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

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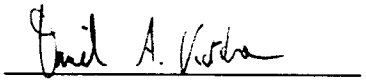
| In the Matter of<br><br>HOECHST MARION ROUSSEL, INC.,<br>a corporation,<br><br>CARDERM CAPITAL L.P.,<br>a limited partnership,<br><br>and<br><br>ANDRX CORPORATION,<br>a corporation. | Docket No. 9293 |

**COMPLAINT COUNSEL'S MOTION TO COMPEL RESPONDENT ANDRX TO PRODUCE DOCUMENTS**

Pursuant to § 3.38 of the Federal Trade Commission's Rules of Practice, complaint counsel hereby move for an order compelling respondent Andrx to produce certain documents responsive to complaint counsel's First Request for Documents and Things issued to Andrx. The bases of this motion are set forth in the accompanying Memorandum in Support of Complaint Counsel's Motion to Compel Andrx to Produce Documents and the attachments to this memorandum.

Respectfully Submitted,



Markus H. Meier
Bradley S. Albert
Daniel A. Kotchen

Counsel Supporting the Complaint

Bureau of Competition
Federal Trade Commission
Washington, D.C. 20580

Dated: July 7, 2000

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

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

TO: The Honorable D. Michael Chappell
Administrative Law Judge

# MEMORANDUM IN SUPPORT OF COMPLAINT COUNSEL'S MOTION TO COMPEL ANDRX TO PRODUCE DOCUMENTS

This case is about Hoechst paying its competitor Andrx more than $89 million to delay the entry of low-cost generic competition to its highly profitable $700 million a year prescription drug Cardizem CD. Hoechst knew that a low-priced generic product would take away roughly 40% of its lucrative Cardizem CD sales in the first year alone. When confronted with the threat of such a precipitous decline in the sales of its flagship product, Hoechst acted quickly to preserve its Cardizem CD franchise by structuring and entering into an agreement with Andrx. Andrx was promised $10 million a quarter (and up to an additional $60 million a year) to refrain from marketing its generic diltiazem product, Cartia XT, in competition with Hoechst's Cardizem CD, and to forgo taking any steps that would permit the entry of any other generic diltiazem competitor. Andrx has raised ten affirmative defenses in an attempt to justify this

agreement, but now refuses to produce the documentary evidence that would tend to prove or disprove its assertions.[1]

Andrx claims that the Court's schedule in this matter leaves the parties with barely sufficient time to develop its case. Responding to this concern, complaint counsel have sought to move ahead with discovery and narrow the issues. We produced to respondents virtually all non-privileged responsive documents by May 31, 2000, before the due date of their respective document requests. Although Hoechst failed to produce documents by the due date of our first document request, it is in the process of producing documents on a rolling basis. Andrx, by contrast, has stonewalled with respect to even the most basic discovery requests. In fact, to date, Andrx has not produced a single document in response to our document request served on it more than two months ago. We have made numerous attempts to address Andrx's concerns about our document request, but because Andrx has failed to produce any documents since the complaint was filed, we ask this Court to compel Andrx to produce the following information,[2]

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[1] Andrx asserted nine additional "defenses" that are unrelated to the merits of this matter or plainly inadequate as a matter of law. These defenses are the subject of a pending motion to strike. *See* Complaint Counsel's Motion to Strike Affirmative Defenses (April 28, 2000).

[2] This Motion to Compel addresses only Andrx's objections to specifications 3, 5, 7, 8, 12, 16, and 17. Andrx has also refused to produce any documents, including documents that Andrx acknowledges are responsive and non-privileged, unless we provide additional commitments consistent with their interpretation of ¶ 4 of the protective order, as set forth in their letter of June 28, 2000. *See* Letter from Jonathan Lupkin to Brad Albert, dated June 28, 2000 (attached as Exhibit 5). This issue has already been fully briefed by the parties, *see* Respondent Andrx's Motion for an Order (dated May 30, 2000) and Complaint Counsel's Memorandum in Opposition to Andrx's May 30th Motion, and Your Honor denied Andrx's motion. We will be requesting a separate status conference to resolve the issue of Andrx's continued refusal to abide by Your Honor's ruling.

which relates directly to the issues in the complaint, to respondents' defenses, or to the proposed relief:

- Notes or minutes of Andrx Board of Director meetings, and other meetings relating to the development, marketing, or sale of Andrx's generic Cardizem CD product, Cartia XT (specification 3);

- Documents sufficient to show Andrx's research and development budgets, which will provide the information necessary to test whether Andrx really needed the $10 million quarterly payments from Hoechst to fund the research and development of its generic Cardizem CD, as it claims (specification 5);

- Documents relating to the marketing of Andrx's generic version of Cardizem CD, Cartia XT, which would include information bearing on whether Andrx expected to, or considered, marketing Cartia XT prior to resolution of the patent infringement suit with Hoechst (specification 7);

- Documents relating to Andrx's research and development of Cartia XT, which would, among other things, provide evidence of whether Andrx slowed its development of its generic diltiazem product after entering into the non-compete agreement with Hoechst (specification 8);

- All of Andrx's generic Cardizem CD marketing, business, and strategic plans; which documents will help define the relevant product market and identify the significant impact that generic competition has in the marketplace (specification 12); and

- A copy of each patent settlement and licensing or joint development agreement to which Andrx is or was a party; which documents could provide evidence of Andrx's intent in entering into its agreement with Hoechst and the validity of Andrx's purported justifications by showing the types of terms typically included in such agreements (specifications 16 and 17).

## A. Factual Overview

On May 3, 2000, we issued to Andrx a document request containing seventeen specifications relevant to allegations in the Commission's complaint and to respondents' defenses. Ignoring the scheduling order's 20-day response time (which the respondents themselves originally insisted upon), Andrx served its objections to our document request more

than a week late. But Andrx did not produce a single document with this overdue response. Instead, Andrx simply asserted that it already had produced responsive documents (presumably referring to its pre-complaint production more than 18 months ago), and it refused to produce other documents unless we withdraw our document request and instead present them with more "narrowly tailored" requests. To this day – more than two months after we served our document request – Andrx has not produced even one document.

This behavior is particularly ironic coming from Andrx, who has accused us of "stonewalling in providing discovery,"[3] when, in fact, we have provided them all of our non-privileged documents (35 boxes) at the earliest possible time after entry of the protective order. As Andrx has repeatedly reminded us and Your Honor, "time is extremely limited . . . to conduct discovery."[4] Apparently, Andrx does not feel the same urgency when it is its turn to respond to our discovery requests.

Notwithstanding Andrx's lack of cooperation in producing any documents, we have sought in good faith to address its purported concerns regarding our discovery request. Over a three week period we conducted several "meet and confer" sessions in which we negotiated with Andrx the scope of each of the seventeen specifications, further narrowing our requests.[5] We reached an apparent understanding with respect to certain specifications, but are at an impasse

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[3] Andrx's Preliminary Witness List, at 1.

[4] Andrx's Memorandum in Support of Its Motion to Compel, at 1.

[5] *See* Kotchen Declaration ¶ 3 (attached as Exhibit 1).

with respect to seven specifications.[6] As demonstrated below, these specifications are narrowly-tailored requests that directly relate to both the allegations in the Commission's complaint and to Andrx's defenses. Nonetheless, Andrx has refused to produce these documents based largely on the claim of relevance. As also is detailed below, Andrx's objection to producing the materials responsive to these specifications on the grounds of relevancy has no basis in law or fact.

**B. The Documents Responsive to Complaint Counsel's Specifications in Dispute Are Directly Relevant to Many Issues in this Matter**

Commission Rule 3.31(c)(1) provides that parties "may obtain discovery 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."[7] The Commission's rules of practice adopt a liberal approach to discovery,[8] and it has long been established that the scope of discovery in Commission proceedings is broad.[9] As Your Honor observed in *Motor Up Corporation*, so long as a document request "is relevant to the allegations of the complaint and respondents' defenses, or is likely to lead to the discovery of relevant information," such a request is appropriate and merits the production of documents.[10] This is precisely the case here.

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[6] Several issues remain open between complaint counsel and Andrx regarding Andrx's response to our document request. Since we are hopeful that we will be able to resolve these issues without the court's intervention, we have not raised them here.

[7] 16 C.F.R. § 3.31(c)(1).

[8] *Chain Pharmacy Ass'n*, Dkt. No. 9227, 1990 FTC Lexis 193, at *3 (June 20, 1990).

