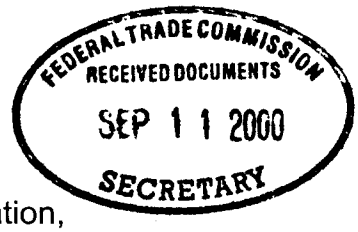
UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION



In the Matter of

HOECHST MARION ROUSSEL, INC., a corporation,
CARDERM CAPITAL L.P., a limited partnership,

and

ANDRX CORPORATION, a corporation.

DOCKET NO. 9293

RESPONDENT ANDRX CORPORATION'S MEMORANDUM IN OPPOSITION TO THE FOOD AND DRUG ADMINISTRATION'S MOTION TO QUASH

Respondent Andrx Corporation ("Andrx") submits this memorandum in opposition to the Food and Drug Administration's ("FDA") motion to quash the subpoena duces tecum served by Andrx upon the agency in this proceeding.

PRELIMINARY STATEMENT

Time is running out for the parties in this matter to complete their fact discovery. Unfortunately, despite diligent efforts, Andrx has been unable to obtain important discovery from an agency with a role central to this action -- the FDA. Andrx applied for, made an appropriate showing and obtained an order from this Court authorizing the issuance of a subpoena to the agency, and Andrx served its subpoena in early July.

Andrx has attempted to work with FDA's counsel to obtain the requisite documents while imposing the least possible inconvenience upon the agency. Andrx and the FDA had even negotiated an agreement for the production of documents -- one that FDA's counsel itself memorialized in writing. The FDA, however, has now chosen to reconsider its position, and has not only refused to provide Andrx with any of the

documents it seeks, but has even refused to provide a privilege log, as required by the Rules of Practice.

As set out more fully below, the FDA's motion to quash is wholly without merit and should be denied in its entirety. Furthermore, and given the time constraints under which the parties are working to complete discovery, the FDA should be directed to produce forthwith responsive documents and a privilege log to the extent privileges are asserted.

BACKGROUND

A. The Hatch-Waxman Act

The conduct at issue in this case must not only be analyzed in the context of the federal antitrust laws, but since it involves the manufacture and distribution of a generic pharmaceutical product, in the context of the so-called Hatch-Waxman Act as well. See 21 U.S.C. §355(j). Indeed, Complaint Counsel has conceded as much. See Complaint Counsel's Purported Reply Memorandum In Support of Motion To Strike Certain Affirmative Defenses (5/26/00) at 6 ("[C]omplaint Counsel agrees with Andrx that it is important to place the Hoechst/Andrx agreement to delay marketing of Andrx's generic product in the context of the Hatch-Waxman and FDA implementing regulations . . . .")

As Andrx explained in its papers seeking issuance of a subpoena on the FDA, the Hatch-Waxman Act governs the development and marketing of generic pharmaceutical products.[1] Among other things, the Act authorizes generic

[1] See Respondent Andrx Corporation's Memorandum In Support of Its Motion for the Issuance of a Subpoena Duces Tecum to the Food and Drug Administration (6/10/00)

manufacturers such as Andrx to seek regulatory approval from the FDA of a generic product based on an abbreviated new drug application ("ANDA"), by which the bioequivalency of the product to the band name version is assessed by the FDA without the need for extensive clinical trials.

B. The Subpoena at Issue

Because the FDA is the agency at the heart of the pharmaceutical approval process in both the brand name and generic context, it is obviously the repository for information critical to this case. By motion dated June 10, 2000, Andrx applied to this Court for an order approving the issuance of a subpoena duces tecum to the FDA. On July 5, 2000, the motion was granted, providing for the issuance of a subpoena calling for the production of two narrow classes of documents. Andrx served the FDA on July 6, the very next day.

The first category of documents relates to the FDA's consideration of the applications submitted by Biovail International Corporation ("Biovail") and Faulding, Inc. ("Faulding") to the FDA for the manufacture and marketing of pharmaceutical products purporting to be the "bioequivalent" to Cartizem® CD (Request nos. 1-2). The relevance of these documents is that both Biovail and Faulding were identified by Complaint Counsel as entities that might have been affected by the 1997 Stipulation. However, HMR filed a patent infringement action against Faulding, thereby delaying its FDA approval for 30 months. In May 1999, shortly before the expiration of this 30-month waiting period expired, Faulding settled its patent action and entered into a licensing agreement with HMR to market a generic version of Cardizem® CD once Faulding received final FDA approval. HMR did not file a patent infringement action

against Biovail. Instead, Biovail struggled to obtain FDA approval. Due, in part, to safety concerns, the FDA did not approve Biovail's ANDA until December 23, 1999.

