UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of **Hoechst Marion Roussell, Inc.,** **Carderm Capital L.P.**, and **Andrx Corporation**	)	Docket No. 9293

PETITION OF PhRMA TO AMEND PROTECTIVE ORDER TO COVER MATERIALS PRODUCED BY THIRD PARTIES DURING INVESTIGATION

The Pharmaceutical Research and Manufacturers of America ("PhRMA") hereby petitions Administrative Law Judge D. Michael Chappell to bring the Protective Order (the "Protective Order" or "Order") issued by him on April 28, 2000, into conformity with the requirements of the Federal Trade Commission's Rule 4.10 by amending Paragraph 3 of the Terms and Conditions. The requested amendment would clarify as intended by FTC counsel that all Discovery Material obtained from Third Parties by compulsory process or voluntarily in lieu thereof, which were obtained during the pre-complaint stage of this Matter, shall be treated as Confidential Discovery Material, regardless of whether it has been marked "Confidential," and such Discovery Material shall only be available for use in this proceeding once an independent basis has been demonstrated for such use.

from Third Parties should be afforded at least as much, if not more, protection from disclosure than discovery from Parties.

Moreover, requiring FTC Complaint Counsel to produce materials obtained from Third Parties during its investigation without covering them under the Protective Order could profoundly chill Third Party cooperation in future investigations. Rule 4.10 serves precisely to reassure potential providers of information to FTC investigators that confidential information will remain confidential, at least unless and until an administrative law judge or a federal district court has determined that disclosure is required for the conduct of an enforcement action. Violating its own Rule immediately undermines the Commission's credibility regarding confidentiality. If the Commission cannot be trusted to maintain the confidentiality of materials provided voluntarily or under subpoena during an investigation, then future Third Parties, even those otherwise inclined to cooperate fully, may decline to volunteer information, await a subpoena, then move to quash in a federal district court, simply to ensure the issuance of a adequate and binding protective order.

The inequity and adverse affects on the Commission's credibility are heightened by the FTC investigators' actions to date regarding PhRMA's and IMS Health's materials provided in this matter. As outlined above, PhRMA and IMS Health provided their documents to FTC investigators in specific reliance upon the protections of Rule 4.10. Prior to producing them they specifically sought and received written assurances that Rule 4.10 applied and that the FTC would seek to limit their disclosure in a future administrative action. After production, when it became clear that these materials would

need to be produced, the FTC again assured PhRMA in writing that "[o]f course, we will not give any documents to the parties before an appropriate protective order has been approved by the administrative law judge trying the case." These assurances quite properly restated the Commission's obligations under its own Rule 4.10. Production of PhRMA's and IMS Health's materials under a Protective Order that does not accord them protection as Confidential Discovery Materials would vitiate these assurances.

Finally, because FTC Complaint Counsel has informed PhRMA that it intends to produce PhRMA's materials on May 9, 2000, PhRMA respectfully requests expedited review of this petition to amend the Protective Order, to ensure that adequate protections are in place by then. In the alternative, PhRMA requests the issuance of a supplemental order either staying further discovery relating to Third Party materials obtained during the investigation or permitting such discovery subject to the condition that disclosure be limited to outside counsel for the Parties, pending resolution of PhRMA's petition.[2]

CONCLUSION

For the reasons discussed above, including that disclosure of PhRMA's and IMS Health's materials provided to the FTC during the pre-complaint investigation under the existing Protective Order would violate Commission Rule 4.10 and constitute arbitrary

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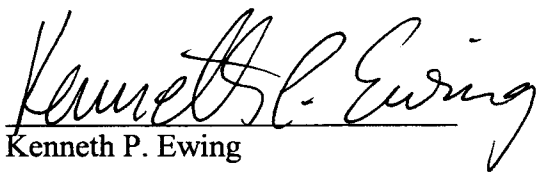
[2] PhRMA understands that Andrx Corporation objects to amending the Protective Order so as to include Third Party materials in Paragraph 3 in part out of concern that Paragraph 5 does not allow disclosure of Confidential Discovery Material to any of its business people. The scope of Paragraph 5 is unrelated to the scope of Paragraph 3 and this concern should not stand in the way of bringing the Order into compliance with the Commissions' Rules. In any case, PhRMA would not object to expanding Paragraph 5 to include one designated business person, so long as this extension applied across the board to all Confidential Discovery Material, not just Third Party or PhRMA materials.

