involved in the settlements or partial settlements referenced in Request No. 1 above, together with any analyses of any such agreements.

3. Copies of all Licensing Agreements and Joint Development Agreements to which your Company is or was a party, that involved any form of:

(a) payment from the brand name company to the generic company; or

(b) licensing and/or royalty arrangement between the brand name company and the generic company.

4. All documents relating to any agreements or contracts between you and Upsher-Smith Laboratories, Inc. concerning or relating to K-Dur.

5. All communications and documents which relate to communications between the Company and the FTC concerning any of the agreements referenced in Requests Nos. 1-4 above.

6. Documents concerning any decision, by your Company or any other, to market or not market a pharmaceutical product in the context of an actual or threatened patent litigation with respect to that product.

## DEFINITIONS AND INSTRUCTIONS

1. Unless otherwise stated, the requests herein refer to the time period of January 1, 1992 through present.

2. As used herein, the words "you" or "your," "your Company," or "the Company" shall mean the individual and/or entity to whom this subpoena was directed, and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of your present or former officers, directors, employees, agents, controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.

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

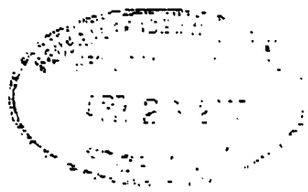
4. Except for privileged materials, produce each responsive document in its entirety by including all attachments and all pages, regardless of whether they directly relate to the specified subject matter. Submit any appendix, table, or other attachment by either physically attaching it to the responsive document or clearly marking it to indicate the responsive document to which it corresponds. Except for privileged material, do not mask, cut, expunge, edit, or delete any responsive document or portion thereof in any manner.

5. As used herein, the connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope.

6. The response to each document production request is to be numbered in a manner consistent with these requests and is to be preceded by the specific request.

7. If any form of privilege or immunity is claimed as a ground for withholding a response, submit a written statement that describes the factual basis of the purported privilege or claim of immunity in sufficient detail to permit the court to adjudicate the validity of the claim.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION



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| In the Matter of<br><br>HOECHST MARION ROUSSEL, INC.,<br>a corporation,<br><br>CARDERM CAPITAL L.P.,<br>a limited partnership,<br><br>and<br><br>ANDRX CORPORATION,<br>a corporation. | Docket No. 9293 |

**PROTECTIVE ORDER GOVERNING DISCOVERY MATERIAL**

For the purpose of protecting the interests of the parties and third parties in the above-captioned matter (the "Matter") against improper use and disclosure of confidential information submitted or produced in connection with this Matter:

IT IS HEREBY ORDERED THAT this Protective Order Governing Confidential Material ("Protective Order") shall govern the handling of all Discovery Material, as hereafter defined.

DEFINITIONS

1. "Matter" means the matter captioned *In the Matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corporation*, Docket Number 9293, pending before the Federal Trade Commission, and all subsequent appellate or other review proceedings related thereto.

2. "Commission" or "FTC" means the Federal Trade Commission, or any of its employees, agents, attorneys, and all other persons acting or purporting to act on its behalf,

excluding persons retained as consultants or experts for purposes of this Matter.

3. "HMR" means Aventis Pharmaceuticals Inc., formerly known as Hoechst Marion Roussel, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at Parsippany, New Jersey.

4. "Carderm" means Carderm Capital L.P., a limited partnership organized, existing, and doing business under and by virtue of the laws of the Delaware, with its office and principal place of business located at Hamilton, Bermuda.

5. "Andrx" means Andrx Corporation, a corporation organized, existing, and doing business under and by virtue of the laws of the State of Florida, with its office and principal place of business located at Fort Lauderdale, Florida.

6. "Party" means either the FTC, HMR, Carderm or Andrx.

7. "Respondents" means HMR, Carderm and Andrx.

8. "Outside Counsel" means the law firm(s) that is/are counsel of record for Respondents in this Matter and its/their associated attorneys; persons regularly employed by such law firm(s) (including legal assistants, clerical staff, and information management personnel) and temporary personnel retained by such law firm(s) to perform legal or clerical duties, or to provide logistical litigation support with regard to this Matter; provided that any attorney associated with Outside Counsel shall not be a director, officer or employee of Respondents. The term Outside Counsel does not include persons retained as consultants or experts for the purposes of this Matter.

9. "Producing Party" means a Party or Third Party that produced or intends to produce Confidential Discovery Material to any of the Parties. For purposes of Confidential Discovery Material of a Third Party that either is in the possession, custody or control of the FTC or has been produced by the FTC in this Matter, the Producing Party shall mean the Third Party that originally provided the Confidential Discovery Material to the FTC. The Producing Party shall also mean the FTC for purposes of any document or material prepared by, or on behalf of the FTC.

