### UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

In the Matter of

HOECHST MARION ROUSEL, INC., a corporation,

CARDERM CAPITAL L.P., a limited partnership,

and

ANDRX CORPORATION, a corporation.



Docket No. 9293

ELAN PHARMACEUTICALS, INC.'S MOTION TO QUASH THIRD-PARTY SUBPOENAS BY ANDRX CORPORATION

Pursuant to Rule 3.34(c) of the Federal Trade Commission's Rules of Practice, Elan Pharmaceuticals, Inc. hereby moves to quash the third-party subpoenas served on it by Andrx Corporation. The grounds for this motion are set forth in the attached Memorandum in Support of Motion to Quash.

Dated: September 11, 2000

New York, New York

CAHZIL GORDON & REINDEL

Laurence T. Sorkin (LS 3906) Joel Kurtzberg (JK 1552)

80 Pine Street

New York, New York 10005

(212) 701-3000

Attorneys for Elan Pharmaceuticals, Inc.

# UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

In the Matter of

HOECHST MARION ROUSEL, INC.,
a corporation,

CARDERM CAPITAL L.P.,
a limited partnership,
and

ANDRX CORPORATION,
a corporation.

ORDER GRANTING ELAN PHARMACEUTICALS, INC.'S MOTION TO QUASH THIRD-PARTY SUBPOENAS BY ANDRX CORPORATION

IT IS HEREBY ORDERED that Elan Pharmaceuticals,

Inc.'s motion to quash third-party subpoenas by Andrx Corporation is GRANTED.

D. Michael Chappell Administrative Law Judge

Dated: September \_\_\_, 2000

# UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

In the Matter of :

HOECHST MARION ROUSEL, INC., a corporation,

CARDERM CAPITAL L.P., : Docket No. 9293 a limited partnership, :

and

ANDRX CORPORATION, a corporation.

MEMORANDUM OF ELAN PHARMACEUTICALS, INC. IN SUPPORT OF MOTION TO QUASH THIRD-PARTY SUBPOENAS BY ANDRX CORPORATION

Elan Pharmaceuticals, Inc. ("Elan Inc."), a thirdparty to these proceedings, moves to quash the subpoenas served
on it by Andrx Corporation ("Andrx") in this case for the following reasons:

- All of the requests for information relate either to matters irrelevant to the allegations of the complaint in this matter or to defenses that are invalid as a matter of law;
- The subpoenas impermissibly attempt to define the term "Company" so broadly as to include documents solely in the possession, custody or control of Elan Inc.'s Irish parent company, Elan Corporation, PLC, without properly complying with the service requirements of Irish law; and
- The confidential nature of the information sought by Andrx weighs heavily against its production in this proceeding.

#### FACTS

The FTC has instituted this action against Andrx and Hoechst Marion Rousel ("Hoechst"), alleging that various agreements entered into between Andrx and Hoechst in connection with patent litigation concerning Hoechst's brand name hypertension drug, Cardizem CD, and Andrx's generic bioequivalent, violate the antitrust laws. Elan Inc., a Delaware corporation with its principal place of business in California, is not a party to this action and has no involvement in the market for antihypertension drugs, Cardizem CD or any of its generic bioequivalents. In fact, as a drug research company devoted to the discovery, development and marketing of new therapeutic products principally for pain management and neurological disorders such as Alzheimer's disease, Elan Inc. makes no drug products, branded or generic, that compete with Cardizem CD. Elan Inc. is not a manufacturer of generic drugs and does not hold any ANDA's for any drug product. It has never licensed any of its products to a generic drug manufacturer, and it has never been a party to any patent litigation involving a generic drug. Elan Inc. is a wholly owned subsidiary of Elan Corporation, PLC ("Elan PLC"), an Irish corporation.

Andrx has served two third-party subpoenas on Elan

Inc. -- one seeking the production of documents and the other a

deposition 1 -- concerning documents and communications relating to patent settlement agreements and license agreements entered into not only by Elan Inc., but by its Irish parent, Elan PLC, and any other entity, regardless of country of incorporation, controlled by Elan PLC. The subpoenas purport to be addressed to "the Company," which is defined so broadly as to include Elan Inc.'s Irish parent:

"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 [Elan Inc.] 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."

Exhibit A, Definition and Instruction No. 2.