The second category of responsive documents in the FDA's files relates to Andrx's own ANDA, excluding both the ANDA itself and any communications between the FDA and Andrx, which Andrx already has in its possession (Request no. 3).

Shortly after serving its subpoena, Andrx began a dialogue with the FDA designed to minimize burden on the agency while simultaneously insuring that Andrx received the documents it required. That dialogue produced an agreement, whereby the FDA agreed, among other things, that:

> by August 15, 2000, FDA will produce, subject to certain privileges and statutory prohibitions, responsive documents that exist in certain official new drug application (NDA) and abbreviated new drug application (ANDA) files, i.e., in Biovail's ANDA and NDA for the bioequivalent of Cardizem CD and Faulding's ANDA for the bioequivalent of Cardizem CD. (See letter from Claudia J. Zuckerman, dated July 18, 2000, annexed to accompanying Shaftel Declaration as Exhibit A thereto.)

Notwithstanding its agreement, the FDA reconsidered its position, refused to provide Andrx with any documents whatsoever, and instead, filed a motion to quash on August 10.

ARGUMENT[2]

I. THE DOCUMENTS SOUGHT FROM THE FDA ARE CLEARLY RELEVANT TO THIS PROCEEDING

At pages 5-6 of the FDA's motion, the agency purports to justify its decision to withhold responsive documents on the theory that they are irrelevant to the

[2] Aventis has also served the FDA with a subpoena in this proceeding, and the FDA has moved to quash that subpoena as well. Given similarity of issues raised by the FDA's two motions, Andrx hereby adopts the arguments advanced by Aventis in its opposition papers.

issues in this proceeding. As a threshold matter, non-parties such as the FDA do not have a legitimate ground to object to discovery on relevancy grounds. As one federal court noted in a case where the non-party resisting discovery was the Federal Bureau of Investigation:

> the Court has serious reservations about the propriety of a non-party deponent moving to quash a subpoena duces tecum on the ground that the information sought is not relevant to the pending action. The FBI is not a party to the pending action and generally has no interest in the outcome.

Ghandi v. Police Dep't of the City of Detroit, 74 F.R.D. 115 (E.D. Mich. 1977); see also Cooney v. Sun Shipbuilding & Dry-dock Co., 288 F. Supp. 708 (E.D. Pa 1968).

In any event, the documents sought are clearly germane to this proceeding. As noted above, the Andrx subpoena seeks documents falling into two distinct categories: a) documents concerning the FDA's consideration of the applications submitted by Biovail and Faulding to the FDA for the manufacture and marketing of pharmaceutical products purporting to be the "bioequivalent" to Cartizem® CD (Request nos. 1-2); and b) documents in the FDA's files concerning Andrx's own ANDA, excluding both the ANDA itself and any communications between the FDA and Andrx, which Andrx already has in its possession (Request no. 3).

The documents in category "a" are clearly relevant to one of the central issues in this proceeding. The gravamen of Complaint Counsel's case is that the Stipulation may have had the "tendency or capacity" (Complaint, ¶ 29) to restrain trade because there was a delay in Andrx's marketing of its generic product. Therefore, documents relating to the status of other ANDAs filed with the FDA bear directly on whether, in fact, any other competitors were far enough along in the regulatory approval process to have been kept off the market as a result of the 1997 Stipulation. Andrx has

reason to believe, for example, that Biovail, Andrx's main competitor, was not prepared to go to market during Andrx's 180-day exclusivity period. Specifically, Andrx believes that the FDA had safety and acceptability issues concerning Biovail's Cardizem® CD bioequivalent – issues that delayed final FDA approval until December 23, 1999, four days after the expiration of Andrx's 180 day exclusivity period. Were the FDA's files to substantiate this, Andrx would be able to further establish the absence of a causal link between the 1997 Stipulation and Biovail's delayed entry into the market place.

Documents in category "b," pertaining to Andrx's ANDA , are germane to rebutting the contention that the 1997 Stipulation was anti-competitive because it provided Andrx with an incentive to keep its generic product off the market. Put simply, the theory goes, because Andrx received certain payments under the 1997 Stipulation without marketing its Cardizem® CD generic, Andrx had no incentive to – and did not – aggressively prosecute its ANDA. Andrx believes that the FDA's files will show just the opposite – that notwithstanding the 1997 Stipulation, Andrx pushed its ANDA aggressively through the FDA approval process in order to get its product to market quickly and, indeed, Andrx intends to prove that it was the 1997 Stipulation that facilitated Andrx's entry into the marketplace.

