UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of

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

and

ANDRX CORPORATION, a corporation.

DOCKET NO. 9293

RESPONDENT ANDRX'S MOTION FOR THE ISSUANCE OF A SUBPOENA DUCES TECUM TO THE FOOD AND DRUG ADMINISTRATION

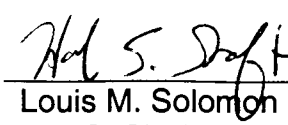
Pursuant to § 3.36 of the Federal Trade Commission's Rules of Practice, Respondent Andrx Corporation hereby moves for an Order (1) authorizing the issuance of a subpoena duces tecum to the United States Food and Drug Administration calling for the production of those categories of documents identified in Exhibit 1 to the accompanying Declaration of Hal S. Shaftel; and (2) granting such other and further relief as the Court deems just and proper. Complaint Counsel has indicated that it will not oppose this motion, and respondents have indicated that they consent to the motion.

The bases of this motion are set forth in the accompanying Memorandum in Support of its Motion for Approval to Issue a Subpoena Duces Tecum to the Food and Drug Administration (dated June 8, 2000); and the accompanying Declaration of Hal S. Shaftel, executed on June 10, 2000.

Dated: New York, New York
June 10, 2000

Respectfully Submitted,

SOLOMON, ZAUDERER, ELLENHORN,
FRISCHER & SHARP

By: 

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RESPONDENT ANDRX CORPORATION'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR THE ISSUANCE OF A SUBPOENA DUCES TECUM TO THE FOOD AND DRUG ADMINISTRATION

Pursuant to § 3.36 of the FTC's Procedures and Rules of Practice, Respondent Andrx Corporation ("Andrx") submits this memorandum in support of its motion for an order approving the issuance of a subpoena duces tecum to the United States Food and Drug Administration ("FDA").[1] Complaint Counsel has indicated that it does not oppose this motion, and the other respondents have indicated that they consent to this motion.

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

[1] A proposed schedule identifying those categories of documents that Andrx seeks from the FDA is annexed as Exhibit 1 to the accompanying Declaration of Hal S. Shaftel (the "Shaftel Declaration").

Memorandum In Support of Motion To Strike Certain Affirmative Defenses 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 . . . .")

The Hatch-Waxman Act governs, among other things, the development and marketing of generic pharmaceutical products. The Act authorizes generic 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. By permitting manufacturers to rely on studies previously performed for drugs already on the market, the Hatch-Waxman Act enables relatively quicker FDA approval for generic forms of those drugs.

The Act, however, also permits brand name manufacturers such as HMR to delay regulatory approval of the generic product, if there is a belief that the generic infringes patents covering the brand name product. The Act accomplishes this by requiring a generic manufacturer filing an ANDA for a drug protected by patents to notify the patent holder and to make a "certification" concerning the patents (21 U.S.C. §355(j) (2) (A) (vii)).

The type of certification relevant to this matter is known as a "Paragraph IV" certification, in which the applicant certifies that its product will not infringe the patents covering the innovator drug or that those patents are invalid and unenforceable (§355(j) (2) (A) (vii) (IV)). The Hatch-Waxman Act expressly

permits a manufacturer that receives a Paragraph IV certification to initiate a patent infringement action against the applicant. The commencement of such an action imposes, as a matter of law, a stay during which the FDA must hold its consideration of the generic's ANDA in abeyance. That stay remains in place for 30 months, or until the patent action is resolved in favor of the ANDA applicant, whichever is earlier. See 21 U.S.C. § 355(j)(5)(B)(iii).

To create an incentive for the company that first steps up to challenge a brand name manufacturer and its patents, the Hatch-Waxman Act provides the first applicant filing a Paragraph IV certification 180 days of market exclusivity, during which it is the sole authorized marketer of the generic product (§355(j) (5) (B) (iv)). Presently, this 180-day exclusivity period begins on the earlier of (1) the date of a final decision in favor of the ANDA files in the patent litigation (§355(j) (5) (B) (iv)) or (2) the date upon which the first ANDA applicant begins to market its product (such as in the case where the applicant has not been sued) (§355(j) (5) (B) (iv) (I)).