Elan Inc. has objected to producing documents in the possession, custody or control of Elan PLC because the subpoenas seek irrelevant information and because Elan PLC has not been served with the subpoenas in accordance with Irish law.

Despite this, Andrx's counsel has persisted in its requests for documents from both Elan Inc. and Elan PLC.

The subpoena served on Elan Inc. seeks six categories of documents:

The two subpoenas were served on Elan Inc. on August 21, 2000 and are attached hereto as Exhibit A.

Request No. 1. All documents sufficient to identify each settlement or partial settlement of patent litigation which your Company has entered into 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.<sup>2</sup>

Elan Inc. has never been a party to any patent litigation between a brand-name pharmaceutical company and a generic company, and has never entered into a settlement or partial settlement of any such litigation.

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

This request is vague and ambiguous, as it fails to define the key term "operative agreements." In any event, it does not add anything to Request No. 1 as modified.

Request No. 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 arrangements between the brand name company and the generic company.

This request is also vague, ambiguous and overbroad.

The key terms "Licensing Agreements" and "Joint Development

Agreements" -- both of which are capitalized as if they were

Request No. 1 of the subpoena was modified pursuant to an August 25, 2000 letter from Laurence T. Sorkin to Hal Shaftel, which is attached hereto as Exhibit B.

defined terms -- are not defined. Moreover, the terms "brand name company" and "generic company" are also undefined and their meaning is by no means clear in this context. The request also appears to be directed at agreements that are wholly unrelated to patent litigation and have absolutely no connection to this case. In any event, based on our best understanding of this unintelligible request, Elan Inc. has not entered into any such agreements.

Request No. 4. All documents relating to any agreements or contracts between you and Biovail Corporation concerning or relating to Adalat.

Elan Inc. has not entered into any such agreements or contracts with Biovail Corporation. Nor would any such agreements have any relevance to this proceeding.

Request No. 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.

Elan Inc. has not had any communications with the FTC concerning any agreements covered by Requests Nos. 1-4. In any event, any such communications with the FTC would be both irrelevant to this proceeding and confidential as the subject of a non-public investigation.

Request No. 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.

Elan Inc. has no documents responsive to this request.

### ARGUMENT

I. The Subpoenas Seek Documents Which Are Either Irrelevant To This Proceeding Or Which Relate To Defenses Which Are Invalid As A Matter Of Law

Under FTC rules, parties may 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, a subpoena issued in an FTC proceeding is invalid if the requested information is not "reasonably relevant" to the allegations of the complaint or to any valid defenses. See Linde Thomson Langworthy Kohn & Van Dyke, P.C. v. Resolution Trust Corporation, 5 F.3d 1508, 1516 (D.C. Cir. 1993); FTC v. Invention Submission Corp., 965 F.2d 1086, 1089 (D.C. Cir. 1992), cert. denied, 507 U.S. 910 (1993); FTC v. Anderson, 631 F.2d 741, 745 (D.C. Cir. 1979). Andrx's subpoenas should be quashed because they seek information from Elan Inc. that is plainly irrelevant to both the charges in this case and any valid defenses.

Not a single one of Andrx's document requests deals with the subject matter of this litigation -- namely, the allegation that Andrx's agreements with Hoechst harmed competition in the market for Cardizem CD and its generic equivalent.

Rather, all of the requests deal with patent settlement agreements and other agreements entered into by Elan Inc. -- or, more accurately, its foreign parent Elan PLC -- that have no obvious relevance to the allegations in this case. None of the requested documents involve products in the relevant market.

Nor are any of Andrx's requests directed toward information that is "reasonably relevant" to any valid defense in this action. Andrx's requests appear to be designed to support Andrx's twelfth affirmative defense in this case -- namely, that the "FTC is acting unlawfully and arbitrarily in attempting to single out Andrx for challenge with respect to the[] commonplace provisions [of the Andrx-Hoechst agreements]." Andrx Answer ¶ 51. But this "selective enforcement" defense -which is the subject of a pending motion to strike by Complaint Counsel -- has been emphatically rejected by the U.S. Supreme Court as invalid as a matter of law in Commission proceedings. See, e.g., FTC v. Universal-Rundle Corp., 387 U.S. 244, 249-50 (1967) ("[A]lthough an allegedly illegal practice may appear to be operative throughout an industry," the Commission's discretionary judgment about who to prosecute within the industry cannot be overturned "in the absence of a patent abuse of discretion"); Moog Industries, Inc. v. FTC, 355 U.S. 411, 413 (1958), rehearing denied, 356 U.S. 905 (1958) (even if an allegedly illegal practice is operative throughout an industry "whether all firms in the industry should be dealt with in a single proceeding or should receive individualized treatment

are questions that call for discretionary determination by the administrative agency").