and capricious action, PhRMA respectfully requests that the Protective Order be modified so as to include materials produced by Third Parties to the FTC during the investigation within the protections of Paragraph 3 of the Order. PhRMA also requests expedited review of its petition so as to ensure the existence of an adequate order by the time that FTC Complaint Counsel produces PhRMA's materials to the Parties or, in the alternative, PhRMA requests a supplemental order delaying that production until the petition has been ruled on or allowing production but limiting disclosure to outside counsel for the Parties until the petition has been ruled on.

Dated: May 5, 2000.



Kenneth P. Ewing

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Kenneth P. Ewing
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November 19, 1998

Dan Kotchen, Esq.
Bureau of Competition
Federal Trade Commission
601 Pennsylvania Ave., NW
Washington, D.C. 20580

Re: FTC File No. 981 0368
PhRMA Subpoena

Dear Dan

This letter memorializes the results of the telephone conversations we had on November 17, 18 and 19, 1998, to facilitate the response of the Pharmaceutical Research and Manufacturers of America ("PhRMA") to the subpoena issued to it in the above-referenced investigation (the "Subpoena"). As a result of those conversations, the Federal Trade Commission ("FTC") and PhRMA have agreed to modify the subpoena in accordance with the conditions and limitations described below.

PhRMA will make a good faith effort to comply with each of the Definitions, Instructions, and Specifications set forth in the Subpoena, unless modified as stated herein. The scope of the search for documents responsive to the Specifications in the Subpoena shall be limited in accordance with the provisions described below.

The documents sought under the Subpoena relate solely to generic or brand name drugs marketed in the United States; they do not relate to such products to the extent that they are marketed outside the United States.

The following modifications correspond to the numbered Specifications in the Subpoena:

1. & 2. PhRMA will not produce copies of publicly available compilations of information about generic or brand name drugs, such as those commonly known as the "Physician's Desk Reference," the "Red Book," or the "Orange Book." PhRMA will produce other documents responsive to Specifications 1. and 2., including a copy of any report by the Congressional Budget Office within its custody that is responsive.

6. PhRMA will produce copies of reports by economists, securities analysts and similar industry analysts on the interrelationship of generic and brand name drugs. PhRMA will not produce documents published in the trade press or in medical journals.

7. PhRMA will produce copies of documents relating to 21 U.S.C. § 355(j)(5)(B)(iv) of the Hatch-Waxman Amendments, which relates to the 180-day market exclusivity for the first generic manufacturer to market. PhRMA will not produce other documents relating to the other provisions of section 355(j).

PhRMA will search its offices in Washington, DC. PhRMA will not search the following: (1) offices of state lobbyists and consultants not on the PhRMA staff, (2) offices of members of its Board of Directors and of other PhRMA officers not on the PhRMA staff, (3) PhRMA's Tokyo and Brussels offices, and (4) PhRMA's regional field offices in Sacramento, CA, Golden, CO, St. Paul, MN, and Albany, NY.

In accordance with Section 21(d) of the Federal Trade Commission Act, regulations promulgated thereunder, and the FTC's policies and practices, the FTC will treat all information furnished by PhRMA pursuant to the Subpoena as confidential, and will not be disclosed without PhRMA's written permission, except in the limited circumstances described in Section 21 of the FTC Act.

PhRMA will make a good faith effort to produce documents on a "rolling" basis beginning December 11, 1998, until the completion of its response.

PhRMA appreciates your willingness to listen to its concerns and to modify the Subpoena as described above. Please sign below and return a copy to me to indicate the FTC's acceptance of these modifications to the Subpoena. We look forward to working with you as we complete the task of complying with the Subpoena.