[9] *Motor Up Corp.*, Dkt. No. 9291, 1999 FTC Lexis 207, at *2 (Aug. 5, 1999); *R.R.. Donnelley & Sons Co.*, Dkt. No. 9243, 1991 FTC Lexis 268, at *1 (June 6, 1991).

[10] *Motor Up Corp.*, 1999 FTC Lexis at *2. *See also*, Fed. R. Civ. P. 26(b)(1) ("Parties may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action, whether it relates to the claim or defense of the party seeking

The information we seek directly bears on the allegations raised in the complaint, as well as the defenses raised by Andrx and are reasonably calculated to lead to the discovery of relevant information.

**1. Specification 3 – Meeting Minutes**

We have requested minutes from Andrx meetings, relating to its generic version of Cardizem CD. In response, Andrx has agreed to provide only certain Board of Director meeting minutes from September 1997 through approximately June 1999.[11] Without any legitimate explanation, Andrx has refused to provide all other responsive information, including: (1) Board of Director meeting minutes after June 1999; and (2) any minutes or notes whatsoever from non-Board of Director meetings.

The meeting notes that Andrx refuses to produce are directly relevant to a variety of issues and defenses in this litigation, including, among others:

- Whether Andrx delayed development of its reformulated version of generic Cardizem CD after entering into its agreement with Hoechst;
- The post launch price, sales, profits, and competitors of Cartia XT (relating to the product market definition as alleged in ¶ 12 of the complaint);
- Whether Andrx would have refrained from launching its reformulated version of generic Cardizem CD even after receiving FDA approval if it had not terminated its agreement with Hoechst (relating to the anticompetitive effects of the agreement as alleged in ¶ 29 of the complaint);
- Whether Andrx had the means – other than the $10 million quarterly payments from Hoechst – to finance the development of its generic Cardizem CD product (relating to Andrx's affirmative defense number 6); and

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discovery or to the claim or defense of any other party [as long as] the information sought appears reasonably calculated to lead to the discovery of admissible evidence.")

[11] Letter from Hal Shaftel to Brad Albert, dated June 28, 2000 (attached as Exhibit 4).

- Whether Andrx will enter into future agreements to delay introduction of other generic products (relating to the Commission's proposed relief).

Moreover, Andrx has stated its intention to introduce testimony on these various points.[12] Therefore, based on the relevancy of the documents to a number of issues here, Andrx should be compelled to comply fully with specification 3.

**2. Specification 5 – Research and Development Budgets**

We have requested documents sufficient to show Andrx's monthly research and development budgets for each product until June 1999 – the month the FDA approved Andrx's reformulated version of generic Cardizem CD. Andrx has agreed to provide such budgets only for its generic Cardizem CD product, but refuses to produce similar budgets either for its other products or in the aggregate.

Information concerning Andrx's overall research and development efforts is needed to assess Andrx's affirmative defense number 6. Specifically, Andrx claims that its agreement with Hoechst was procompetitive because it provided Andrx with the funds necessary to "reformulate its product and receive FDA approval for that product."[13] The implication of this defense is that without the $10 million quarterly payments from Hoechst, Andrx lacked the means necessary to fund the reformulation of its generic Cardizem CD product. Further, according to its preliminary

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[12] *See, e.g.*, Andrx Preliminary Witness List at 2, 7 (expected testimony of Dr. Xiu-Xiu Cheng and Dr. Dat Trieu concerning the "manufacturing and technical aspects of Andrx's efforts at developing its generic versions of Cardizem CD"); and at 3, 5 (expected testimony of Dr. Eliot Hahn and Angelo Malahias including "Andrx's financial situation").

[13] Andrx Aff. Def. No. 6. *See also* Andrx's Opposition to Complaint Counsel's Motion to Strike, at 13 (the Stipulation "enabled Andrx, at the time only five years in existence and relatively cash poor, to defend itself in the Patent Action, reformulate its product, and get its product to market"); Andrx Answer at ¶ 34 (Stipulation "provided Andrx with funding that permitted it to develop its non-infringing reformulated product").

witness list, Andrx's Chief Financial Officer is "expected to testify concerning Andrx's financial situation during the period relevant to the development of its generic versions of Cardizem CD."[14] Thus, we need the requested research and development budgets to assess the validity of this defense by discovering:

- Whether, in the absence of the $10 million quarterly payments, Andrx would have had adequate funding for its generic Cardizem CD project;
- The amount Andrx spent on research and development for each of its other products prior to receiving the $10 million quarterly payments from Hoechst, and whether Andrx could have diverted financial resources from these products to Cartia XT; and
- Whether Andrx's overall research and development budget increased after it began receiving the $10 million quarterly payments from Hoechst.

In light of the relevance of this information, Andrx's own reliance on the information in asserting its defenses, and its failure to assert a legitimate objection, Andrx should be compelled to respond fully to specification number 5.

**3. Specification 7 – Cartia XT Documents**

We have requested documents relating to Andrx's generic Cardizem CD product, Cartia XT, such as steps taken to market the product, the likelihood the product infringes an Hoechst patent, expectations as to when Andrx could market the product, and Andrx's obligation under its agreement with Hoechst to refrain from marketing the product. In response, Andrx agreed to provide only documents "sufficient to reflect Andrx's marketing practices with respect to Cartia XT."[15]

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[14] Andrx Preliminary Witness List, at 5.

[15] Letter from Hal Shaftel to Brad Albert, dated June 28, 2000 (attached as Exhibit 4).

Information concerning Andrx's Cartia XT is relevant and necessary to assess, among other things, the anticompetitive effects of the Hoechst-Andrx agreement, as alleged in paragraphs 29-35 of the complaint. For example, the development, manufacturing, and marketing of Cartia XT are all relevant as to when Andrx expected to, would have been in a position to, and would have decided to launch Cartia XT. Andrx itself recognizes the relevance of this information, as it relies upon similar information in various affirmative defenses, including numbers 5 and 10.[16]

Andrx should not be allowed to put at issue in this case when and if it intended to market its Cartia XT product and then decide for itself which documents it believes are "sufficient to reflect Andrx's marketing practices." Given the relevance of these documents to the allegations in the complaint and to Andrx's defenses, Andrx should be required to respond fully to the specification 7.

**4. Specification 8 – Research, Development, and Manufacturing**

We have requested documents created prior to July 1, 1999, relating to Andrx's research, development, and manufacturing of a generic version of Cardizem CD. Andrx, however, seeks to limit its production to only "documents sufficient to demonstrate [its] R&D efforts for Cartia XT."[17] Again, these limitations are insufficient in light of the issues raised by the complaint and Andrx's defenses. Information concerning Andrx's research, development, and manufacturing of

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[16] *See* Andrx Aff Def No. 5 (no anticompetitive effects) and No. 10 (unwilling and unable to market product during pendency of suit).

[17] Letter from Hal Shaftel to Brad Albert, dated June 28, 2000 (attached as Exhibit 4).

its generic Cardizem CD is relevant, among other things, to: (1) the anticompetitive effects of the Hoechst-Andrx agreement, and (2) Andrx's affirmative defense number 6.

First, the complaint alleges that the Hoechst-Andrx agreement was intended to "deter Andrx from selling any non-infringing or potentially non-infringing version of its generic Cardizem CD product" while the agreement was in place.[18] Knowing that it could not market a generic version of Cardizem CD during the pendency of the agreement, Andrx likely had a diminished incentive to develop aggressively and launch a non-infringing generic version of Cardizem CD. To assess fully whether the agreement slowed Andrx's development of a non-infringing product, we need discovery relating to Andrx's generic Cardizem CD research, development, and manufacturing efforts. This will enable us to compare Andrx's development patterns both before and after it entered into the agreement, and assess whether the agreement had an effect on the immediacy with which Andrx sought to develop and launch a non-infringing product. Relying merely on documents selected by Andrx that it believes are "sufficient to demonstrate" its practices is simply not enough to probe Andrx's pattern of development.

Second, in Andrx's affirmative defense number 6, Andrx asserts that the $10 million quarterly payments from Hoechst enabled Andrx to develop successfully a non-infringing generic version of Cardizem CD. The documents requested here will test this defense by showing whether or not Andrx completed most (or all) of its development work prior to receiving payments from Hoechst.

For these reasons, Andrx should be required to respond fully to specification 8.

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[18] *See* Complaint, at ¶ 32.