10. "Third Party" means any natural person, partnership, corporation, association, or other legal entity not named as a party to this Matter -- including without limitation Biovail Corporation ("Biovail") and Faulding Inc. ("Faulding") -- and their employees, directors, officers, attorneys and agents.

11. "Expert/Consultant" means experts or other persons who are retained to assist complaint counsel or Respondents' counsel in preparation for trial or to give testimony at trial.

12. "Document" means the complete original or a true, correct and complete copy and any non-identical copies of any written or graphic matter, no matter how produced, recorded, stored or reproduced, including, but not limited to, any writing, letter, envelope, telegraph meeting minute, memorandum statement, affidavit, declaration, book, record, survey, map, study, handwritten note, working paper, chart, index, tabulation, graph, tape, data sheet, data processing card, printout, microfilm, index, computer readable media or other electronically stored data, appointment book, diary, diary entry, calendar, desk pad, telephone message slip, note of interview or communication or any other data compilation, including all drafts of all such documents. "Document" also includes every writing, drawing, graph, chart, photograph, phono

record, tape and other data compilations from which information can be obtained, and includes all drafts and all copies of every such writing or record that contain any commentary, notes, or marking whatsoever not appearing on the original.

13. "Discovery Material" includes without limitation deposition testimony, deposition exhibits, interrogatory responses, admissions, affidavits, declarations, documents produced pursuant to compulsory process or voluntarily in lieu thereof, and any other documents or information produced or given to one Party by another Party or by a Third Party in connection with discovery in this Matter.

14. "Confidential Discovery Material" means all Discovery Material that is designated by a Producing Party as confidential and that is covered by Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. § 46(f), and Commission Rule of Practice § 4.10(a)(2), 16 C.F.R. § 4.10(a)(2); submitted to the FTC pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. § 18a, or formal interpretations or rules promulgated thereunder, 16 C.F.R. Part 800; or Section 26(c)(7) of the Federal Rules of Civil Procedure and precedents thereunder. Confidential Discovery Material shall include non-public commercial information, the disclosure of which to Respondent or Third Parties would cause substantial commercial harm or personal embarrassment to the disclosing party. The following is a non-exhaustive list of examples of information that likely will qualify for treatment as Confidential Discovery Material: strategic plans (involving pricing, marketing, research and development, product roadmaps, corporate alliances, or mergers and acquisitions) that have not been fully implemented or revealed to the public; trade secrets; customer-specific evaluations or data (e.g., prices, volumes, or revenues); personnel files and evaluations; information subject to

confidentiality or non-disclosure agreements; proprietary technical or engineering information; proprietary financial data or projections; and proprietary consumer, customer or market research or analyses applicable to current or future market conditions, the disclosure of which could reveal Confidential Discovery Material.

TERMS AND CONDITIONS OF PROTECTIVE ORDER

1. Discovery Material, or information derived therefrom, shall be used solely by the Parties for purposes of this Matter, and shall not be used for any other purpose, including without limitation any business or commercial purpose. The Parties, in conducting discovery from Third Parties, shall attach to such discovery requests a copy of this Protective Order and a cover letter that will apprise such Third Parties of their rights hereunder.

2. Discovery Material may be designated as Confidential Discovery Material by Producing Parties by placing on or affixing, in such manner as will not interfere with the legibility thereof, the notation "CONFIDENTIAL - FTC Docket No. 9293" (or other similar notation containing a reference to this Matter) to the first page of a document containing such Confidential Discovery Material, or, by Parties by instructing the court reporter to denote each page of a transcript containing such Confidential Discovery Material as "Confidential." Such designations shall be made within fourteen (14) days from the initial production or deposition and constitute a good-faith representation by counsel for the Party or Third Party making the designations that the document constitutes or contains "Confidential Discovery Material."

3. To the extent any such material is made part of this proceeding, all documents heretofore obtained by compulsory process or voluntarily from any Party, regardless of whether

designated confidential by the Party, and transcripts of any investigational hearings, interviews and depositions, which were obtained during the pre-complaint stage of this Matter shall be treated as Confidential Discovery Material. Material previously produced by Respondents and designated as a "Confidential," regardless of whether such materials have been marked in accordance with paragraph 2 above, shall be treated as Confidential Discovery Material as provided herein. The material referred to in this paragraph shall only be available for use in this proceeding once an independent basis has been demonstrated for such use.

4. Confidential Discovery Material shall not, directly or indirectly, be disclosed or otherwise provided to anyone except, in accordance with paragraphs 5 and 6, to:

(a) complaint counsel and the Commission, as permitted by the Commission's Rules of Practice;

(b) Outside Counsel;

(c) Experts/Consultants;

(d) witnesses or deponents at trial or deposition;

(e) the Administrative Law Judge and personnel assisting him;

(f) court reporters and deposition transcript reporters;

(g) judges and other court personnel of any court having jurisdiction over any appeal proceedings involving this Matter; and

(h) any author or recipient of Confidential Discovery Material (as indicated on the face of the document, record or material), and any individual who was in the direct chain of supervision of the author at the time the Confidential Discovery Material was created or received.