Not surprisingly then, the Commission has routinely quashed requests for documents that relate to such defenses. For instance, in In the Matter of Outdoor World Corporation, Docket No. 9229, 1989 FTC LEXIS 142 (November 3, 1989), a subpoena requesting documents needed "to prove . . . affirmative defenses that [the Respondent] has been unfairly singled out from an industry where the practice alleged in the complaint is rampant" was quashed on the ground that the demand was "irrelevant" in light of the legal insufficiency of the selective enforcement defense. Id. at \*2. For the same reasons, the Commission has also repeatedly stricken selective enforcement defenses from the pleadings when asked to do so. See, e.g., In the Matter of Synchronal Corporation, Docket No. 9251, 1992 FTC LEXIS 61 at \*2 (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 Industries, Inc., Docket No. 9167, 1984 FTC LEXIS 94 at \*2 (April 6, 1984) (same); In the Matter of The Kroger Company, Docket No. 9102 C, 1977 FTC LEXIS 70 at \*3 (October 18, 1977) (defense of selective enforcement is "insufficient as a matter of law").

In any event, even if a selective enforcement defense were legally cognizable -- which it is not -- the requested agreements would not be relevant to such a defense unless they

contained terms that were in fact similar to the Andrx-Hoechst agreements. To entertain this defense would thus invite a series of protracted, collateral litigations concerning the similarity of each settlement agreement Andrx claims to be comparable to the Andrx-Hoechst agreements. The prospect of litigating such collateral issues alone is sufficient reason to reject such discovery requests now. See, e.g., In the Matter of

Volkswagen of America, Inc., FTC Docket No. 9154, (March 12, 1985) (discovery concerning collateral matters prohibited); In the Matter of Borg-Warner Corp., Docket No. 9120, 1979 FTC

LEXIS 166 (October 19, 1979) (quashing request for discovery that would generate "a number of collateral issues unduly delaying the proceeding").

Moreover, the agreements and documents requested by Andrx bear no relation to any rule of reason defense that it may attempt to assert in this case. The rule of reason requires courts to weigh the procompetitive effects of the agreement at issue with the anticompetitive effects in the market in question. The agreements Andrx seeks to discover of have no bearing on the market for Cardizem CD and its generic equiva-

At least one court in a related proceeding has already found rule of reason analysis inapplicable to Andrx's agreement with Hoechst, finding that the agreement constitutes a per se violation of the antitrust laws. See In reCardizem CD Antitrust Litigation, 105 F. Supp.2d 692 (E.D. Mich. 2000).

lent and say nothing about the effects that the Andrx-Hoechst agreement may have had on competition in that market. As such, they are irrelevant to any rule of reason analysis in this case.

II. The Subpoenas Impermissibly Seek Documents That Are Solely In The Possession, Custody Or Control Of Elan PLC Without Complying With The Service Requirements Of Irish Law

As noted above, the subpoenas were served on Elan Inc., a Delaware corporation with its principal place of business in California. Not only does Elan Inc. have no direct involvement with the market for Cardizem CD, but it also has never been a party to any of the agreements Andrx seeks in order to establish its irrelevant defense of selective enforcement. The only documents potentially responsive to Andrx's requests pertain to documents in the possession of Elan Inc.'s parent company, Elan PLC.

Elan PLC is an Irish corporation. It has not been served with either subpoena. However, Andrx, by defining the term "Company" in the subpoenas so broadly, 4 seeks the production not only of documents in the possession, custody, and control of Elan Inc., but also those in the possession, custody, and control of the foreign parent company, Elan PLC. Such a

See page 3 above.

reading of the subpoenas is an affront to Irish sovereignty and violates principles of both international and U.S. law.