### 5. Specification 12 – Cartia XT Marketing, Business, and Strategic Plans

We have requested Andrx's marketing, business, and strategic plans related to Cartia XT. Believing that such documents created after terminating its agreement with Hoechst are irrelevant, Andrx agreed to produce only "documents responsive to Specification 12 for the time period up to the execution of the Termination Agreement."[19] We seek to have Andrx produce documents responsive to this specification through the present.

Andrx's most recent marketing, business, and strategic plans are relevant both to the allegations in the complaint and to Andrx's defenses. First, these documents will show that the appropriate product market in which to assess the legality of the Hoechst-Andrx agreement is no broader than once-a-day diltiazem.[20] For instance, the planning documents likely reflect, among other things: (1) which calcium channel blocker products have been, and are projected to be, affected by the entry of generic Cardizem CD; (2) the past, present, and future pricing of Cartia XT and of other competing products; and (3) the products that Andrx perceives as the competitors to Cartia XT.

Second, these documents will help measure the actual or intended anticompetitive effects of the Hoechst-Andrx agreement.[21] Entry of a generic version of Cardizem CD has a significant

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[19] Letter from Hal Shaftel to Brad Albert, dated June 28, 2000 (attached as Exhibit 4).

[20] The complaint alleges that the product market is no broader than the U.S. market for once-a-day diltiazem. *See* Complaint, at ¶ 14. Andrx, in its answer, denies this allegation. *See* Respondent Andrx's Answer, at ¶ 14.

[21] Again, the complaint alleges that: (1) the Hoechst-Andrx agreement had the purpose or effect of restraining competition (¶ 29); (2) earlier entry of a generic version of Cardizem CD would have had a significant procompetitive impact in the relevant market (¶ 30); and (3) the agreement deterred Andrx from selling a generic version of Cardizem CD (¶ 32).

competitive impact in the relevant market. Pharmacists generally are permitted, and in some instances required, to substitute low-cost generic drugs for their branded counterparts, without obtaining the prescribing physicians' approval, and certain health plans encourage or insist on the use of generic drugs for their members whenever possible. As a result, a generic product can quickly and efficiently enter the market at substantial discounts, generally leading to a significant erosion of the branded drug's sales and a significant cost savings to consumers. Indeed, this anticipated erosion of Cardizem CD sales is what drove Hoechst to enter into this anticompetitive agreement. The planning documents that Andrx seeks to withhold could provide information, such as the expected and actual rate of Cartia XT's market penetration, as well as Cartia XT's pricing discounts relative to Cardizem CD, to assess the likely and actual cost to consumers from the delayed entry of generic competition.

For these reasons, Andrx should be required to produce its planning documents through the present as requested in specification 12.

### 6. Specifications 16 and 17 – Patent Settlement and Licensing and Joint Development Agreements

We have requested a copy of each patent settlement (spec. 16), and licensing or joint development agreement to which Andrx is or was a party (spec. 17). This request is directly relevant to a number of issues in this litigation, including, among other things: (1) Andrx's intent in entering its agreement with Hoechst; (2) whether the terms of the Hoechst-Andrx agreement are unique relative to other settlement or joint development agreements to which Andrx is a party (*i.e.*, has Andrx ever been paid not to market a product); and (3) whether Andrx's purported justifications here are unique relative to other agreements.

Even though Hoechst has agreed to produce other agreements to which it is a party, Andrx refuses to produce any of these materials – not because it claims they are privileged, nor because it disputes their relevance. Rather, Andrx's refusal to produce these admittedly non-privileged, relevant, and responsive documents is solely because we have objected to produce what Andrx believes are "similar" documents. Contrary to what Andrx believes, however, the documents withheld by complaint counsel – patent settlements involving other pharmaceutical companies and the FTC staff legal analyses of such agreements – are not at all similar. First, these documents come from the files of the Commission's other non-public law enforcement investigations – files that Congress and the Commission have presumed confidential, and for which we have raised legitimate and well-established privileges to protect from disclosure. Additionally, unlike Andrx's all-encompassing document requests (which seek agreements involving third parties), we have carefully limited our discovery to agreements entered into by the parties in this case. Finally, Andrx's refusal to produce these relevant documents rests on the legally incorrect assumption that Andrx is entitled to discovery "equal" to that of complaint counsel.[22]

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[22] *Sperry and Hutchinson Co. v. F.T.C.*, 256 F. Supp. 136, 143-44 (S.D.N.Y. 1966) (rejecting a similar demand for identical discovery because that would "appear[] to be tantamount to a complete disclosure of the Commission's [investigatory] files"). *See also Exxon Corp.*, 1980 FTC Lexis 121 at *7-8 n.9 (finding no due process right to "access to all materials which complaint counsel have examined"); *Standard Oil Co. v. F.T.C.*, 475 F. Supp. 1261, 1275 (N.D. Ind. 1979) (rejecting due process argument that respondents "are entitled to 'any evidence' in the hands of complaint counsel, or that . . . [respondents] are entitled to discovery 'equal' to the discovery of complaint counsel").

In light of Andrx's failure to provide any legitimate basis for its refusal to respond to appropriate discovery requests, Andrx should be compelled to respond fully to specifications 16 and 17.

### C. Andrx has not Demonstrated – and Cannot Demonstrate – that the Specifications Here are Unduly Burdensome

Andrx's boilerplate objection claiming burden in responding to the disputed document requests should not be credited. "[O]ne who opposes an agency's subpoena necessarily must bear a heavy burden."[23] The question is whether the "demand is unduly burdensome or unreasonably broad. Some burden on subpoenaed parties is to be expected and is necessary in furtherance of the agency's legitimate inquiry and the public interest."[24] As one Administrative Law Judges explained, where the information requested "appears generally relevant to the issues in the proceeding" compliance will not be excused even where the subpoenaed party "adequately demonstrates" that the subpoena will impose a "substantial degree of burden, inconvenience, and cost."[25] Here, Andrx has failed to make any showing that compliance with our narrowly-tailored, relevant requests would pose such a burden that it would "unduly disrupt or seriously threaten normal operations."[26]

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[23] *FTC v. Dresser Industries Inc.*, 1977 WL 1394, at *3 (D.D.C.).

[24] *FTC v. Texaco, Inc.*, 555 F.2d 862, 882 (D.C. Cir. 1977), *cert denied* 431 U.S. 974.

[25] *Kaiser Aluminum & Chemical Corp.*, Dkt. No. 9080, 1976 FTC Lexis 68, at *18 (Nov. 12, 1976); *see also United States v. Morton Salt Co.*, 338 U.S. 632, 653-54 (1950).

[26] *FTC. v. Dresser Industries Inc.*, at *4.

### D. The Fact that Andrx Produced Some Documents during the Pre-Complaint Investigation Has No Bearing on Its Obligation to Produce Documents Here

Andrx implies that, because it produced documents during the Commission's pre-complaint investigation of this matter, complaint counsel is not prejudiced by Andrx's refusal to cooperate here.[27] The logical implication of Andrx's position is that we are not entitled to conduct discovery after filing a complaint. The Commission rules, however, "are designed to facilitate discovery 'in the light of the issues raised by the complaint,'"[28] and the Commission has consistently rejected arguments that compliance with pre-complaint subpoenas somehow obviates the duty to comply with post-complaint document requests.[29]

We do not ask here that Andrx re-produce the five boxes of documents that it produced during our pre-complaint investigation, most of which was produced more than eighteen months ago. Indeed, instruction 5 of our document request to Andrx specifically states that "if [Andrx] has produced documents responsive to this request in the course of the pre-complaint investigation of this matter, FTC File No. 981-0368, those documents need not be produced

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[27] *See* Andrx's Response to Complaint Counsel's First Request for Documents and Things, at 1-2 (discussing the documents Andrx produced in the pre-complaint investigation of this matter).

[28] *Food Fair Stores*, 83 F.T.C. 1578, 1581 (1974) (*quoting Lehigh Portland Cement Co.*, 74 F.T.C. 1589, 1592 (1968)).

[29] *See, e.g., Exxon Corporation*, 83 F.T.C. 1759, 1760 (1974) ("Post-complaint discovery by complaint counsel is entirely proper and the sole limits on its proper scope are the requirements of due process that govern in any judicial proceeding, e.g., definiteness of the demand, relevance of the data sought to the issues raised in the pleadings, etc. (*citing United States v. Morton Salt Co.*, 338 U.S. 632, 641 (1950)). *See also Food Fair Stores*, 83 F.T.C. at 1582 ("It shall not be a grounds to challenge complaint counsel's discovery to argue that the precomplaint investigation was the proper time to obtain the information sought, if such information is relevant to the issues raised in the pleadings.").

again." We do ask, however, that Andrx produce relevant documents responsive to our document request that were not produced during the investigation. As Andrx has repeatedly reminded this court, discovery is a two-way street,[30] and it is time for Andrx to adhere to the same discovery rules with which every other party to this litigation has thus far complied.