5. In addition to the above-designated persons, certain named designated

individuals and in-house counsel not to exceed two attorneys per corporate party who do not have day to day business responsibilities shall be provided with access on the condition that each such in-house counsel or designated executive signs a declaration in the form attached hereto as Exhibit "A," which is incorporated herein by reference. For Respondent Carderm, the designated individual is Stephan Petri. For Respondent HMR, the designated individual is Edward Stratemeier, Vice President and General Counsel. For Respondent Andrx, the designated individual is Scott Lodin, Vice President and General Counsel.

6. Confidential Discovery Material shall not, directly or indirectly, be disclosed or otherwise provided to an Expert/Consultant unless such Expert/Consultant agrees in writing:

(a) to maintain such Confidential Discovery Material in separate locked room(s) or locked cabinet(s) when such Confidential Discovery Material is not being reviewed;

(b) to return such Confidential Discovery Material to complaint counsel or Respondent's Outside Counsel, as appropriate, upon the conclusion of the Expert/Consultant's assignment or retention;

(c) to not disclose such Confidential Discovery Material to anyone, except as permitted by the Protective Order; and

(d) to use such Confidential Discovery Material and the information contained therein solely for the purpose of rendering consulting services to a Party to this Matter, including providing testimony in judicial or administrative proceedings arising out of this Matter.

7. This paragraph governs the procedures for the following specified disclosures and challenges to designations of confidentiality.

(a) Disclosure to Experts

If any Party desires to disclose Confidential Discovery Material to any expert who may testify, who is not an FTC employee, and who may have interests in the pharmaceutical industry beyond their employment as an expert in this Matter, the disclosing Party shall notify the Producing Party of its desire to disclose such material. Such notice shall identify the specific expert who may testify to whom the Confidential Discovery Material is to be disclosed. Such identification shall include, but not be limited to, the full name and professional address and/or affiliation of the proposed expert who may testify, and a current curriculum vitae of such expert identifying all other present and prior employers and/or firms in the pharmaceutical industry for which or on behalf of which the identified expert has been employed or done consulting work in the preceding four (4) years. The Producing Party may object to the disclosure of the Confidential Discovery Material within five (5) business days of receiving notice of an intent to disclose the Confidential Discovery Material to the identified expert by providing the disclosing Party with a written statement of the reasons for the objection. If the Producing Party timely objects, the disclosing Party shall not disclose the Confidential Discovery Material to the identified expert, absent a written agreement with the Producing Party or order of the Administrative Law Judge. The Producing Party lodging an objection and the disclosing Party shall meet and confer in good faith in an attempt to determine the terms of disclosure to the identified expert. If at the end of five (5) business days of negotiating the parties have not resolved their differences or if counsel determine in good faith that negotiations have failed, the disclosing Party may make written application to the Administrative Law Judge as provided by paragraph 7(c) of this Protective Order. If the Producing Party does not object to the disclosure of Confidential Discovery Material to the identified expert within five (5) business days, the

disclosing Party may disclose the Confidential Discovery Material to the identified expert.

(b) Challenges to Confidentiality Designations

If any Party seeks to challenge a Producing Party's designation of material as Confidential Discovery Material or any other restriction contained within this Protective Order, the challenging Party shall notify the Producing Party and all Parties of the challenge to such designation. Such notice shall identify with specificity (i.e., by document control numbers, deposition transcript page and line reference, or other means sufficient to locate easily such materials) the designation being challenged. The Producing Party may preserve its designation within five (5) business days of receiving notice of the confidentiality challenge by providing the challenging Party and all Parties with a written statement of the reasons for the designation. If the Producing Party timely preserves its rights, the Parties shall continue to treat the challenged material as Confidential Discovery Material, absent a written agreement with the Producing Party or order of the Administrative Law Judge. The Producing Party preserving its rights and the challenging Party shall meet and confer in good faith in an attempt to negotiate changes to any challenged designation. If at the end of five (5) business days of negotiating the parties have not resolved their differences or if counsel determine in good faith that negotiations have failed, the challenging Party may make written application to the Administrative Law Judge as provided by paragraph 7(c) of this Protective Order. If the Producing Party does not preserve its rights within five (5) business days, the challenging Party may alter the designation as contained in the notice. The challenging Party shall notify the Producing Party and the other Party of any changes in confidentiality designations.

Regardless of confidential designation, copies of published magazine or

newspaper articles, and excerpts from published books and public documents filed with the Securities and Exchange Commission may be used by any Party without reference to the procedures of this subparagraph.