As this court has recently noted in this case in its July 14, 2000 Order granting Biovail's motion to quash a subpoena that failed to comply with Canadian law, a subpoena issued by an administrative agency of the United States must not violate international law. See FTC v. Compagnie de Saint-Gobain-Pont-A-Mousson, 636 F.2d 1300, 1304 (D.C. Cir. 1980). Andrx's attempt to assert jurisdiction over Elan PLC without complying with Ireland's laws regarding service of process is nothing short of an impermissible attempt to circumvent Irish law pertaining to service of process on Irish companies. Andrx cannot, consistent with the ruling in Saint-Gobain, seek to obtain documents in the possession of an Irish company by mailing a copy of the subpoena to a subsidiary located in California. Accordingly, Elan Inc. moves to limit the definition of "Company" in the subpoenas so that the only documents required to be produced are those in the possession, custody or control of Elan Inc.

III. The Confidential Nature Of The Information Sought By Andrx's Subpoenas Weighs Heavily Against Its Production In This Proceeding

Even assuming, <u>arguendo</u>, that the subpoenas could properly reach documents in the possession, custody or control of Elan PLC, the subpoenas should nonetheless be quashed be-

cause they seek highly sensitive and confidential business information from a direct competitor.

Parties seeking disclosure of confidential information typically must make a strong showing that the information sought is relevant and that there is a specific need for the documents in order to prepare for trial. Blue Cross and Blue Shield of Missouri v. Anderson, 897 S.W.2d 167, 170 (Mo. Ct. App. 1995); Hartley Pen Co. v. U.S. District Court for the Southern District of California, Central Division, 287 F.2d 324, 328-31 (9th Cir. 1961), cert. denied, 375 U.S. 945 (1963); Duplan Corp. v. Deering Milliken Inc., 397 F. Supp. 1146, 1186 (D. S.C. 1974) (requiring a "clear showing that the documents are relevant to the issues involved"). In this case, no such showing has been made. Any claim of relevance is dubious at best and would be outweighed by the highly sensitive and confidential nature of the materials sought.

Moreover, courts have been particularly reluctant to force third-parties to a litigation to disclose confidential information to their competitors. See Berrie v. Berrie, 457 A.2d 76, 82 (N.J. Super. 1983) ("As to business records, courts have been most reluctant to force a nonparty competitor to divulge confidential information."); United States v. Serta Associates, Inc., 29 F.R.D. 136, 138 (N.D. Ill. 1961). The fact that Andrx competes directly with Elan PLC therefore further militates in favor of quashing the subpoenas.

In light of the lack of relevance of the documents in question, these confidentiality concerns weigh even more heavily in favor of quashing the subpoenas. The fact that there is a protective order presently in place does not warrant a different outcome. "A protective order is not a substitute for establishing relevance or need." Micro Motion, Inc. v. Kane Steel Co., Inc., 894 F.2d 1318, 1325 (Fed. Cir. 1990). Moreover, there is nothing in the current protective order that would prevent parties in other ongoing proceedings from obtaining access to any confidential documents turned over to Andrx in this proceeding.

### CONCLUSION

Andrx's subpoenas should be quashed because they (1) relate to matters that are irrelevant to the allegations of the complaint in this matter and are not related to any valid defenses, (2) impermissibly seek discovery of documents solely in the possession, custody or control of Elan Inc.'s foreign parent in violation of international, Irish, and U.S. law, and (3) request that highly confidential and sensitive information be disclosed to a competitor without an adequate showing of need.

Dated: September 11, 2000 New York, New York

CAHILL GORDON & REINDEL

Laurence T. Sorkin (LS 3906)

Joel Kurtzberg (JK 1552)

80 Pine Street

New York, New York 10005

(212) 701-3000

Attorneys for Elan Pharmaceuticals, Inc.

### CERTIFICATE OF SERVICE

I, Joel Kurtzberg, hereby certify that on September 11, 2000, I caused a copy of Elan Pharmaceuticals, Inc.'s Motion to Quash Third-Party Subpoenas by Andrx Corporation to be served upon the following persons by hand:

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

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

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

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

James M. Spears, Esq. Shook, Hardy & Bacon, L.L.P. 801 Pennsylvania Avenue, N.W. Suite 800 Washington, D.C. 20004

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

Joel Kurtzbe

# UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

In the Matter of

HOECHST MARION ROUSEL, INC.,
a corporation,

CARDERM CAPITAL L.P.,
a limited partnership,

and

ANDRX CORPORATION,
a corporation.