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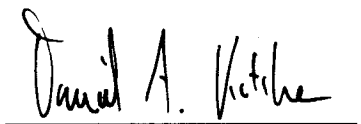
For the reasons discussed above, our Motion to Compel Respondent Andrx to Produce Documents Responsive to Complaint Counsel's First Request for Documents and Things should be granted.

Respectfully Submitted,



Markus H. Meier
Bradley S. Albert
Daniel A. Kotchen
Robin Moore

Counsel Supporting the Complaint

Bureau of Competition
Federal Trade Commission
Washington, D.C. 20580

Dated: July 7, 2000

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[30] *See* Andrx's Motion to Compel Complaint Counsel to Produce Documents, at 3 (quoting *Wardius v. Oregon*, 412 U.S. 470, 475 (1973)).

**UNITED STATES OF AMERICA**
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**ORDER GRANTING COMPLAINT COUNSEL'S MOTION TO COMPEL RESPONDENT ANDRX TO PRODUCE DOCUMENTS**

IT IS HEREBY ORDERED that complaint counsel's motion for an order compelling respondent Andrx to produce certain documents responsive to complaint counsel's First Request for Documents and Things issued to Andrx is GRANTED.

Dated: _____, 2000

_____
D. Michael Chappell
Administrative Law Judge

## CERTIFICATE OF SERVICE

I, Daniel A. Kotchen, hereby certify that on July 7, 2000, I caused a copy of Complaint Counsel's Motion to Compel Andrx to Produce Documents, Proposed Order, and Memorandum in Support of Counsel's Motion to Compel Andrx to Produce Documents (including the attachments to the memorandum) to be served upon the following persons either by hand or by Federal Express:

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
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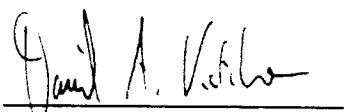

Daniel A. Kotchen

# EXHIBIT 1

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

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

**Declaration of Daniel A. Kotchen**

Pursuant to 16 C.F.R. § 3.22(f), Daniel A. Kotchen declares as follows:

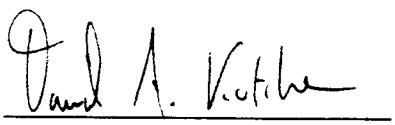
1. I am an attorney with the Federal Trade Commission and serve as complaint counsel In the Matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corp., Docket No. 9293. I submit this declaration to represent that complaint counsel has conferred with Andrx in an effort in good faith to resolve by agreement the issues raised in complaint counsel's Motion to Compel Andrx to Produce Documents. Complaint counsel and Andrx have been unable to reach such an agreement.

2. On May 3, 2000, complaint counsel issued to Andrx our First Request for Documents and Things. Andrx responded to this request on June 1, 2000, objecting to each of the specifications within the document request and failing to produce any responsive documents.

3. Bradley Albert, a Commission attorney also serving as complaint counsel in this matter, and I participated in three "meet and confer" sessions (on June 7, 13, and 30) with Hal

Shaftel and Jonathan Lupkin, counsel for Andrx. During each of these conferences, we discussed and negotiated the scope of the specifications within our document request. As a result of these discussions, we were able to narrow the scope of our differences, reaching agreement with respect to Andrx's production in response to several specifications (1, 4, 6, 11, and 15). Despite our best efforts, however, we were unable to resolve our differences relating to Andrx's response to specifications 3, 5, 7, 8, 12, 16, and 17, which are subject to our motion to compel. In addition, issues relating to Andrx's response to the remaining requests (2, 9, 10, 13, and 14) remain under discussion and may be the subject of a future motion to compel.

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



Daniel A. Kotchen

Dated: July 7, 2000

# EXHIBIT 2

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

**COMPLAINT COUNSEL'S FIRST REQUEST FOR PRODUCTION OF DOCUMENTS AND THINGS ISSUED TO ANDRX CORPORATION**

Pursuant to the Federal Trade Commission's Rules of Practice, 16 C.F.R. § 3.37, complaint counsel hereby requests that respondent Andrx Corporation (hereinafter "Andrx") produce all documents and other things responsive to the following requests, within its possession, custody, or control, within twenty days in accordance with the Definitions and Instructions set forth below.

**DEFINITIONS**

A. The term "the company" means Andrx, its domestic and foreign parents, predecessors, divisions, and wholly or partially owned subsidiaries, affiliates, partnerships, and joint ventures; and all directors, officers, employees, consultants, agents and representatives of the foregoing. The terms "subsidiary," "affiliate," and "joint venture" refer to any person in which there is partial (25 percent or more) or total ownership or control by the company.

B. The term "document" means all written, recorded, or graphic materials of every kind, prepared by any person, that are in the possession, custody, or control of the company. It includes all electronically-stored data accessible through computer or other information retrieval systems or devices. The term "document" includes the complete original document (or a copy thereof if the original is not available), all drafts, whether or not they resulted in a final document, and all copies that differ in any respect from the original, including any notation, underlining, marking, or information not on the original. Documents covered by this subpoena include, but are not limited to, the following: letters; memoranda; reports; contracts and other agreements; studies; plans; entries in notebooks, calendars and diaries; minutes, records, and transcripts of conferences, meetings, telephone calls or other

communications; published and unpublished speeches or articles; typed and handwritten notes; electronic mail; facsimiles (including the header showing the receipt date and time); tabulations; statements, ledgers, and other records of financial matters or commercial transactions; diagrams, graphs, charts, blueprints, and other drawings; technical plans and specifications; advertising and product labels; photographs, photocopies, slides, microfilm, microfiche, and other copies or reproductions; film, audio and video tapes; tape, disk, and other electronic recordings; and computer printouts.

C. The term "relating to" means, in whole or in part, addressing, analyzing, concerning, constituting, containing, commenting on, discussing, describing, identifying, referring to, reflecting, reporting on, stating, dealing with, or in any way pertaining to.

D. The term "documents sufficient to show" means documents that are necessary and sufficient to provide the specified information. If summaries compilations, lists or synopses are available that provide the information, these should be provided in lieu of the underlying documents.

E. The terms "each," "any," and "all" mean "each and every."

F. The terms "and" and "or" have both conjunctive and disjunctive meanings as necessary to bring within the scope of this subpoena anything that might otherwise be outside its scope.

G. The singular form of a noun or pronoun includes its plural form, and vice versa; and the present tense of any word includes the past tense, and vice versa.

H. The term "plan" means a proposal, recommendation or consideration, whether or not precisely formulated, finalized, authorized, or adopted.

I. The term "year" means either the calendar year or, for financial records, the fiscal year.

J. The term "communication" means any exchange, transfer, or dissemination of information, regardless of the means by which it is accomplished.

K. The term "agreement" means any oral or written contract, arrangement or understanding, whether formal or informal, between two or more persons, together with all modifications or amendments thereto.

L. The term "person" includes Andrx and means any natural person, corporate entity, sole proprietorship, partnership, association, governmental entity, or trust.

M. The phrase "HMRI's patent infringement suit against Andrx" means the patent infringement suit filed against Andrx by Hoechst Marion Roussel, Inc. (hereinafter "HMRI"), in the United States District Court for the Southern District of Florida, for Andrx's alleged infringement of patents covering HMRI's Cardizem CD.

N. The term "Stipulation and Agreement" means the Stipulation and Agreement HMRI and Andrx entered into on or about September 24, 1997.

O. The term "Termination Agreement" means the Stipulation and Order entered into between HMRI and Andrx on or about June 8, 1999 which resolved HMRI's patent infringement suit against Andrx and terminated the Stipulation and Agreement.

P. The term "Reformulated Product" means the formulation of Andrx's generic Cardizem CD product which was approved for sale by the FDA pursuant to a supplement to ANDA 74-752 filed by Andrx on September 11, 1998.

Q. The term "Joint Development Agreement" means any agreement with any person to research, develop, manufacture, or market a product that, at the time the agreement is executed, has not received final FDA approval.

R. The term "Licensing Agreement" means any agreement with any person in which one party to the agreement is paid or pays a royalty in connection with the marketing of a product.