(c) Resolution of Disclosure or Confidentiality Disputes

If negotiations under subparagraphs 7(a)-(b) of this Protective Order have failed to resolve the issues, a Party seeking to disclose Confidential Discovery Material or challenging a confidentiality designation or any other restriction contained within this Protective Order may make written application to the Administrative Law Judge for relief. Such application shall be served on the Producing Party and the other Party, and be accompanied by a certification that the meet and confer obligations of this paragraph have been met, but that good faith negotiations have failed to resolve outstanding issues. The Producing Party and any other Party shall have five (5) business days to respond to the application, which time may be extended by the Administrative Law Judge. While an application is pending, the Parties shall maintain the pre-application status of the Confidential Discovery Material. Nothing in this Protective Order shall create a presumption or alter the burden of persuading the Administrative Law Judge of the propriety of a requested disclosure or change in designation.

8. Confidential Discovery Material shall not be disclosed to any person described in subparagraphs 4(b), 4(c) and 4(d) and paragraph 5 of this Protective Order until such person has executed and transmitted to Respondent's counsel or complaint counsel, as the case may be, a declaration or declarations, as applicable, in the form attached hereto as Exhibit "A," which is incorporated herein by reference. Respondents' counsel and complaint counsel shall maintain a file of all such declarations for the duration of the litigation. Confidential Discovery Material

shall not be copied or reproduced for use in this Matter except to the extent such copying or reproduction is reasonably necessary to the conduct of this Matter, and all such copies or reproductions shall be subject to the terms of this Protective Order. If the duplication process by which copies or reproductions of Confidential Discovery Material are made does not preserve the confidentiality designations that appear on the original documents, all such copies or reproductions shall be stamped "CONFIDENTIAL - FTC Docket No. 9293."

9. The Parties shall not be obligated to challenge the propriety of any designation or treatment of information as confidential and the failure to do so promptly shall not preclude any subsequent objection to such designation or treatment, or any motion seeking permission to disclose such material to persons not referred to in paragraphs 4 and 5 above. If Confidential Discovery Material is produced without the legend attached, such document shall be treated as Confidential from the time the Producing Party advises complaint counsel and Respondents' counsel in writing that such material should be so designated and provides all the Parties with an appropriately labeled replacement. The Parties shall return promptly or destroy the unmarked documents.

10. If the FTC: (a) receives a discovery request that may require the disclosure by it of a Third Party's Confidential Discovery Material; or (b) intends to or is required to disclose, voluntarily or involuntarily, a Third Party's Confidential Discovery Material (whether or not such disclosure is in response to a discovery request), the FTC promptly shall notify the Third Party of either receipt of such request or its intention to disclose such material. Such notification shall be in writing and, if not otherwise done, sent for receipt by the Third Party at least five (5) business days before production, and shall include a copy of this Protective Order and a cover letter that

will apprise the Third Party of its rights hereunder.

11. If anyone receives a discovery request in another proceeding that may require the disclosure of a Producing Party's Confidential Discovery Material, the subpoena recipient promptly shall notify the Producing Party of receipt of such request. Such notification shall be in writing and, if not otherwise done, sent for receipt by the Producing Party at least five (5) business days before production, and shall include a copy of this Protective Order and a cover letter that will apprise the Producing Party of its rights hereunder. The Producing Party shall be solely responsible for asserting any objection to the requested production. Nothing herein shall be construed as requiring the subpoena recipient or anyone else covered by this Order to challenge or appeal any such order requiring production of Confidential Discovery Material, or to subject itself to any penalties for noncompliance with any such order, or to seek any relief from the Administrative Law Judge or the Commission.

12. This Order governs the disclosure of information during the course of discovery and does not constitute an *in camera* order as provided in Section 3.45 of the Commission's Rules of Practice ("Rule"), 16 C.F.R. § 3.45.

13. (a) The Commission's Rules of Practice require that material may not be withheld from the public record unless it falls within the scope of an order by the Administrative Law Judge that such material, or portions thereof, be placed *in camera*. 16 C.F.R. § 3.45(b) and (d). To comply with this rule, the Party seeking to introduce into evidence by filing a pleading, an exhibit thereto, or otherwise placing on the record Confidential Discovery Material ("filing Party") must first obtain an order by the Administrative Law Judge that such information has been granted *in camera* status.

An application for *in camera* treatment must: (1) specifically identify or describe the materials for which *in camera* treatment is sought; (2) provide reasons for granting such materials *in camera* status; (3) specify the time period for which *in camera* treatment is sought for each document; and (4) attach as exhibits to the application the documents containing the specific information for which *in camera* treatment is sought.