### STATEMENT PURSUANT TO RULE 3.22(f)

I am a partner in the law firm of Cahill Gordon & Reindel, counsel for Elan Pharmaceuticals, Inc. ("Elan Inc.") and submit this statement pursuant to Rule 3.22(f) of the Federal Trade Commission's Rules of Practice in connection with Elan Inc.'s motion to quash subpoenas served on it by Andrx Corporation ("Andrx"). On August 24 and September 6, 2000, I spoke with Hal Shaftel of Solomon, Zauderer, Ellenhorn, Frischer, & Sharp, counsel for Andrx, in a good faith effort to resolve by agreement the issues raised by Elan Inc.'s motion to quash.

Mr. Shaftel agreed to modify Request No. 1 of the subpoena, but we were not able to reach agreement as to objections I raised regarding the lack of relevance of Andrx's requests and whether the subpoenas could properly reach Elan Inc.'s foreign parent company. Mr. Shaftel said that he was particularly interested

in patent settlement agreements entered into by Elan Inc. and Elan Corporation PLC and that he would call me back to identify the particular agreements he was seeking. Because he has not called me back as of this date, and because we have been unable to resolve our differences, Elan Inc. has filed the attached motion to quash.

Dated: September 11, 2000 New York, New York

CAHIII GORDON & BEINDEL

Laurence T. Sorkin (LS 3906)

80 Pine Street

New York, New York 10005

(212) 701-3000

Attorneys for Elan Pharmaceuticals, Inc.



# SUBPOENA AD TESTIFICANDUM

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

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UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subposts requires you to oppose and give testimony, of the date and time specified in Item 5. It the request of Council listed in Item 8, in the proceeding described in Item 6.

3. PLACE OF HEARING GIRSON, DUNN & CRUTCHER, LLP One Montgomery Tower, 26th Floor San Francisco. CA 94104

or at such order location as is makeally threed

4. YOUR APPEARANCE WILL BE BEFORE
Notary Poblin
(as the request of Respondent
Andra Corporation)

5. DATE AND TIME OF HEARING OR DEPOSITION

September 13, 2000 at 10:30 a.m.

A. SUBJECT OF PROCEEDING

In the maner of Hoechst Marion Ropssel, Inc., et al.

7. ADMINISTRATIVE LAW JUDGE

The Honorable D. Michael Chappell

Federal Track Commission Washington, D.C. 20580

B. COUNSEL REGUESTING SUBPOENA

SOLOMON. ZAUDERER, ELLENHORN. FRISCHER & SHARP 45 Rockefeller Plaza, 7<sup>th</sup> Floor New York, NY 10111

Attorneys for Respondent Andre Corporation

DATE ISSUED

SECRET ARY'S SIGNATURE

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GENERAL INSTRUCTIONS

### APPEARANCE

The delivery of this subpoend 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 follow to comply.

### MOTION TO LIMIT OR GUASH

The Commission's Rules of Practice require that any motion to limit or quash this subposed be filled within the earlier of 10 abys after service or the time for compliance. The original and ten copies of the petition must be filled with the Secretary of the petition must be filled with the Secretary of the Federal Trade Commission, accompanied by an afficient for service of the document upon counsel listed in Item 6, 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 and by the party that requested your appearance. You should present your admit to Coursel listed in Item 6 for payment. If you are permanently or temporarily living somewhere other than the address on this subposera and it would require excessive travel for you to appear, you must get prior approval from Course listed in Item 8.

This subpoend does not require approval by CMB under the Paperwork Reduction Act of 1980.

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

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500 Cateway Boulevard South San Francisco, CA 94080 2 FROM

# UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoend requires you to produce and permit inspection and copying of assignated books, documents (as defined in Rule 3.34(b)), or tangete things - or to permit inspection of premises - at the case and time specified in Item 5, of the request of Coursel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION

GIBSON, DUNN & CRUTCHER, 11P One Montgomery Tower, 26th Floor San Francisco, CA 94104

or at tuch other location at is institutily appeared upon Attention: Joel S. Sanders. Esq. 128-393-8200

4. MATERIAL WILL BE PRODUCED TO Housey Public (as the request of Respondent Andra Corporation)

5. DATE AND TIME OF PRODUCTION OR INSPECTION

September 13, 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 SUBPOEMA

SCLOMON, ZAUDERER, ELLENHORN, FRISCHER & SHARP 45 Rockeleller Plaza, 7th Floor New York, NY 10111

Alterneys for Respondent Andre Corporation

DATE ISSUED

SECRET ARY'S SIGNATURE

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GENERAL INSTRUCTIONS

### APPEARANCE

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

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The Commission's Rules of Practice require that tees and mileage be paid by the party that requested your oppearable. You should present your dain to coursel listed in them 9 for payment. If you are permanently or temporarily living somewhere ather than the cooress on this suppoend and it would require excessive travel for you to appear, you must get pile approval from counsel listed in them 9.