Sincerely yours,

Kenneth P. Ewing

Kenneth P. Ewing
Counsel for PhRMA

Agreed

David Kotchen

Federal Trade Commission

11-23-98

Date

ATTACHMENT B

IMS HEALTH

100 Campus Road
Totowa, NJ 07512

January 25, 1999

Kenneth P. Ewing, Esquire
Steptoe & Johnson, LLP
1330 Connecticut Avenue, NW
Washington, DC 20036

Re: Subpoena to Pharmaceutical Research and Manufacturers of America ("PhRMA")
Federal Trade Commission File No.: 981 0368 (the "Investigation")

Dear Mr. Ewing:

You have requested that IMS Health Incorporated ("IMS") consent to the production by PhRMA of certain IMS proprietary information to the Federal Trade Commission ("FTC") in response to the subpoena issued to PhRMA in connection with the Investigation. Subject to the terms of this letter, this letter constitutes IMS's consent to PhRMA to provide such information to the FTC, which information is described in the letter dated January 20, 1999 (the "January 20th Letter") from you to Bradley Alpert, Esq. of the FTC (the "Requested Information").

As you may be aware, IMS data and confidential information retain their value to IMS so long as such data and information are treated in accordance with the requirements of law affording certain protections for such data and information (e.g., laws governing trade secrets and copyright). In addition, IMS has certain contractual obligations of confidentiality with its data sources and its clients. Based on the foregoing, it is necessary that IMS receive adequate assurances that any use or disclosure of the Requested Information will be treated in a manner which does not compromise such protections or obligations.

The Requested Data may be produced to the FTC in response to the Subpoena, provided that:

a. Any production of Requested Information to the FTC shall be made only in connection with the Investigation and only under the terms of the January 20th letter.

b. In the event PhRMA receives any notice that the FTC or other governmental agency intends to make any of the Requested Information available to parties not connected to the Investigation or intends to make any of the Requested Information available publicly, then PhRMA shall promptly apprise IMS of such notice and, to the extent IMS does not have standing, convey IMS's request for additional protections to maintain the confidentiality of the Requested Information.

c. Prior to the Requested Information being produced, all documents containing Requested Information shall be marked "CONFIDENTIAL" and marked in such other manner so as to be identified as a document requiring confidential treatment under the terms of the January 20th letter.

If the above terms are acceptable, please have a copy of this letter signed where indicated and returned to my attention.

Very truly yours,

Harvey A. Ashman
Vice President & Associate General Counsel

Accepted and agreed this 25th **day of** January, **1999**:

Steptoe & Johnson, LLP
Attorneys for PhRMA

By: Kenneth P. Ewing

Name: Kenneth P. Ewing

Title: Associate

ATTACHMENT C

STEPTOE & JOHNSON LLP

1330 Connecticut Avenue, NW
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Telephone 202.429.3000
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Kenneth P. Ewing
202.429.8284
kewing@steptoe.com

January 20, 1999

By Telecopy
Bradley Albert, Esq.
Bureau of Competition
Federal Trade Commission
Room 3115
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Re: **FTC File No. 981 0368**
Subpoena to PhRMA

Dear Brad:

I write to summarize the results of our discussions during the past week regarding the Federal Trade Commission's ("FTC's") requests, pursuant to subpoena issued as part of the investigation referred to above, for data contained in certain publications of IMS America. As we discussed, the FTC agrees to limit these requests as follows, and PhRMA agrees to provide copies of the following:

(i) From National Prescription Audit Plus™: Therapeutic Category Report (Vol. 1, December 1997)

(a) the first two pages of the volume (immediately inside the cover);
(b) the three "Sample Pages" (the only blue pages in the volume, and the pages that follow page 48 of the yellow pages in the volume);
(c) pages 121 to 124 (relating to therapeutic class number 10100);
(d) pages 199 to 200 (relating to therapeutic class number 15180);
(e) pages 417 to 420 (relating to therapeutic class number 31440);
(f) pages 430 to 444 (relating to therapeutic class number 31700).

Also, if PhRMA has a 1996 volume and a 1995 volume of this publication, the volumes' first two pages, sample pages, and pages relating to the following therapeutic classes and class numbers; anti-coagulants (class number 1110), quinolones (class number 15180),

alpha blockers (class number 31400), and calcium channel blockers (class number 31700).