A blanket *in camera* order for an entire pleading is contrary to public policy and will not be granted. The parties must specifically identify the portions of a pleading, document, deposition transcript, or exhibit for which *in camera* treatment is sought. Entire documents or exhibits will rarely, if ever, be eligible for *in camera* treatment. The parties are reminded that Rule 3.45 places the burden of showing that public disclosure will likely result in a clearly defined, serious injury upon the person requesting *in camera* treatment. In addition, to sustain the burden of proof, an application must be supported by proper evidence, such as affidavits, to support all factual issues. See 16 C.F.R. § 3.43.

(b) The Scheduling Order requires the parties to file motions to request *in camera* treatment of materials marked confidential pursuant to a protective order no later than September 1, 2000.

A Party that has produced materials or information that it reasonably expects to include in a pleading, motion, exhibit or other paper to be filed with the Secretary ("pleading") and that it believes meets the standards for *in camera* treatment must file a motion with the Administrative Law Judge to request *in camera* treatment of such materials no later than September 1, 2000.

A Party that has received materials or information from another Party or a

Third Party that it reasonably expects to include in a pleading must provide the opposing Party or Third Party with a list of such materials no later than August 18, 2000. A Third Party shall be provided with a copy of this Order along with such list. This list will not be filed with the Secretary's Office, but must be served on the Administrative Law Judge.

(c) If any Party seeks to introduce into evidence, by filing a pleading or otherwise placing on the record, information which includes its own Confidential Discovery Material which has not previously been granted *in camera* status, and the Party seeks to prevent its own materials or information from being placed on the public record, at least 10 days prior to filing such pleading, -- unless it is impracticable (e.g., when filing a response or reply brief) in which case at least 5 days prior to filing such pleading -- the Party shall make an application to the Administrative Law Judge to request that such materials or information be treated as *in camera* information.

If any Party seeks to introduce into evidence, by filing a pleading or otherwise placing on the record, information which includes another Party's Confidential Discovery Material which has not previously been granted *in camera* status, the filing Party must notify the other Party's counsel at least 14 days prior to such proposed filing -- unless it is impracticable (e.g., when filing a response or reply brief). If 14 days advance notice cannot be provided, the other Party's counsel must be notified as soon as possible and prior to the time of introduction of such documents or information. The Producing Party's counsel shall have 7 days from the date of notice to make an application to the Administrative Law Judge to request that such materials be treated as *in camera* information. The parties shall not file pleadings or attachments thereto that contain another Party's Confidential Discovery Material unless the Party

seeking to introduce such material has first obtained an *in camera* order or certifies that the other Party has been given proper notice prior to the introduction of such material.

The parties shall not file pleadings or attachments thereto that contain a Third Party's Confidential Discovery Material unless the Party seeking to introduce such material has first obtained an *in camera* order or certifies that the Third Party has been given 14 days notice prior to the introduction of such material and a copy of this Order.

(d) The parties are cautioned that compliance with this Order will require them to submit applications for *in camera* treatment in advance of filing motions which include confidential materials and that deadlines for filing motions attaching confidential materials will not be extended for failure to file applications for *in camera* treatment in a timely manner. The parties are further cautioned that it is rarely necessary to attach confidential information in support of pleadings. Absent strict adherence to these procedures, pleadings should be composed in a manner which sufficiently apprises the Court of the matter at issue and which does not identify or disclose any confidential information. Failure to comply with these procedures may result in pleadings or portions thereof being stricken from the record.

14. Nothing in this Protective Order shall be construed to conflict with the provisions of Sections 6, 10, and 21 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 50, 57b-2, or with Rules 3.22, 3.45 or 4.11(b)-(e), 16 C.F.R. §§ 3.22, 3.45 and 4.11(b)-(e).[1] Any Party or Producing Party may move at any time for, treatment *in camera* of any Confidential

[1] The right of the Administrative Law Judge, the Commission, and reviewing courts to disclose information afforded *in camera* treatment or Confidential Discovery Material, to the extent necessary for proper disposition of the proceeding, is specifically reserved pursuant to Rule 3.45, 16 C.F.R. § 3.45.

Discovery Material or any portion of the proceedings in this Matter to the extent necessary for proper disposition of the Matter.

15. At the conclusion of this Matter, Respondent's counsel shall return to the Producing Party, or destroy, all originals and copies of documents and all notes, memoranda, or other papers containing Confidential Discovery Material which have not been made part of the record in this Matter. Complaint counsel shall dispose of all documents in accordance with Rule 4.12, 16 C.F.R. § 4.12.

16. The provisions of this Protective Order, insofar as they restrict the communication and use of Confidential Discovery Material shall, without written permission of the Producing Party or further order of the Administrative Law Judge hearing this Matter, continue to be binding after the conclusion of this Matter.

17. This Protective Order shall not apply to the disclosure by a Producing Party or its Counsel of such Producing Party's Confidential Discovery Material to such Producing Party's employees, agents, former employees, board members, directors, and officers.