II. ANDRX DOES NOT SEEK DOCUMENTS THAT CAN BE "REASONABLY OBTAINED BY OTHER MEANS"

The FDA's alternative argument -- that the Andrx subpoena should be quashed because it seeks documents that can be "reasonably obtained by other means" -- is also without merit. Andrx wants to be very clear: While it intends to be extremely thorough in its discovery efforts, it does not wish the FDA to produce documents that Andrx both has access to and may use in this proceeding.

With respect to communications between the FDA, on one hand, and Biovail and Faulding on the other -- the category of documents to which the agency directs this particular objection -- Andrx does not dispute that it has access to responsive documents from Biovail and that seeks similar documents from Faulding in its proceeding. But Andrx has no way to insure that these productions are complete, and given the clear relevance -- indeed, importance -- of these documents to Andrx's defense, a complete set of these documents is essential.

In an effort to accommodate the agency, Andrx would be content with a log of all responsive communications so that it can compare the log with the Biovail and Faulding productions. Only the comparison reveals documents that are missing from the Biovail and Faulding productions, would Andrx then insist that the FDA produce the missing documents.

III. THE FDA'S INVOCATION OF THE DELIBERATIVE PROCESS PRIVILEGE IS INSUFFICIENT

Nor can the FDA avoid its obligations under the Andrx subpoena by asserting, in a conclusory fashion, that predecisional agency documents "are covered by the deliberative process." As this Court noted in its August 18, 2000 order:

> Assertion of the deliberative process privileges requires: (1) a formal claim of privilege by the head of the department having control over the requested information; (2) assertion of the privilege based on actual personal consideration by that official; and (3) a detailed specification of the information for which the privilege is claimed, with an explanation why it properly falls within the scope of the privilege.

Order on Motions to Compel Discovery from Complaint Counsel Filed by Andrx and By Aventis, dated August 18, 2000, at 4 (citing Landry v. FDIC, 204 F.3d 1125, 1135 (D.C. Cir. 2000))(emphasis added). The FDA's motion papers do not come close to satisfying these criteria for successful invocation of the privilege.

Moreover, the FDA's so-called invocation of the deliberative process privilege is additionally defective because the agency has refused to provide a privilege log, as is required by §3.38A of the FTC' s Rules of Practice. The privilege log contemplated by the rules would enable Andrx to challenge the FDA's claims of privilege on a document-by-document basis by arguing, for example, that a particular document contains severable factual data that could be produced in redacted form or that the production of a particular document should be compelled because Andrx can establish substantial need to overcome the privilege. See e.g. In re Sealed Case, 121 F.3d 729, 737 (D.C. Cir. 1997).

Because the FDA has failed to invoke properly the deliberative process privilege and, additionally, has failed to comply with this Court's rule that a privilege log be provided, the agency's privilege claim should be summarily rejected.

CONCLUSION

For the foregoing reasons, Andrx respectfully request that the FDA's motion to quash be denied in all respects.

Dated: New York, New York
September 11, 2000

Respectfully Submitted,

SOLOMON, ZAUDERER, ELLENHORN,
FRISCHER & SHARP

By: Hal S Shaftel /BMD

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Counsel for Respondent Andrx Corporation

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of

HOECHST MARION ROUSSEL, INC., a corporation,
CARDERM CAPITAL L.P., a limited partnership,

and

ANDRX CORPORATION, a corporation.

Docket No. 9293

DECLARATION OF HAL S. SHAFTEL

Hal S. Shaftel declares as follows, pursuant to 28 U.S.C. § 1746:

1. I am a member of the firm of Solomon, Zauderer, Ellenhorn, Frischer & Sharp, counsel for respondent Andrx Corporation ("Andrx"). I submit this declaration to put before the Court a copy of a letter, dated July 18, 2000, from Claudia J. Zukerman, Assistant Chief Counsel of the Food and Drug Administration. The letter is annexed as Exhibit A hereto.

2. Andrx's response is annexed hereto as Exhibit B.

I declare under penalty of perjury that the foregoing is true and correct. Executed in New York, New York, on September 11, 2000

Hal S. Shaftel

HAL S. SHAFTEL

EXHIBIT A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

July 18, 2000

BY FACSIMILE / CONFIRMATION COPY BY MAIL

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

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

Dear Mr. Lupkin:

This letter confirms our conversation of July 14, 2000, regarding the subpoena you served as counsel for Andrx Corporation on the Food and Drug Administration (FDA or agency) in the above-captioned action.