S. The term "SKU" means stock keeping unit.

T. The term "net sales" means total gross sales after deducting discounts, rebates, returns, allowances and excise taxes. Gross sales includes sales whether manufactured by the company itself or purchased from sources outside the company and resold by the company in the same manufactured form as purchased.

U. The term "gross profit" means total net sales less cost of goods sold.

V. The term "net profit" means gross profit less direct business unit expenses, including, but not limited to, national marketing and promotion costs, business research costs, clinical trial costs and supplies, samples, and processing costs.

W. The term "Cardiovascular Therapy Products" means the products within code 31000 of IMS's Uniform System of Classification.

X. The term "Machine Readable Form" means magnetic media, electronic data, and information submitted in machine readable form shall be submitted in the following forms and formats:

1. Magnetic Storage Media: (a) 9-track computer tapes recorded in ASCII or EBCDIC format at either 1600 or 6250 BPI; (b) 5.25-inch microcomputer floppy diskettes recorded in high or low densities; (c) 3.5-inch microcomputer floppy diskettes recorded in high or low densities; (d) CD-readable disks formatted to ISO 9660 specifications; (e) QIC-80 magnetic tapes formatted to Travan®-1, 2120 Ximat XL, or 2120 Ximat specification, uncompressed; (f) 5.25-inch ISO-standard rewritable optical disks with 512 sectors, formatted to 1.2 gigabytes; or (g) Iomega ZIP® disk. The FTC will accept 4mm and 8mm DAT and other cassette, mini-cartridge, cartridge, and DAT/helical scan tapes by pre-authorization only. In all events, files provided on 4mm DAT cassettes must not be compressed or otherwise altered by proprietary backup programs. Files provided on 8mm DAT cassettes must not be compressed or otherwise altered by proprietary backup programs but may be accepted with files compressed using TAR or CPIO or created using DD copy or ufsdump.

2. File and Record Structures

   a. Magnetically-Recorded Information from Centralized Non-Microcomputer-Based Systems:

      (1) File Structures: Only sequential files are acceptable. All other file structures must be converted into sequential format.

      (2) Record Structures: Only fixed length records are acceptable. All data in the record is to be provided as it would appear in printed format: *i.e.*, numbers unpacked, decimal points, and signs printed.

   b. Magnetically-Recorded Information from Microcomputers: Microcomputer-based word-processing documents should be in DOS-text (ASCII), WordPerfect 8 or prior version, or Microsoft Word 97 or prior version format. Spreadsheets should be in Microsoft Excel (.xls) 97 or prior version, or Lotus-compatible (.wk1) format. Database files should be in Microsoft Access (.mdb) 97 or earlier version, or dBase-compatible (.dbf), version 4 or prior format. Database or spreadsheet files also may be submitted after conversion

to ASCII delimited, comma separated or fixed length field format, with field names as the first record. Graphic images must be in TIFF 4 format, compressed and unencrypted. Other proprietary software formats for word processing documents, spreadsheets, databases, graphics, and other data files will be accepted by pre-authorization only. For microcomputer files that are too large for one disk, files may be provided in a proprietary backup program format with prior authorization only or in compressed PKZip® or WINZIP® format.

3. Documentation: Brief documentation of each file on tape or disk must be provided.

   a. Files provided on disk must be accompanied by the following information:

      (1) full pathname; and

      (2) the disk on which the files reside. In the case of complex files, all component files that are part of a given file must be specified with full pathnames. Where necessary, paths that must be created in order to successfully read submitted files on respondents' equipment also must be provided.

   b. For sequential database files, the documentation also must include:

      (1) the number of records in the file;

      (2) the length and block size of each record; and

      (3) the record layout, including (i) the name of each element, (ii) the respective element size in bytes, and (iii) the element's data type. The documentation should be included in the same package as the tape, along with a printout of the first 100 records in report format.

4. Shipping: Magnetic media must be shipped clearly marked:
**MAGNETIC MEDIA DO NOT X-RAY**

## INSTRUCTIONS

1. Except for privileged material, the company will produce each responsive document in its entirety by including all attachments and all pages, regardless of whether they directly relate to the specified subject matter. The company should 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, the company will not mask, cut, expunge, edit, or delete any responsive document or portion thereof in any manner.

2. Unless otherwise indicated, each specification in this subpoena covers documents dated, generated, received, or in effect from **January 1, 1995**. Respondent Andrx should supplement, amend or correct the disclosure and responses to these requests, on a continuing basis, to the extent it ascertains any additional responsive information.

3. In lieu of original hard-copy documents or electronically-stored documents, the company may submit legible copies. However, if the coloring of any document communicates any substantive information, the company must submit the original document or a like-colored photocopy.

4. If it is claimed that any document responsive to any request is privileged, work product or otherwise protected from disclosure, identify such information by its subject matter and state the nature and basis for any such claim of privilege, work product or other ground for nondisclosure. As to any such document, state: (a) the reason for withholding it or other information relating to it; (b) the author of the documents; (c) each individual to whom the original or a copy of the document was sent; (d) the date of the documents or oral communication; (e) the general subject matter of the document; and (f) any additional information on which you base your claims of privilege. Any part of an answer to which you do not claim privilege or work product should be given in full.

5. If the company has produced documents responsive to this request in the course of the pre-complaint investigation of this matter, FTC File No. 981-0368, those documents need not be produced again, provided that the company clearly indicates in its answer to the document request the portion of the document request for which it has already supplied the information called for.

6. Unless otherwise stated, each paragraph or subparagraph herein shall be construed independently and without reference to any other paragraph or subparagraph for purpose of limitation.

7. In the event that any document required to be identified or produced has been destroyed, lost, discarded, or otherwise disposed of, any such document is to be identified as completely as possible, including, but not limited to, the following information: date of disposal, manner of disposal, reason for disposal, person authorizing the disposal and person disposing of the document.

## SPECIFICATIONS

In accordance with the instructions and definitions above, submit the following:

SPECIFICATION 1: Documents relating to Andrx's financial condition, including, but not limited to, financial statements (both internal and audited), financial plans, gross profit, net profit, cash reserves, cash flows, stock sales, lines of credit, private placements, long-term debt, short-term debt, stock analyst reports, and any communication from any person that relates to Andrx's financial condition.

SPECIFICATION 2: Documents relating to any communications between Andrx and any person relating to Cardizem CD or a bioequivalent or generic version of Cardizem CD, including, but not limited to:

(a) U.S. Patent No. 5,470,584,

(b) HMRI's patent infringement suit against Andrx,

(c) the Stipulation and Agreement,

(d) the Termination Agreement, and

(e) Andrx's ANDA application for a generic or bioequivalent version of Cardizem CD.

SPECIFICATION 3: Minutes from meetings of any Andrx Board of Directors, Andrx management, executive, ad hoc or any other committee or working group relating to an Andrx generic version of Cardizem CD, including, but not limited to:

(a) minutes relating to the manufacture and sale of a bioequivalent or generic version of Cardizem CD,

(b) Andrx's Reformulated Product,

(c) HMRI's patent infringement suit against Andrx,

(d) the Stipulation and Agreement,

(e) any actual or potential legal challenge or legal scrutiny of the Stipulation and Agreement, and

(f) the Termination Agreement.

SPECIFICATION 4: Documents relating to the Termination Agreement, including, but not limited to, discussions, communications, or negotiations concerning the Termination Agreement, and drafts of the Termination Agreement (whether or not incorporated in the executed agreement).

SPECIFICATION 5: Documents sufficient to show Andrx's research and development budgets, projections, and expenditures by month and product.

SPECIFICATION 6: Documents relating to Andrx's actual and projected legal expenditures for HMRI's patent infringement suit against Andrx.

SPECIFICATION 7: Documents relating to Andrx's Reformulated Product, including, but not limited to the likelihood that the product infringed (or infringes) a patent owned or controlled by HMRI; Andrx's ability to market the product; any actual, considered, or possible effect the product had or would have had on any HMRI obligation pursuant to the Stipulation and Agreement; and any actual, considered, possible, or proposed effect the product had or would have had on Andrx's obligation pursuant to the Stipulation and Agreement.

SPECIFICATION 8: Documents created prior to July 1, 1999 relating to Andrx's research, development, or manufacture of a bioequivalent or generic version of Cardizem CD, including, but not limited to, Andrx's Reformulated Product.