(ii) From National Prescription Audit Plus™: Company Report (December 1996):

If PhRMA has a 1997 volume of this publication, PhRMA will submit information relating to sections (a) and (b), below, from the 1997 volume and not from the 1996 volume. However, if PhRMA does not have a 1997 volume, PhRMA will provide a copy of the following pages from the 1996 volume:

(a) the first 22 pages of the volume (immediately inside the cover, up to the first page of Part I of the volume);
(b) pages in Part III, entitled "Company Report," of the volume relating to the following companies:

- Hoechst Marion Roussel, Inc.
- Rhone-Poulenc Rorer
- Biovail Corporation
- Pfizer, Inc.
- Bayer Corporation
- Searle & Company
- Astra Pharmaceuticals
- Novartis Pharmaceuticals
- Roche Pharmaceuticals
- Abbott Laboratories
- Andrx Corporation
- Watson Pharmaceuticals, Inc.
- Barr Laboratories, Inc.
- Torpharm, Inc.
- Faulding, Inc.
- Geneva Pharmaceuticals, Inc.
- Mylan Laboratories, Inc.
- Invamed, Inc.
- Zenith Laboratories, Inc.

(iii) From National Prescription Audit Plus™: Basic Data Report (Dispensed Data) (Vol. 1, October-December 1997, USC 01100-29000)

(a) the seventh page of the volume (the first white page immediately following the six yellow pages);
(b) the "Basic Data Report General Summary" section (the only blue and pink pages in the volume);
(c) pages 243 to 248 of the "Basic Data Report" section (relating to therapeutic class number 1110);
(d) pages 395 to 398 of the "Basic Data Report" section (relating to therapeutic class number 15180);
(e) all pages relating to the alpha blockers therapeutic class (therapeutic class number 31440) and to the calcium channel bocker therapeutic class (therapeutic class number 31700).

If PhRMA has 1996 volumes and 1995 volumes of this publication, copies of the volumes' cover pages (like the page requested in part (a), above), "Basic Data Report

General Summary™ sections, and pages relating to the following therapeutic classes and class numbers: anti-coagulants (class number 1110), quinolones (class number 15180), alpha blockers (class number 31440), and calcium channel blockers (class number 31700).

(iv) From Pharmaceutical Pricing Update™ (Vol. 6, No. 1, September 1998)

(a) the first two pages of the volume (immediately inside the cover);
(b) pages 66 to 67;
(c) pages 68 to 69;
(d) pages 74 to 77;
(e) pages 86 to 87;
(f) pages 98 to 99;
(g) pages 110 to 111;
(h) pages 121 to 136;
(i) pages 164 to 184.

Pages 143 to 152 of this volume focus on pricing data of two therapeutic categories unrelated to any of the Commission's investigations. To the extent that other volumes of this publication – from January 1995 to the present – have sections focusing on any of the following therapeutic classes and class numbers (similar to the manner in which pages 143 to 152 focus on two therapeutic classes), PhRMA will provide these sections: anti-coagulants (class number 1110), quinolones (class number 15180), alpha blockers (class number 31440), and calcium channel blockers (class number 31700).

As also discussed with you, the volumes referred to above are published and copyrighted by IMS America and in PhRMA's possession pursuant to a subscription contract which restricts unauthorized disclosure to anyone other than employees of PhRMA. Accordingly, the FTC confirms that it will provide the following protections regarding the materials that PhRMA will provide under this letter agreement: The FTC will treat these materials as confidential under its stated policy for protection of nonpublic material, as set forth in those applicable provisions in 16 C.F.R. § 4.10. In the event of a request by a third party other than Federal and State law enforcement agencies for disclosure of these materials, the FTC will assert all reasonable exemptions from disclosure permitted by law and will make reasonable efforts to give PhRMA ten days' notice prior to disclosure, to provide it a reasonable opportunity to seek protection. In the event of a request from Congress, the FTC will give prompt prior notice to PhRMA by telephone to the PhRMA Law Department and by facsimile to the PhRMA Office of the President, when feasible and permitted by law, to provide it a reasonable opportunity to seek protection. If the FTC will incorporate any of these confidential materials in a complaint or other public court or agency filing, it will advise the court or agency of the confidential nature of the materials and will make reasonable efforts to limit disclosure to the lawyers and court or agency involved until PhRMA has had a reasonable opportunity to appear and seek a ruling on protecting the material.