18. The production or disclosure of any Discovery Material made after entry of this Protective Order which a Producing Party claims was inadvertent and should not have been produced or disclosed because of a privilege will not automatically be deemed to be a waiver of any privilege to which the Producing Party would have been entitled had the privileged Discovery Material not inadvertently been produced or disclosed. In the event of such claimed inadvertent production or disclosure, the following procedures shall be followed:

(a) The Producing Party may request the return of any such Discovery Material within twenty (20) days of discovering that it was inadvertently produced or disclosed

(or inadvertently produced or disclosed without redacting the privileged content). A request for the return of any Discovery Material shall identify the specific Discovery Material and the basis for asserting that the specific Discovery Material (or portions thereof) is subject to the attorney-client privilege or the work product doctrine and the date of discovery that there had been an inadvertent production or disclosure.

(b) If a Producing Party requests the return, pursuant to this paragraph, of any such Discovery Material from another Party, the Party to whom the request is made shall return immediately to the Producing Party all copies of the Discovery Material within its possession, custody, or control – including all copies in the possession of experts, consultants, or others to whom the Discovery Material was provided – unless the Party asked to return the Discovery Material in good faith reasonably believes that the Discovery Material is not privileged. Such good faith belief shall be based on either (i) a facial review of the Discovery Material, or (ii) the inadequacy of any explanations provided by the Producing Party, and shall not be based on an argument that production or disclosure of the Discovery Material waived any privilege. In the event that only portions of the Discovery Material contain privileged subject matter, the Producing Party shall substitute a redacted version of the Discovery Material at the time of making the request for the return of the requested Discovery Material.

(c) Should the Party contesting the request to return the Discovery Material pursuant to this paragraph decline to return the Discovery Material, the Producing Party seeking return of the Discovery Material may thereafter move for an order compelling the return of the Discovery Material. In any such motion, the Producing Party shall have the burden of showing that the Discovery Material is privileged and that the production was inadvertent.

19. Entry of the foregoing Protective Order is without prejudice to the right of the Parties to apply for further protective orders or for modification of any provision of this Protective Order.

ORDERED.

D. Michael Chappell
Administrative Law Judge

Dated: April 28, 2000

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

**EXHIBIT A**

| | |
|---|---|
| In the Matter of<br><br>HOECHST MARION ROUSSEL, INC.,<br>a corporation,<br><br>CARDERM CAPITAL L.P.,<br>a limited partnership,<br><br>and<br><br>ANDRX CORPORATION,<br>a corporation. | Docket No. 9293 |

**DECLARATION CONCERNING PROTECTIVE ORDER GOVERNING DISCOVERY MATERIAL**

I, [NAME], hereby declare and certify the following to be true:

1. [Statement of employment]

2. I have read the "Protective Order Governing Discovery Material" ("Protective Order") issued by Administrative Law Judge D. Michael Chappell on April 28, 2000, in connection with the above captioned matter. I understand the restrictions on my use of any Confidential Discovery Material (as this term is used in the Protective Order) in this action and I agree to abide by the Protective Order.

3. I understand that the restrictions on my use of such Confidential Discovery Material include:

a. that I will use such Confidential Discovery Material only for the purposes of preparing for this proceedings, and hearing(s) and any appeal of this proceeding and for no other purpose;

b. that I will not disclose such Confidential Discovery Material to anyone, except as permitted by the Protective Order; and

c. that upon the termination of my participation in this proceeding I will promptly return all Confidential Discovery Material, and all notes, memoranda, or other papers containing Confidential Discovery Material, to complaint counsel or respondent's counsel, as appropriate.

[4. I understand that if I am receiving Confidential Discovery Material as an Expert/Consultant, as that term is defined in this Protective Order, the restrictions on my use of Confidential Discovery Material also include the duty and obligation.

a. to maintain such Confidential Discovery Material in separate locked room(s) or locked cabinet(s) when such Confidential Discovery Material is not being reviewed;

b. to return such Confidential Discovery Material to complaint counsel or Respondent's Outside Counsel, as appropriate, upon the conclusion of my assignment or retention; and

c. to use such Confidential Discovery Material and the information contained therein solely for the purpose of rendering consulting services to a Party to this Matter, including providing testimony in judicial or administrative proceedings arising out of this Matter.]

5 I am fully aware that, pursuant to Section 3.42(h) of the Commission's Rules of Practice, 16 C.F.R. § 3.42(h), my failure to comply with the terms of the Protective Order may constitute contempt of the Commission and may subject me to sanctions imposed by the Commission.