SPECIFICATION 9: For each SKU of Cartia XT and Diltia XT, by month, documents in Machine Readable Form relating to any measure of the sale, price, revenues, and profit of each SKU, including, but not limited to:

(a) gross and net sales to all customers in units and dollars;

(b) gross number and dollar value of promotional sample units distributed;

(c) sales returns in units and dollars;

(d) cost of goods sold in dollars;

(e) gross and net profit in dollars;

(f) sales, promotion, or marketing expenses;

(g) the list price and wholesale acquisition cost;

(h) product returns in units and dollars; and

(i) rebates, credits, allowances, chargebacks, and any other adjustment to price.

SPECIFICATION 10: IMS data and reports in Machine Readable Form relating to all Cardiovascular Therapy Products.

SPECIFICATION 11: All documents relating to any projected, forecasted, or actual period of market exclusivity for which Andrx may have been entitled or eligible, is or was entitled or eligible, or may have enjoyed, with respect to a bioequivalent or generic version of Cardizem CD.

SPECIFICATION 12: All documents relating to Andrx's or any other person's plans relating to Cartia XT, including, but not limited to, business plans; short term and long range strategies and objectives; collaboration plans; budgets and financial projections; research and development plans; manufacturing plans; regulatory plans; and presentations to management committees, executive committees, and boards of directors.

SPECIFICATION 13: Documents relating to Andrx's contracts involving Cartia XT, including, but not limited to, actual contracts or drafts thereof, as well as discussions, communications, or negotiations related to an actual or proposed contract.

SPECIFICATION 14: Provide a copy in Machine Readable Form of each invoice for Cartia XT.

SPECIFICATION 15: Documents relating to any plans, discussions, or considerations by Andrx to sell, license or otherwise transfer, waive, relinquish, or compromise any right accruing under its Abbreviated New Drug Application for generic Cardizem CD, including its rights to 180 days of generic market exclusivity as provided by 21 U.S.C. § 355(j)(4)(B)(iv), including, but not limited to, documents relating to any proposal by Biovail Corporation to enter into an agreement with Andrx involving a diltiazem product.

SPECIFICATION 16: Provide a copy of each settlement of any patent infringement action to which Andrx is or was a party, and include drafts (whether or not included in the settlement), as well as any communications relating to the settlement.

SPECIFICATION 17: Provide a copy of each Licensing Agreement and Joint Development Agreement to which Andrx is or was a party.

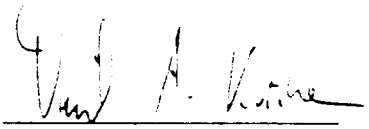
## CERTIFICATE OF SERVICE

I, Daniel A. Kotchen, hereby certify that on May 3, 2000, I caused a copy of Complaint Counsel's First Request for Production of Documents and Things Issued to Carderm Capital L.P. to be served upon the following persons by facsimile and by Federal Express:

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

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

James M. Spears, Esq.
Shook, Hardy & Bacon, L.L.P.
600 14th Street, N.W.
Suite 800
Washington, D.C. 20005-2004



Daniel A. Kotchen

# EXHIBIT 3

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

# ANDRX CORPORATION'S RESPONSE TO COMPLAINT COUNSEL'S FIRST REQUEST FOR PRODUCTION OF DOCUMENTS AND THINGS ISSUED TO ANDRX CORPORATION

Pursuant to § 3.37 of the Federal Trade Commission's Procedures and Rules of Practice, respondent Andrx Corporation ("Andrx") hereby responds to Complaint Counsel's First Request for Production of Documents and Things Issued to Andrx (the "Request"), as follows:

## SPECIFIC REQUESTS

**Specification 1**: Documents relating to Andrx's financial condition, including, but not limited to, financial statements (both internal and audited), financial plans, gross profit, net profit, cash reserves, cash flows, stock sales, lines of credit, private placements, long-term debt, short-term debt, stock analyst reports, and any communication from any person that relates to Andrx's financial condition.

**Response to Specification 1**:

On November 24, 1997, the Commission issued a subpoena duces tecum ("Subpoena") and Civil Investigative Demand ("CID") to Andrx. Andrx reviewed those requests in detail with the Commission's staff and, together with the staff, reached agreement on the types and categories of documents that the staff wanted. Andrx fully satisfied the staff's requests, and the Commission so indicated. The Commission issued yet another Subpoena and CID on October 23, 1998, the breadth of which necessitated that Andrx move for a protective order. Subsequent

to making that motion. Andrx again conferred with the staff and, with the staff, agreed to additional types and categories of documents to be produced. Andrx then fully complied with the second Subpoena and CID, as limited by its agreement with the staff. In addition to the 1997 and 1998 Subpoenas and CIDs, the staff also made numerous informal requests of Andrx during the course of the investigation. In fact, the staff continued to make informal requests of Andrx even after it had recommended the commencement of the present enforcement proceeding. Andrx has fully complied with all of these informal requests.

In short, during more than two years of investigation, the Commission has requested (either formally or informally) and received from Andrx all the documents it deemed relevant to the issues here. This Request, due to its over-breadth, clearly seeks information that is irrelevant to the present proceeding and was propounded solely to derail Andrx's trial preparation and further to capitalize on Complaint Counsel's preparational advantage.

To the extent that Specification 1 calls for the production of non-privileged documents relevant to this proceeding, it is duplicative of requests that the Commission staff made during the investigation, and Andrx satisfied the staff's request for documents responsive to this request. If Complaint Counsel seeks the production of additional documents, Andrx will consider narrowly-tailored requests geared to the production of relevant non-privileged documents, if any. To the extent this request seeks any other documents, Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

**Specification 2**: Documents relating to any communications between Andrx and any person relating to Cardizem CD or a bioequivalent or generic version of Cardizem CD, including, but not limited to:

(a) U.S. Patent No 5,470,584

(b) HMRI's patent infringement suit against Andrx

(c) the Stipulation and Agreement,

(d) the Termination Agreement, and

(e) Andrx's ANDA application for a generic or bioequivalent version of Cardizem CD.

**Response to Specification 2**:

Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.[1]

To the extent that Specification 2 calls for the production of non-privileged documents relevant to this proceeding, it is duplicative of requests that the Commission staff made during the investigation, and Andrx satisfied the staff's requests for documents responsive to this request. For example, Andrx has already produced the pertinent court papers related to HMRI's patent infringement suit; its communications concerning Patent No. 5,470,584; its communications with the Food and Drug Administration; and its ANDA for a generic or bioequivalent version of Cardizem® CD. To the extent that the Complaint Counsel seeks the

[1] For example, Specification 2, read literally, would call for the production of correspondence between Andrx and "any person", which is facially overbroad. This would include, for example, correspondence between the Andrx sales force and potential end users of Cardia XT that post-date the commencement of this action – documents that are clearly irrelevant to any issue in this proceeding and not reasonably calculated to lead to the discovery of admissible evidence.

production of additional documents, Andrx will consider narrowly tailored requests geared to the production of relevant non-privileged documents, if any.

**Specification 3**: Minutes from meetings of any Andrx Board of Directors, Andrx management, executive, ad hoc or any other committee or working group relating to an Andrx generic version of Cardizem CD, including, but not limited to:

(a) minutes relating to the manufacture and sale of a bioequivalent or generic version of Cardizem CD,

(b) Andrx's Reformulated Product,

(c) HMRI's patent infringement suit against Andrx,

(d) the Stipulation and Agreement,

(e) any actual or potential legal challenge or legal scrutiny of the Stipulation and Agreement, and

(f) the Termination Agreement.

**Response to Specification 3**:

Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

To the extent that Specification 3 calls for the production of non-privileged documents relevant to this proceeding, it is duplicative of requests that the Commission staff made during the investigation, and Andrx satisfied the staff's request for documents responsive to this request. If Complaint Counsel seeks the production of additional documents, Andrx will consider narrowly-tailored requests geared to the production of relevant non-privileged documents, if any.

**Specification 4**: Documents relating to the Termination Agreement, including, but not limited to, discussions, communications, or negotiations concerning the Termination Agreement, and drafts of the Termination Agreement (whether or not incorporated in the executed agreement).

**Response to Specification 4**:

Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

Consistent with agreements reached with the staff during the investigation, Andrx has already produced non-privileged documents concerning the Termination Agreement, including an executed copy of the Termination Agreement itself. To the extent there are additional non-privileged documents relating to the Termination Agreement, and subject to the foregoing objections, Andrx will produce such documents.

**Specification 5**: Documents sufficient to show Andrx's research and development budgets, projections, and expenditures by month and product.

**Response to Specification 5**:

Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

To the extent that Specification 5 calls for the production of non-privileged documents relevant to this proceeding, it is duplicative of requests that the Commission staff made during the investigation, and Andrx satisfied the staff's request for documents responsive to this request.