The statute thus gives the first ANDA applicant a right to 180 days of market exclusivity. Critically, the statute does not *require* the applicant to go to market at any particular time. By protecting the first ANDA applicant's right to await the conclusion of patent infringement litigation before the commencement of marketing, the Hatch-Waxman Act does no more than acknowledge the reality of the situation. Until the patent claims are disposed of, the patent holder almost certainly would be entitled to a preliminary injunction precluding the marketing of the allegedly infringing product, and the ANDA applicant would therefore be

unable to enter the market whether it wished to or not. Also, given the substantial risks of marketing an infringing product, an ANDA applicant will almost certainly refrain from marketing its product until the brand name manufacturer's patent claims were resolved.

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 Andrx's defense of this case.

B. Other Competitors

Well after Andrx filed its ANDA for generic Cardizem® CD, two other companies, Faulding, Inc. ("Faulding") and Biovail International Corporation ("Biovail"), both of which were identified by Complaint Counsel as entities that might have been affected by the 1997 Stipulation, filed their own ANDAs for what they asserted were bioequivalent formulations of Cardizem® CD. HMR promptly 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.

ARGUMENT

GIVEN THE CENTRALITY OF THE FDA TO THE PHARMACEUTICAL PROCESS AT ISSUE IN THIS CASE, ANDRX SHOULD BE PERMITTED TO SEEK THE DISCOVERY OF RELEVANT DOCUMENTS FROM THE AGENCY

Section 3.36 of the FTC's Rules of Practice expressly authorizes the issuance of subpoenas upon other governmental agencies in the context of an FTC administrative proceeding. See 16 C.F.R. §3.36(a). Subpoenas directed to other governmental agencies must satisfy the following tripartite showing:

> (1) the material sought is reasonable in scope;
>
> (2) if for the purposes of discovery, the material falls within the limits of discovery under §3.31(b)(1) . . .; and
>
> (3) the information and material sought cannot reasonably be obtained by other means.

16 C.F.R. §3.36(b). Andrx's proposed subpoena is narrowly drawn and satisfies these criteria.

The information Andrx seeks from the FDA (see Shaftel Declaration, Ex. 1) falls 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.

In addition to being relevant, Andrx's proposed requests are extremely focused, and will only require the FDA to search for responsive documents in discrete files at the agency. Moreover, given the nature of the documents requested, subpoenaing the FDA will be by far the most expeditious (if not the only) method for Andrx to secure the desired information.

CONCLUSION

For the foregoing reasons, Andrx respectfully request that its motion be granted in all respects.

Dated: New York, New York
June 10, 2000

Respectfully Submitted,

SOLOMON, ZAUDERER, ELLENHORN,
FRISCHER & SHARP

By: Hal S. Shaftel

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Hal S. Shaftel
Jonathan D. Lupkin
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Counsel for Respondent Andrx Corporation

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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: a) to place before the Court a schedule of those documents Andrx seeks to obtain from the FDA; and b) to apprise the Court that Complaint Counsel has indicated that it will not oppose Andrx's motion and that the other respondents consent to the motion.

2. Annexed hereto as Exhibit A is a copy of "Schedule A," which identifies those categories of documents Andrx seeks from the United States Food and Drug Administration.

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

Executed in New York, New York, on June 10, 2000

Hal S. Shaftel

HAL S. SHAFTEL

EXHIBIT A

SCHEDULE "A"

Documents Requested

1. All documents concerning any ANDA and NDA submitted by Biovail for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD, excluding the ANDA and NDA themselves. This request includes, by way of example, but is not limited to:

    a) All communications between the FDA and Biovail; and

    b) All communications between the FDA and any third party; and

    c) All responsive internal FDA documents.

2. All documents concerning the ANDA submitted by Faulding for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD, excluding the ANDA itself. This request includes, by way of example, but is not limited to:

    a) All communications between the FDA and Faulding.

    b) All communications between the FDA and any third party; and

    c) All responsive internal FDA documents.

3) All communications between the FDA and any other party (excluding Andrx) concerning Andrx's ANDA for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD. This request includes, by way of example, but is not limited to:

    a) All communications between the FDA and the FTC concerning Andrx's ANDA; and

b) All documents concerning the FDA's decision to grant approval for Andrx's ANDA, including Andrx's reformulated product approved by the FDA on June 9, 1999 .