This subpoend abes not require approval by CMB under the Paperwork Reduction Act of 1980

## RETURN OF SERVICE

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## 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 Biovail Corporation concerning or relating to Adalak
- 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 us 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 subpoend 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 maner. 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

SION

In the Matter of

HOECHST MARION ROUSSEL. INC., a corporation.

CARDERM CAPITAL L.P., a limited partnership,

and

ANDRX CORPORATION.

a comporation

Docket No. 9295

### PROTECTIVE ORDER GOVERNING DISCOVERY MATERIAL.

For the purpose of protecting the interests of the parties and third parties in the abovecaptioned 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 Motter of Hoechst Morion

  Roussel, Inc., Carderm Capital L.P., and Andre 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, automeys, and all other persons acting or purporting to act on its behalf,

- 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 restimony 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.

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.

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. 6.4.10(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

- 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 bereunder.
- 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 mittal 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

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 Counsti;
  - (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 Andre, 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 Parry 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 Parry 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 in 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 at 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 Parry 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 after 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 subperagraphs 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 linigation. 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."

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 our 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

- 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 rise 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. 6.3.45.
- 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 comera. 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 comera status.

An application for in comera treatment must: (1) specifically identify or describe the materials for which in comera treatment is sought. (2) provide reasons for granting such materials in comera status; (3) specify the time period for which in comera treatment is sought for each document, and (4) attach as exhibits to the application the documents containing the specific information for which in comera 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 vamera treatment of materials marked confidential pursuant to a protective order no later than <u>September</u>
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 comera 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 of Third Party with a list of such materials no later than <u>August 18, 2000</u>. 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.

or otherwise placing on the record, information which mediades its own Confidential Discovery Material which has not previously been granted in comern 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 think 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

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 comerci information. The parties shall not file pleadings or attachments thereto that contain another Party's Confidential Discovery Material unless the Party

sceking to introduce such material has first obtained an in comero 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 camero* 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 Orger

(d) The parties are cautioned that compliance with this Order will require them to submit applications for in comera 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 comera 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). Any Party or Producing Party may move at any time for, treatment an camera of any Confidential

The right of the Administrative Law Judge, the Commission, and reviewing courts to disclose information afforded in comera 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
- 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 madvertent 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

for inadvertently produced or disclosed without reducting 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 inagiverent 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 uniess 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 madequacy 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 thereefter 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 Juage

Dated: April 28, 2000

## UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

#### EXRIBIT A

In the Maner of

HOECHST MARION ROUSSEL, INC., a corporation,

Docket No 9293

CARDERM CAPITAL L.P. a limited partnership.

and

ANDRX CORPORATION, a corporation.

## DECLARATION CONCERNING PROTECTIVE ORDER GOVERNING DISCOVERY MATERIAL

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

- [Statement of employment]
- 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 Comfidential 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 maimain 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

Commission	
	Date:
Full Name [Typed or Printed]	
Signature	•

## UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION



In the Matter of	<b>ý</b> .	•
	)	
HOECHST MARION ROUSSEL, INC.,	}	
a corporation,	)	
	)	
CARDERM CAPITAL L.P.	j	
a limited partnership,	j	Docker No. 9293
	i	
and	í	
	<b>`</b>	
ANTIDO CODDOD ATION	,	
ANDRX CORPORATION,	)	
a corporation	)	
	)	

# 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, emered in this matter on April 25, 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 precomplaint 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

### GAHILL GORDON & REINDEL

### EIGHTY PINE STREET

NEW YORK, N.Y. 10005-1702

FLOYD ABRAMS L. HOWARD ADAMS ROBERT & ALESSI ROGER ANDRUS HELENE R. BANKS MICHAEL A BECKER SUSAN BUCKLEY KEVIN J. BURKE P. KEVIN CASTEL JAMES J. CLARK BENJAMIN J. COHEN W. LESLIE DUFFY RICHARD E FARLEY PATRICIA FARREN JOAN MURTAGH FRANKEL BART FRIEDMAN CIRO A GAMBONI WILLIAM B. GANNETT CHARLES A GILMAN STEPHEN A GREENE ROBERT M. HALLMAN WILLIAM M. HARTNETT CRAIG M. HOROWITZ DAVID G. JANUSZEWSKI THOMAS J. KAVALER LAWRENCE A KOBRIN IMMANUEL KOHN EDWARD P. KRUGMAN GEOFFREY E LIEBMANN WILLIAM T. LIFLAND