If Complaint Counsel seeks the production of additional documents, Andrx will consider narrowly-tailored requests geared to the production of relevant non-privileged documents, if any.

**Specification 6**: Documents relating to Andrx's actual and projected legal expenditures for HMRI's patent infringement suit against Andrx.

**Response to Specification 6**:

Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

Without waiver of the foregoing objections, and subject to an agreement from Complaint Counsel that no waiver of work product would result, Andrx will produce non-privileged documents sufficient to show, to the extent Andrx is able, Andrx's "actual and projected legal expenditures" for HMRI's patent infringement suit.

**Specification 7**: Documents relating to Andrx's Reformulated Product, including, but not limited to the likelihood that the product infringed (or infringes) a patent owned or controlled by HMRI; Andrx's ability to market the product; any actual, considered, or possible effect the product had or would have had on any HMRI obligation pursuant to the Stipulation and Agreement; and any actual, considered, possible, or proposed effect the product had or would have had on Andrx's obligation pursuant to the Stipulation and Agreement.

**Response to Specification 7**:

Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant

to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

To the extent that Specification 7 calls for the production of non-privileged documents relevant to this proceeding, it is duplicative of requests that the Commission staff made during its investigation, and Andrx satisfied the staff's request for documents responsive to this request. If Complaint Counsel seeks the production of additional documents, Andrx will consider narrowly-tailored requests geared to the production of relevant non-privileged documents, if any.

**Specification 8**: Documents created prior to July 1, 1999 relating to Andrx's research, development, or manufacture of a bioequivalent or generic version of Cardizem CD, including, but not limited to, Andrx's Reformulated Product.

**Response to Specification 8**:

Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

To the extent that Specification 8 calls for the production of non-privileged documents relevant to this proceeding, it is duplicative of requests that the Commission staff made during its investigation, and Andrx satisfied the staff's request for documents responsive to this request. To the extent not already produced, Andrx will produce, subject to the foregoing objections, non-privileged documents sufficient to describe Andrx's "research, development, or manufacturer of a bio-equivalent or generic version of Cardizem® CD, including, but not limited to, Andrx's Reformulated Product."

**Specification 9**: For each SKU or Cartia XT and Diltia XT, by month, documents in Machine Readable Form relating to any measure of the sale, price, revenues, and profit of each SKU, including, but not limited to:

(a) gross and net sales to all customers in units and dollars;

(b) gross number and dollar value of promotional sample units distributed;

(c) sales returns in units and dollars;

**Response to Specification 9**:

Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

To the extent that Specification 9 calls for the production of non-privileged documents relevant to this proceeding, it is duplicative of requests that the Commission staff made during its investigation, and Andrx satisfied the staff's request for documents responsive to this request. If Complaint Counsel seeks the production of additional documents, Andrx will consider narrowly-tailored requests geared to the production of relevant non-privileged documents, if any.

**Specification 10**: IMS data and reports in Machine Readable Form relating to all Cardiovascular Therapy Products.

**Response to Specification 10**:

Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

Andrx is willing to produce data in machine-readable form to the extent that Complaint Counsel provides Andrx with a request that is more narrowly-tailored to seek the discovery of information relevant to this proceeding or reasonably calculated to lead to the discovery of admissible evidence.

**Specification 11**: All documents relating to any projected, forecasted, or actual period of market exclusivity for which Andrx may have been entitled or eligible, is or was entitled or eligible, or may have enjoyed, with respect to a bioequivalent or generic version of Cardizem CD.

**Response to Specification 11**:

Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

To the extent that Specification 11 calls for the production of non-privileged documents relevant to this proceeding, it is duplicative of requests that the Commission staff made during its investigation, and Andrx satisfied the staff's request for documents responsive to this request. If Complaint Counsel seeks the production of additional documents, Andrx will consider narrowly-tailored requests geared to the production of relevant non-privileged documents, if any.

**Specification 12**: All documents relating to Andrx's or any other person's plans relating to Cartia XT, including, but not limited to, business plans; short term and long range strategies and objectives; collaboration plans; budgets and financial projections; research and development plans; manufacturing plans; regulatory plans; and presentations to management committees, executive committees, and boards of directors.

**Response to Specification 12**:

Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

To the extent that Specification 12 calls for the production of non-privileged documents relevant to this proceeding, it is duplicative of requests that the Commission staff made during its investigation, and Andrx satisfied the staff's request for documents responsive to this request. If Complaint Counsel seeks the production of additional documents, Andrx will consider narrowly-tailored requests geared to the production of relevant non-privileged documents, if any.

**Specification 13**: Documents relating to Andrx's contracts involving Cartia XT, including, but not limited to, actual contracts or drafts thereof, as well as discussions, communications, or negotiations related to an actual or proposed contract.

**Response to Specification 13**:

Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

To the extent that Specification 13 calls for the production of non-privileged documents relevant to this proceeding, it is duplicative of requests that the Commission staff made during its investigation, and Andrx satisfied the staff's request for documents responsive to this request. If Complaint Counsel seeks the production of additional documents, Andrx will consider narrowly-tailored requests geared to the production of relevant non-privileged documents, if any.

**Specification 14**: Provide a copy in Machine Readable Form of each invoice for Cartia XT.

**Response to Specification 14**:

Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to the foregoing objections, Andrx is willing to discuss the production of the requested materials if Complaint Counsel can articulate how these materials are relevant. It should be noted that in connection with the investigation, Andrx has already produced documents sufficient to establish its pricing of Cardia XT.

**Specification 15**: Documents relating to any plans, discussions, or considerations by Andrx to sell, license or otherwise transfer, waive, relinquish, or compromise any right accruing under its Abbreviated New Drug Application for generic Cardizem CD, including its rights to 180 days of generic market exclusivity as provided by 21 U.S.C. § 355(j)(4)(B)(iv), including, but not limited to, documents relating to any proposal by Biovail Corporation to enter into an agreement with Andrx involving a diltiazem product.

**Response to Specification 15**:

Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

To the extent that Specification 15 calls for the production of non-privileged documents relevant to this proceeding, it is duplicative of requests that the Commission staff made during its investigation, and Andrx satisfied the staff's request for documents responsive to this request. If Complaint Counsel seeks the production of additional documents, Andrx will consider narrowly-tailored requests geared to the production of relevant non-privileged documents, if any.

**Specification 16**: Provide a copy of each settlement of any patent infringement action to which Andrx is or was a party, and include drafts (whether or not included in the settlement), as well as any communications relating to the settlement.

**Response to Specification 16**:

Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

To the extent that Specification 16 calls for the production of non-privileged documents relevant to this proceeding, it is duplicative of requests that the Commission staff made during its investigation, and Andrx satisfied the staff's request for documents responsive to this request. If Complaint Counsel seeks the production of additional documents, Andrx will consider narrowly-tailored requests geared to the production of relevant non-privileged documents, if any.

**Specification 17**: Provide a copy of each Licensing Agreement and Joint Development Agreement to which Andrx is or was a party.

**Response to Specification 17**:

Andrx objects to this request on all of the grounds set forth in the General Objections annexed hereto as Appendix A, including, without limitation, that the request is overly broad and unduly burdensome, vague and ambiguous, intended to harass, and seeks information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

To the extent that Specification 17 calls for the production of non-privileged documents relevant to this proceeding, it is duplicative of requests that the Commission staff made during its investigation, and Andrx satisfied the staff's request for documents responsive to this request. If

Complaint Counsel seeks the production of additional documents, Andrx will consider narrowly-tailored requests geared to the production of relevant non-privileged documents, if any.

Dated: June 1, 2000

SOLOMON, ZAUDERER, ELLENHORN
FRISCHER & SHARP

By: _____

Louis M. Solomon
Hal S. Shaftel
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Attorneys for Respondent
Andrx Pharmaceuticals, Inc.

## APPENDIX A

## GENERAL OBJECTIONS

1. Andrx objects to the Request to the extent that it calls for the production of documents by any entity other than Andrx Pharmaceuticals, Inc., the entity that submitted the ANDA for the production of a generic or bioequivalent version of Cardizem ® CD and that entered into the stipulation with HMRI that forms the basis for this proceeding. Consequently, statements that "Andrx" will produce documents should be read to mean that Andrx Pharmaceuticals, Inc. will produce documents. Andrx is, however, willing to reconsider this limitation if Complaint Counsel can articulate a rational basis for doing so in the context of a particular request.