Definitions and Instructions

a. "Andrx" means Andrx Corporation, and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, representatives, predecessors or successors.

b. "Biovail" means Biovail Corporation International and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, lawyers, representatives, predecessors or successors. The term "Biovail" specifically includes Biovail's outside counsel, Cleary Gottlieb Steen & Hamilton.

c. "Faulding" means Faulding, Inc. and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, lawyers, representatives, predecessors or successors.

d. "FDA" means the Federal Food and Drug Administration and its divisions, agents, representatives, predecessors or successors.

e. "FTC" means the Federal Trade Commission, and its divisions (including its enforcement divisions), bureaus (including its Bureau of Competition), agents, representatives, predecessors or successors

f. "NDA" means a New Drug Application submitted to the FDA for approval for the manufacture and marketing of a pharmaceutical product.

g. "ANDA" means an Abbreviated New Drug Application submitted to the FDA for approval for the manufacture and marketing of a

pharmaceutical product that is the "bioequivalent" of an FDA approved, brand name pharmaceutical product.

h. The terms "document" and "documents" are used in their broadest sense, to the full extent permitted by the Federal Rules of Civil Procedure to mean , without limitation, any original written, recorded, filmed, or graphic matter of every type and description, whether produced or reproduced on paper, cards, tapes, film, electronic facsimile, computer storage disks, tapes, or devices, or any other media, and each copy of such writing, record, film, or graphic matter that is different in any way from the original or where such copy contains any commentary or notation whatsoever that does not appear on the original whether by interlineation, receipt stamp notation, inclusion of comments or notations, or otherwise and drafts. Documents specifically include, by way of illustration, but not by way of limitation, all letters, notes, diaries, E-mails, reports, studies, charts, graphs, memoranda, instruments, minutes, ledgers, records, recordings, tapes, microfilm, photographs, correspondence, telegrams, diaries, bookkeeping entries, financial statements, tax returns, checks, check stubs, notebook statements, affidavits, agreements, applications, books, pamphlets, periodicals, appointment calendars and work papers.

i. "Concern" and "concerning" mean relating to, referring to, describing, evidencing, or constituting.

j. The terms "and" and "or" include both the conjunctive and disjunctive, as necessary, to bring within the scope of this request all responses that might otherwise be construed to be outside of its scope.

k. The terms "any" "all" and "each" each shall be construed to mean "any, all and each".

l. The use of a singular form of any word includes the plural, and vice-versa.

m. The terms "include" and "including" are used for illustration and not by way of limitation.

n. If any documents that are responsive to the document requests herein are withheld from production, furnish a list of all such documents withheld. Said list shall contain a complete description of each document, including: (i) the type, date, and number of pages of the document; (ii) its title (if any); (iii) a general description of its subject matter; (iv) the identity of any attachments or appendices to the document; (v) the name and identification of each person to whom it is addressed; (vi) the name and identification of each person who received a copy thereof; (vii) the name and identification of the persons or person by whom it was written or generated; (viii) its present custodian; (ix) the ground or grounds upon which it is being withheld.

o. In the event that any document called for by this document request has been destroyed or discarded, please identify each such document by stating: (i) any addresser and addressee; (ii) the addressees of any indicated or blind copies; (iii) the type, date, subject matter and number of pages of the document; (iv) a description of any attachment or appendices to the document; (v) the names and identification of all persons to whom the document was distributed, shown or explained; (vi) the date when it was destroyed or discarded, and the manner in which it was

destroyed or discarded; and (vii) the names and identification of the persons authorizing and carrying out such destruction or discarding.

p. Unless otherwise indicated, this subpoena calls for the production of documents that were created or utilized during, or otherwise concern, the period from January, 1993 through and including the date of production.

q. This subpoena should be construed as not calling for the production of any documents prepared, authored, created, submitted or filed by Andrx.

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[PROPOSED] ORDER

The motion of Respondent Andrx Corporation for an Order authorizing the issuance of a subpoena duces tecum to the United States Food and Drug Administration ("FDA") calling for the production of those categories of documents identified in Exhibit 1 to the accompanying Declaration of Jonathan D. Lupkin is hereby GRANTED.

It is further ORDERED that the FDA shall comply with the subpoena within ten (10) days of service.

Dated: June _____, 2000

_____
D. Michael Chappell
Administrative Law Judge