_____ Date: _____

Full Name [Typed or Printed]

_____

Signature

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

| | |
|---|---|
| In the Matter of<br><br>HOECHST MARION ROUSSEL, INC.,<br>a corporation,<br><br>CARDERM CAPITAL L.P.,<br>a limited partnership,<br><br>and<br><br>ANDRX CORPORATION,<br>a corporation. | Docket No. 9293 |

**ORDER AMENDING PROTECTIVE ORDER GOVERNING DISCOVERY MATERIAL**

Upon consideration of Complaint Counsel's Motion to Amend Protective Order Governing Discovery Material, Respondents' counsels' opposition thereto, and arguments of counsel, IT IS HEREBY ORDERED that Complaint Counsel's motion is GRANTED, only as herein specified, and that Paragraphs 3 and 19 of the Terms and Conditions of the Protective Order Governing Discovery Material, entered in this matter on April 28, 2000, be amended as follows:

3. To the extent any such material is made part of this proceeding, all documents heretofore obtained by compulsory process or voluntarily from any Party or Third Party, regardless of whether designated confidential by the Party or Third Party, and transcripts of any

investigational hearings, interviews and depositions, which were obtained during the pre-complaint stage of this Matter shall be treated as Confidential Discovery Material. Material previously produced by Respondents or a Third Party, and designated as "Confidential," regardless of whether such materials have been marked in accordance with paragraph 2 above, shall be treated as Confidential Discovery Material as provided herein. The material referred to in this paragraph shall only be available for use in this proceeding once an independent basis has been demonstrated for such use.

19. Entry of the foregoing Protective Order is without prejudice to the right of the Parties or Third Parties to apply for further protective orders or for modification of any provision of this Protective Order.

Except as expressly stated herein the remainder of the Protective Order Governing Discovery Material dated April 28, 2000, shall remain in effect.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Dated: May 8, 2000

# SUBPOENA AD TESTIFICANDUM

## Issued Pursuant to Rule 3.34(c)(1), 16 C.F.R. § 3.34(c)(1) (1997)

1. TO

Key Pharmaceuticals
By one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf concerning the subject matter of this action and/or of the subject matter of the documents described in Exhibit A.
2000 Galloping Hill Rd.
Kenilworth, NJ 07033

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

This subpoena requires you to appear and give testimony, at the date and time specified in Item 5, at the request of Counsel listed in Item 8, in the proceeding described in Item 6.

3. PLACE OF HEARING

SOLOMON, ZAUDERER, ELLENHORN, FRISCHER & SHARP
45 Rockefeller Plaza
New York, NY 10111
or at such other location as is mutually agreed upon.

4. YOUR APPEARANCE WILL BE BEFORE

Notary Public
(at the request of Respondent Andrx Corporation)

5. DATE AND TIME OF HEARING OR DEPOSITION

Aug. 29, 2000 at 10:30 a.m.

LAW DEPARTMENT

AUG 08 2000

6. SUBJECT OF PROCEEDING

In the matter of Hoechst Marion Roussel, Inc., et al.

7. ADMINISTRATIVE LAW JUDGE

The Honorable D. Michael Chappell

Federal Trade Commission
Washington, D.C. 20580

8. COUNSEL REQUESTING SUBPOENA

SOLOMON, ZAUDERER, ELLENHORN, FRISCHER & SHARP
45 Rockefeller Plaza, 7th Floor
New York, NY 10111

Attorneys for Respondent Andrx Corporation

DATE ISSUED

8 AUG 2000

SECRETARY'S SIGNATURE

Donald S. Clark

### GENERAL INSTRUCTIONS

**APPEARANCE**

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

**MOTION TO LIMIT OR QUASH**

The Commission's Rules of Practice require that any motion to limit or quash this subpoena be filed within the earlier of 10 days after service or the time for compliance. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission, accompanied by an affidavit of service of the document upon counsel listed in Item 8, and upon all other parties prescribed by the Rules of Practice.

**TRAVEL EXPENSES**

The Commission's Rules of Practice require that fees and mileage be paid by the party that requested your appearance. You should present your claim to Counsel listed in Item 8 for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from Counsel listed in Item 8.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

**EXHIBIT A**

1. All documents sufficient to identify each settlement or partial settlement of patent litigation, concerning which your Company is aware, involving an innovator or brand name pharmaceutical company, and a generic company, that involved any form of:

(a) payment from the brand name company to the generic company: or

(b) licensing and/or royalty arrangement between the brand name company and the generic company.

2. All operative agreements involved in the settlements or partial settlements referenced in Request No. 1 above, together with any analyses of any such agreements.

3. Copies of all Licensing Agreements and Joint Development Agreements to which your Company is or was a party, that involved any form of:

(a) payment from the brand name company to the generic company; or

(b) licensing and/or royalty arrangement between the brand name company and the generic company.

4. All documents relating to any agreements or contracts between you and Upsher-Smith Laboratories, Inc. concerning or relating to K-Dur.

5. All communications and documents which relate to communications between the Company and the FTC concerning any of the agreements referenced in Requests Nos. 1-4 above.