2. Andrx objects to Instruction No. 2 insofar as it requires Andrx to produce documents responsive to each request that were "dated, generated, received, or in effect" from January 1, 1995 through the present. The time period specified is overbroad and is calculated to impose a substantial and undue burden upon Andrx.

3. Andrx objects to each request in the Request on the grounds that the separate paragraphs and numerous subparagraphs taken as a whole, are overly broad, intended to harass, and seek information irrelevant to the subject matter of this action and not reasonably calculated to lead to the discovery of admissible evidence.

4. Andrx objects to each Request to the extent it purports to call for the production of documents already provided to the FTC, whether by Andrx or any other party.

5. Andrx objects to the Request, including the Request's "Definition and Instructions", to the extent it is vague or ambiguous.

6. Andrx objects to each subpart of each request in the Request to the extent that it seeks proprietary, or confidential, business information or trade secrets.

7. Andrx objects to each subpart of each request in the Request insofar as it purports to request or call for production of documents which reveal confidential information protected from disclosure or which is subject to the attorney-client privilege, work product privilege, or any other privilege or immunity. All of the following responses to the individual requests and subparts set forth in the Request should be read to state that Andrx will not produce any documents that are privileged or otherwise immune from discovery. It should be noted that Andrx produced a privilege log to the Commission's staff in 1998, in connection with the staff's investigation.

8. In its effort to produce requested documents, Andrx may inadvertently produce documents which contain confidential information protected from disclosure, or which otherwise are, or arguably are, privileged or otherwise immune from discovery. The production of any such documents is not intended to and shall not constitute a waiver of any rights, privileges or immunity Andrx may have with respect thereto, and Andrx reserves the right to request or require the return of any document produced which contains protected confidential information to which a privilege or immunity may apply.

9. Andrx objects to each subpart of each request in the Request to the extent that the Request purports to demand production of documents otherwise reasonably available to Complaint Counsel by other means.

10. Andrx objects to each subpart of each request in the Request to the extent it seeks information more readily or properly ascertained through other discovery procedures.

11. Andrx objects to each subpart of each request in the Request to the extent it is improper in form, including, without limitation, insofar as it requests Andrx to identify broad categories of documents or otherwise seeks to propound interrogatories in the form of document requests. Moreover, in virtually each case, the requests are not framed with the required specificity and particularity.

12. Andrx objects to each request in the Request to the extent it calls for Andrx to produce documents from any other entity and/or documents not in its possession.

13. Andrx objects to the Request to the extent that it purports to demand discovery on terms, or to impose obligations upon Andrx, which are beyond the scope of, or different from, the provisions governing discovery in the Federal Trade Commission's Procedures and Rules of Practice, other applicable Federal Rules, and this Court's applicable orders.

14. By furnishing information or producing documents in connection with this response, Andrx is neither agreeing nor representing that any or all of such information or documents are relevant, material, competent or admissible into evidence in connection with this action. The information being provided in response to the Request is qualified as being based on a reasonable inquiry by Andrx. Andrx reserves the right to object on any ground to the use of any such information or documents in any subsequent proceeding or at the trial of this or any other action. Andrx responds to each subpart of each request in the Request without waiver of any objections to the use of the information and documents at the time of trial, including but not limited to authenticity, materiality, competency or admissibility.

Each of the foregoing objections is specifically incorporated into the preceding responses to the Request, regardless of whether the objections are explicitly stated therein.

Unlike Complaint Counsel, however, Andrx is prepared immediately to discuss which objections have lead to the non-production of specific classes of documents and will do so as soon as Complaint Counsel agrees to do the same.

## CERTIFICATE OF SERVICE

I, Jonathan D. Lupkin, hereby certify that on June 1, 2000, I caused a copy of ANDRX CORPORATION'S RESPONSE TO COMPLAINT COUNSEL'S FIRST REQUEST FOR THE PRODUCTION OF DOCUMENTS AND THINGS ISSUED TO ANDRX CORPORATION to be served upon the following persons by Federal Express:

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 and Becker
1140 19th St., N.W.
Washington, D.C. 20036

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

Jonathan D. Lupkin

# EXHIBIT 4

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WRITER'S DIRECT DIAL
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June 28, 2000

**VIA FACSIMILE**

Bradley S. Albert, Esq.
United States Federal Trade Commission
Bureau of Competition, Health Care Division
601 Pennsylvania Avenue, NW
S-3115
Washington, D.C. 20580

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

Dear Brad:

This is in response to your letter of today. We are in a position to shortly begin Andrx's supplemental document production in this case, subject to addressing the points raised in Jonathan Lupkin's letter transmitted earlier today to you. Subject to those critical qualifications, the categories of non-privileged documents we would produce include:

- Andrx's audited financial statements for fiscal years 1995 to the present (Specification 1)
- Board minutes, post-September 16, 1997, discussing the topics identified in subsections (a) through (f) of Specification 3;
- The drafting history of the Termination Agreement (Specification 4);
- Documents sufficient to show Andrx's R&D budget for Cartia® XT for the time period up to the FDA's approval of the Reformulated Product (Specification 5);
- Documents sufficient to show Andrx's actual and projected legal expenditures in HMR's patent infringement action (Specification 6);

- Documents sufficient to reflect Andrx's marketing practices with respect to Cartia® XT (Specification 7)
- Documents sufficient to demonstrate Andrx's R&D efforts for Cartia® XT for the period up to and including Andrx's marketing of the Reformulated Product. These documents will include failed batch records, laboratory notebooks and dissolution profiles. (Specification 8);
- Documents sufficient to show Andrx's pricing of Cartia® XT (Specification 9);
- Invoices for Cartia® XT (in machine-readable form) for one week in December, 1999 and one week in January, 2000 (Specification 14);
- Extant documents, if any, comparing Andrx's actual or projected revenues from Cartia® XT during the 180-day exclusivity period to the actual or projected revenues from the product after the expiration of the exclusivity period (Specification 11);
- Documents responsive to Specification 12 for the time period up to execution of the Termination Agreement
- A list of those customers with whom Andrx has contracts for the purchase of Cartia® XT (Specification 13); and
- Documents responsive to Specification 15.

As we indicated, Andrx objects to the production of documents responsive to Specifications 16 and 17 (i.e. other settlements of patent infringement litigation and licensing or joint development agreements) unless Complaint Counsel agrees to provide similar documents from its own files. In addition, we are still checking about IMS data and reports (in machine readable form) (Specification 10).

Sincerely,

Hal S. Shafter

HSS:se
cc: James M. Spears, Esq. (via fax)

**SOLOMON, ZAUDERER, ELLENHORN, FRISCHER & SHARP**
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New York, NY 10111

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# TELECOPY TRANSMISSION COVER SHEET

**DATE:** June 28, 2000

| **TO** | **FAX NO.:** | **TEL NO.:** |
|---|---|---|
| Bradley S. Albert, Esq. | (202) 326-3384 | (202) 326-3670 |
| James M. Spears, Esq. | (202) 783-4211 | (202) 783-8400 |

| **FROM:** | | |
|---|---|---|
| Hal S. Shaftel, Esq. | (212) 956-4068 | (212) 424-0755 |

**COMMENTS:**

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**Number of Pages:**
**(incl. cover sheet)**

**CLIENT/MATTER NO.** 0228/002

**Fax Operator:** Joyce Ashman

**Secretary:**

# EXHIBIT 5

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June 28, 2000

**VIA FACSIMILE**

Bradley S. Albert, Esq.
United States Federal Trade Commission
Bureau of Competition, Health Care Division
601 Pennsylvania Avenue, NW
S-3115
Washington, D.C. 20580

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

Dear Brad:

We are just about in a position to begin Andrx's supplemental document production in this case. Before we begin our production, however, and given the highly confidential information contained in Andrx's documents, we require written clarification concerning Complaint Counsel's interpretation of ¶4 of Judge Chappell's April 28, 2000 protective order. Specifically, Andrx requires assurances that Complaint Counsel will neither divulge to any non-party any documents or information supplied by Andrx and designated "CONFIDENTIAL" nor summarize, in any way, all or any part of such information in any communications with persons or entities that are not parties to this proceeding, whether that summary is in the form of a letter or otherwise and whether or not the information is deemed by Complaint Counsel to be confidential.

We are confident that Complaint Counsel will grant us these assurances.

Sincerely,

Jonathan D. Lupkin

cc: James M. Spears, Esq. (via fax)

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**COMMENTS:**

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**Number of Pages:** (incl. cover sheet) 2

**CLIENT/MATTER NO.** 0228/002

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**Secretary:**