Brad, thank you for working with PhRMA to narrow the FTC's request and to provide assurances of confidentiality to facilitate authorization by IMS America for disclosure of the materials. If this letter accurately reflects our agreement, please sign below and return to me by facsimile at 202-429-3902.

Sincerely,

Kenneth P. Ewing

Kenneth P. Ewing

Confirmed:

Bradley Albert
Attorney
Federal Trade Commission

ATTACHMENT D

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Bureau of Competition

March 24, 2000

Kenneth P. Ewing
Steptoe & Johnson LLP
1330 Connecticut Avenue, N.W.
Washington, DC 20036-1795

Re: In the Matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corporation, FTC Docket No. 9392

Dear Mr. Ewing:

The Federal Trade Commission has issued an administrative complaint against Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corporation, alleging violations of the antitrust laws, including Section 5 of the FTC Act, arising from an agreement among the parties under which Andrx agreed not to market generic versions of Hoechst's Cardizem CD product. I have enclosed a copy of the complaint for your review.

We are contacting you now because you previously submitted documents to the FTC on behalf of Pharmaceutical Research and Manufacturers of America, in connection with the pre-complaint investigation of Hoechst and Andrx. In the near future, these documents will have to be produced to counsel for the parties as part of the pre-trial discovery process. Of course, we will not give any documents to the parties before an appropriate protective order has been approved by the administrative law judge trying the case. We are currently in the process of drafting a proposed protective order, and will forward to you a copy once it has been entered in the matter. The protective order will spell out your rights, and the procedures to follow, to ensure the continued confidentiality of the materials you provided to us.

Should you have any questions about this, please do not hesitate to contact me at (202) 326-3133. Thank you for your cooperation.

Sincerely,

Robin L. Moore
Attorney

Enclosure

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Bureau of Competition

May 1, 2000

VIA FACSIMILE ((202) 261-7540)

Kenneth P. Ewing
Steptoe & Johnson LLP
1330 Connecticut Avenue, N.W.
Washington, DC 20036-1795

Re: In the Matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corporation, FTC Docket No. 9392

Dear Mr. Ewing:

As you know, on March 16, 2000, the Federal Trade Commission issued an administrative complaint against Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corporation. We are contacting you now, because the respondents in this matter have served document requests to us, and we intend to produce the documents you provided on behalf of Pharmaceutical Research and Manufacturers of America in our pre-complaint investigation. Of course, these documents will be governed by the protective order entered by Administrative Law Judge Chappell on April 28, 2000, which I have attached.

We believe this protective order provides adequate protection for the confidential documents that PhRMA provided. It not only limits the scope of those individuals within the respondents' companies who have access to the documents but also provides a procedure in Paragraph 13 for PhRMA to seek *in camera* treatment of documents. However, should you have concerns about the protection provided by the Order, you may petition Judge Chappell and address your concerns. Under §4.10(g) of the Commission's Rules of Practice, 16 C.F.R. § 4.10(g), PhRMA has "an opportunity to seek an appropriate protective or *in camera* order." Pursuant to Paragraph 10 of the Order, we intend to produce documents to the respondents 5 days from the date you receive this notice.

Should you have any questions about this, please do not hesitate to contact me at (202) 326-3133. Thank you for your cooperation.

Sincerely,

Robin L. Moore
Attorney

Enclosure

CERTIFICATE OF SERVICE

I, Kenneth P. Ewing, hereby certify that on May 5, 2000, I caused the required number of copies of (1) the Notice of Appearance of Kenneth P. Ewing and (2) the Pharmaceutical Research and Manufacturers of America's Petition to Amend Protective Order to Cover Materials Produced by Third Parties During Investigation to be served by messenger and facsimile on the following:

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 Meier, Esq.
Federal Trade Commission
Bureau of Competition
601 Pennsylvania Ave., N.W.
Washington, D.C. 20580

James M. Spears, Esq.
Shook, Hardy & Bacon, LLP
801 Pennsylvania Ave., N.W.
Washington, D.C. 20004

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

and on the following by overnight delivery and facsimile:

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

Kenneth P. Ewing

Kenneth P. Ewing