6. Documents concerning any decision, by your Company or any other, to market or not market a pharmaceutical product in the context of an actual or threatened patent litigation with respect to that product.

## DEFINITIONS AND INSTRUCTIONS

1. Unless otherwise stated, the requests herein refer to the time period of January 1, 1992 through present.

2. As used herein, the words "you" or "your," "your Company," or "the Company" shall mean the individual and/or entity to whom this subpoena was directed, and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of your present or former officers, directors, employees, agents, controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.

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

4. Except for privileged materials, produce each responsive document in its entirety by including all attachments and all pages, regardless of whether they directly relate to the specified subject matter. Submit any appendix, table, or other attachment by either physically attaching it to the responsive document or clearly marking it to indicate the responsive document to which it corresponds. Except for privileged material, do not mask, cut, expunge, edit, or delete any responsive document or portion thereof in any manner.

5. As used herein, the connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope.

6. The response to each document production request is to be numbered in a manner consistent with these requests and is to be preceded by the specific request.

7. If any form of privilege or immunity is claimed as a ground for withholding a response, submit a written statement that describes the factual basis of the purported privilege or claim of immunity in sufficient detail to permit the court to adjudicate the validity of the claim.

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August 14, 2000

**VIA FACSIMILE**

John Wasserman, Esq.
Key Pharmaceuticals
2000 Galloping Hill Rd.
Kenilworth, NJ 07033

Re: In re Hoechst Marion Roussel, Inc. et al. (FTC Docket No. 9293)

Dear Mr. Wasserman:

This is to confirm our agreement that Key Pharmaceuticals has until Friday, August 25, 2000 to move or respond to the subpoenas served upon it by Andrx; provided, however, that no objection will be raised to service-related issues.

If you have any questions, please do not hesitate to call.

Very truly yours,

Hal S. Shaftel

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

| | | |
|---|---|---|
| In the Matter of | ) | |
| HOECHST MARION ROUSSEL, INC., a corporation, | ) | |
| CARDERM CAPITAL, L.P., a limited partnership, | ) | Docket No. 9293 |
| and | ) | |
| ANDRX CORPORATION, a corporation. | ) | |

TO: The Honorable D. Michael Chappell
Administrative Law Judge

**DECLARATION AND STATEMENT OF JONATHAN WASSERMAN PURSUANT TO 16 C.F.R. § 3.22(f)**

I, Jonathan Wasserman, hereby declare as follows:

1. I am an attorney licensed to practice in the state of New Jersey. I am currently employed as Senior Counsel, Antitrust, in the Law Department of Schering-Plough Corporation ("Schering") in Kenilworth, New Jersey.

2. I make this declaration in support of Schering's Motion to Quash and to comply with the rule requiring a statement in accordance with 16 C.F.R. § 3.22(f).

3. On August 8, 2000, Schering was served with subpoenas *duces tecum* and *ad testificandum* issued by Andrx Corporation. The subpoenas seek documents and testimony relating to certain settlement agreements entered into by Schering with generic pharmaceutical manufacturers.

4. On August 14 and August 16 or 17, 2000, I had substantive telephone conversations with counsel for Andrx about the materials sought by the subpoena. In these conversations, I communicated Schering's objections to producing the materials sought.

5. Counsel for Andrx, while reserving Andrx's rights to pursue its requests for all of the specified materials, stated that Andrx was chiefly interested in obtaining copies of agreements between Schering and generic pharmaceutical manufacturers in settlement of patent disputes involving Schering brand-name drugs.

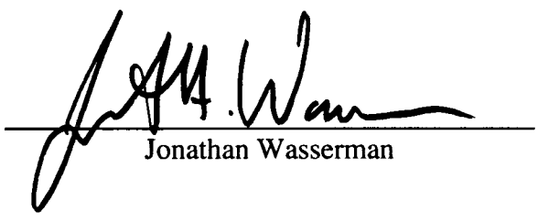
6. On behalf of Schering, I objected to production of the agreements based on their highly confidential nature and their lack of relevance to these proceedings. I explained that each of the potentially responsive agreements with which I was familiar is substantially different from the Stipulation being challenged in the above-captioned proceeding.

7. Counsel for Andrx took the position that the agreements were nonetheless relevant to these proceedings, in that they might show that provisions similar to those in the Stipulation are common in agreements settling patent disputes in the industry. Counsel for Andrx also stated that they would be relevant to a rule of reason analysis. Counsel for Andrx thus persisted in its demand for the documents, and I continued to voice Schering's objections to producing them.

8. I have accordingly conferred with opposing counsel in a good faith effort to resolve by agreement the issues raised in Schering's motion to quash. Counsel were unable to reach such an agreement.

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

Executed this 23d day of August, 2000.



Jonathan Wasserman