The subpoena requests the production of documents by July 31, 2000. As we discussed, the subpoena request is broad and will require considerable effort on the part of the agency. As such, you agreed to strike the July 31, 2000, deadline. Instead, by August 15, 2000, FDA will produce, subject to certain privileges and statutory prohibitions, responsive documents that exist in certain official new drug application (NDA) and abbreviated new drug application (ANDA) files, i.e., in Biovail's ANDA and NDA for the bioequivalent of Cardizem CD and Faulding's ANDA for the bioequivalent of Cardizem CD.

We also agreed that FDA would not be required to review telephone logs for potentially responsive documents. Regarding electronic mail, we agreed that FDA would not be required to review such material for potentially responsive documents, except for material relating to Biovail within the time period from December 18, 1999, to December 25, 1999, inclusive. Pursuant to your request, I agreed to inquire about the practicality of searching for potentially responsive electronic mail relating to Biovail within the stated time period for production by the August 15, 2000, deadline.

Further, you agreed not to set a deadline for the material listed in the subpoena's Exhibit A, request number three. I suggested that, to reduce the burden on FDA, such information should come from the Federal Trade Commission.

FDA will be producing these documents without waiving any objections to the enforceability of the subpoena and for the purpose of settling this matter without litigation. Further, certain statutes and privileges may prevent FDA from releasing some of the requested documents. For example, FDA is prohibited from releasing trade secret and confidential commercial information without authorization. See 18 U.S.C. § 1905; 21 U.S.C. 331(j); 21 C.F.R. 20.61. In addition, other documents you requested may be privileged because, among other things, they reflect internal agency deliberations.[1]

If this letter does not set forth the arrangement we discussed, please let me know immediately.

Sincerely,

Claudia J. Zuckerman
Assistant Chief Counsel

cc: Ms. Anne Smith

[1] This written objection to producing the documents does not preclude FDA from asserting at a later time additional bases for objecting to disclosure of FDA documents.

EXHIBIT B

SOLOMON, ZAUDERER, ELLENHORN, FRISCHER & SHARP

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WRITER'S DIRECT DIAL
(212) 424-0758

July 21, 2000

VIA FACSIMILE

Claudia J. Zuckerman, Esq.
United States Food & Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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

Dear Ms. Zuckerman:

Thank you for your July 18 letter. I write to clarify my understanding of certain aspects of our July 14 telephone discussion.

First, while I am sure that compliance with Andrx's subpoena will require some effort on the part of your agency, I do not agree that the requested categories of documents are "broad," as you suggest in your letter. To the contrary, Andrx took considerable care to ensure that the subpoena would not impose an undue hardship on the agency.

Second, my agreement to have the agency focus its search efforts on "certain official new drug application (NDA) and abbreviated new drug application (ANDA) files" is based upon your expressed understanding that all documents (including correspondence, substantive e-mails and substantive telephone logs) concerning a particular NDA or ANDA are actually filed with that NDA or ANDA, and are not filed elsewhere within the agency.

Third, while I agreed to confer with you later this week with respect to the time within which the agency may respond to request no. 3, I did not agree that Andrx would seek communications between the FDA and the FTC solely from the FTC. As I indicated on the phone last Friday, Andrx has already requested all inter-agency communications from the

FTC, but we must make the same request of your agency to ensure that the FTC's production is complete.

Fourth, Andrx expressly reserves its rights to enforce any and all aspects of its subpoena to the extent that it is deemed necessary. Obviously, the need to seek enforcement of the subpoena will depend entirely on the sufficiency of the FDA's production.

As I indicated on Friday, I am happy to keep the lines of communication between us open with the sincere hope (and belief) that the FDA's compliance with Andrx's subpoena will be sufficient, and will not require judicial intervention.

Thank you, in advance, for your agency's attention to this matter.

Very truly yours,

Jonathan D. Lupkin

Encl.

CERTIFICATE OF SERVICE

I, Peter M. Todaro, hereby certify that on September 11, 2000, I caused to be served upon the following persons, by hand delivery, the following document: Respondent Andrx Corporation's Memorandum In Opposition To the Food and Drug Administration's Motion To Quash (including accompanying declaration and exhibits):

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
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Washington, D.C. 20580

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Federal Trade Commission
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5600 Fishers Lane, GCF-1
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Dated: September 11, 2000

PETER M. TODARO