MICHAEL MACRIS JONATHAN L MARK GERARD M. MEISTRELL ROGER MELTZER CLIFFORD L MICHEL MICHAEL E MICHETTI JOHN P. MITCHELL ATHY A MOBILIA DONALD J. MULVIHILL KENNETH W. ORCE ROY L REGOZIN DEAN RINGEL JAMES ROBINSON THORN ROSENTHAL JONATHAN A SCHAFFZIN JOHN SCHUSTER HOWARD G. SLOANE LAURENCE T. SORKIN LEONARD A. SPIVAK GERALD S. TANENBAUM JONATHAN D. THIER JOHN A TRIPODORO ROBERT USADI GEORGE WAILAND GLENN J. WALDRIP, JR. MICHAEL B. WEISS GARY W. WOLF JOHN R. YOUNG DANIEL J. ZUBKOFF

August 25, 2000

WALTER C. CLIFF DAVID R. HYDE DENIS MCINERNEY MATHIAS E. MONE IRWIN SCHNEIDERMAN JOHN R. VAUGHAN RALPH O. WINGER SEMIOR COUNSEL

CORYDON B. DUNHAM PHILIP A. HEIMOWITZ COUNSEL

WASHINGTON, D.C. OFFICE 1990 K STREET, N.W. WASHINGTON, D.C. 20006-1181

> EUROPEAN OFFICE AUGUSTINE HOUSE 6A AUSTIN FRIARS LONDON EC2N 2MA

TELEPHONE 212-701-3000 FACSIMILE 212-269-5420

WRITER'S DIRECT NUMBER

(212) 701-3210

Re: In the Matter of Hoechst Marion Roussel,

Inc., et al.

Docket No. 9293

Dear Mr. Shaftel:

This will confirm the agreement that we reached when we spoke by telephone yesterday regarding the two subpoenas served on my client, Elan Pharmaceuticals Inc. ("Elan Inc."), at the request of your client, Andrx Corporation ("Andrx"), in the above-captioned FTC proceedings. The subpoenas were served on Elan Inc. in its offices in South San Francisco, California on Monday, August 21, 2000.

### We agreed as follows:

- 1. The time for Elan Inc. to move to limit or quash the subpeona <u>duces</u> tecum shall be extended from August 31, 2000 to September 11, 2000.
- 2. Elan Inc. agrees that it will not move to quash the subpoena <u>duces</u> tecum on the ground of improper service on Elan Inc. However, Elan Inc. does not agree that service of the subpoena on Elan Inc. constitutes effective service on its corporate parent, Elan Corporation, PLC, an Irish corporation, and reserves the right to move to quash or limit the subpoena to the extent that it seeks documents which may be in the possession of Elan Corporation, PLC, but are not in the possession of Elan, Inc. Elan Inc. recognizes that Andrx reserves all of its rights.

- 3. If Elan Inc. does not make a motion to quash or limit the subpoena <u>duces tecum</u>, it will produce non-privileged responsive documents not subject to any such motion by September 18, 2000.
- 4. The deposition pursuant to the subpoena ad testificandum shall be adjourned indefinitely. In the event that any deposition is necessary, we have agreed that the deposition will take place in San Francisco at a date to be agreed upon, and that that date will be scheduled at least seven days in advance.

This will also confirm that you have agreed to modify Request No. 1 of the subpoens <u>duces</u> tecum so that it will call for the production of documents sufficient to identify "each settlement or partial settlement of patent litigation which your Company has entered into involving an innovator or brand name pharmaceutical company and a generic company . . ." The underscored language is intended to replace the words "concerning which your Company is aware" that are contained in Request No. 1 as presently written. As discussed, Elan Inc. reserves its right to move to quash or limit Request No. 1, even as so modified.

I would appreciate it if you would notify me promptly if the foregoing does not accurately reflect our understanding.

Thank you for your cooperation in this matter.

STYCE CITY,

Laurence T. Sorkin

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