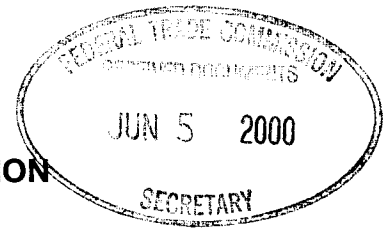

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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 TO COMPEL COMPLAINT COUNSEL TO RESPOND TO INTERROGATORIES OR TO PRECLUDE

Pursuant to § 3.38 of the Federal Trade Commission's Rules of Practice, Respondent Andrx Corporation hereby moves for an Order (1) overruling Complaint Counsel's objections and assertions of purported privileges to Andrx Corporation's First Set of Interrogatories dated April 17, 2000; (2) requiring Complaint Counsel either to provide more complete responses to Andrx's interrogatories or be precluded at trial from proceeding on bases either inconsistent with, or in addition to, those set forth in its interrogatory answers; and (3) granting such other and further relief as the Court deems just and proper.

The bases of this motion are set forth in the accompanying Memorandum in Support of its Motion to Compel Complaint Counsel to Respond to Interrogatories or to Preclude (dated June 5, 2000); and the accompanying Declaration of Jonathan D. Lupkin, executed on June 5, 2000.

Dated: New York, New York
June 5, 2000

Respectfully Submitted,

SOLOMON, ZAUDERER, ELLENHORN,
FRISCHER & SHARP

By: _____

Louis M. Solomon
Hal S. Shaftel
Jonathan D. Lupkin
Sharon M. Sash
45 Rockefeller Plaza
New York, New York 10111
(212) 956-3700

Counsel for Respondent Andrx
Corporation

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of

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

and

ANDRX CORPORATION, a corporation.

DOCKET NO. 9293

RESPONDENT ANDRX CORPORATION'S MEMORANDUM IN SUPPORT OF ITS MOTION TO COMPEL COMPLAINT COUNSEL TO RESPOND TO INTERROGATORIES OR TO PRECLUDE

Pursuant to § 3.38 of the FTC's Procedures and Rules of Practice, Respondent Andrx Corporation ("Andrx") submits this memorandum in support of its motion for an order compelling Complaint Counsel to provide complete responses to Andrx's interrogatories and/or be precluded at trial from proceeding on any bases for its charges or theories of the case not articulated in the present responses. Andrx served upon Complaint Counsel its First Set of Interrogatories on April 17, 2000. Complaint Counsel then served its response on May 15, 2000. With respect to disputes over those responses, Andrx conferred in good faith with Complaint Counsel, as set forth in the accompanying Declaration of Jonathan D. Lupkin, executed June 5, 2000. Andrx brings this motion within 20 days after service of the responses, as required by the Additional Provisions in this Court's Scheduling Order (dated April 26, 2000).[1]

[1] A copy of Andrx's First Set of Interrogatories ("Interrogatories") is annexed as Exhibit A to the accompanying Declaration of Jonathan D. Lupkin (the "Lupkin Declaration"). Complaint Counsel's responses and objections (collectively "Responses") are annexed as Exhibit B thereto.

Preliminary Statement

Recognizing that it is operating under a tight schedule before discovery closes on October 20, 2000, Andrx propounded a set of interrogatories targeted at obtaining information required for it to understand the case against which it must defend. In responding to the Interrogatories, Complaint Counsel has the advantage of all the information derived from a thorough, two-and-a-half year-long pre-complaint investigation. Given that trove of information, coupled with the fact that it has already prepared its complaint, Complaint Counsel has already developed its case and surely knows -- unlike a litigant without a substantial head start in discovery -- the bases for its charges and legal theories, as well as relevant information concerning industry practice and transactions similar to the HMR/Andrx Stipulation. However, Complaint Counsel's responses to the Interrogatories are incomplete and couched with language reserving the right to or modify its contentions at some later point and ambush respondents at trial with new bases or theories for its charges.

Complaint Counsel should be required to "come clean" so that Andrx can effectively and efficiently prepare for trial. In the event that Complaint Counsel is not required immediately to supplement its interrogatory responses, this Court should preclude Complaint Counsel, at the very least, from proceeding at trial on any bases or theories not thus far disclosed.

BACKGROUND

A. The Need to Amplify Complaint Counsel's Pleading

Promptly after the Complaint was filed in this matter, Andrx expressed concern to Complaint Counsel over the ambiguity of its charges. The FTC, for example, first advised Andrx that it was proceeding under a rule of reason theory, then made public comments to the contrary. The Complaint itself does not identify any specific harm to any consumers or to competition, but only alleges that the HMR/Andrx Stipulation had the "tendency or capacity" (Complaint, ¶ 29) -- whatever that means -- potentially to cause harm.

Recognizing the need to amplify the nature of its charges, Complaint Counsel stated, during the initial conference before the Court on April 24, 2000, that it was prepared to provide a statement more fully describing its case. 4/24 Tr. at 19. According to Complaint Counsel:

> That is an old procedure that used to be in the rules, and we would be willing to do that to try to clarify some of the issues. Again if your Honor finds that to be useful, we would be prepared to do that, and I would propose possible some time in June to do that 4/24 Tr. at 19 (emphasis added).

However, Complaint Counsel has not done that.

B. Andrx Met And Conferred With Complaint Counsel In Accordance With 16 C.F.R. §3.22(f)

Andrx telephoned Complaint Counsel on June 2, 2000, in an attempt to persuade Complaint Counsel to respond completely to Andrx's Interrogatories. As Andrx stated during the call, the rules required Complaint Counsel, as part of its initial disclosures, to provide the name, address and

phone number, if known, of each person who would likely have discoverable information. 16 CFR § 3.31(b)(1). Because Complaint Counsel failed to do so, Andrx propounded an interrogatory seeking basically the same information. In part, Interrogatory No. 2 requests that Complaint Counsel "[i]dentify each person, by name and address with whom the FTC communicated in connection with any investigation concerning Andrx or the 1997 Stipulation".

Recognizing that, under the rules, the identity of these individuals must be disclosed, Complaint Counsel agreed on June 2 to provide the information with a single exception -- individual physicians who will not be called to testify. The agreement is more fully described in the Lupkin Declaration.

However, the parties were unable to reach agreement with respect to the other deficiencies in Complaint Counsel's interrogatory responses. See Lupkin Declaration, ¶¶ 4-7. Among other things, Complaint Counsel refused to provide basic information concerning the bases and theories of its charges and the substance of the factual information ascertained during the pre-complaint investigation, including a listing and description of any other deals examined by the Commission staff that are similar to the HMR/Andrx Stipulation (i.e. deals between brand-name and generic pharmaceutical companies).

ARGUMENT

I.

COMPLAINT COUNSEL'S OBJECTION TO "CONTENTION" INTERROGATORIES IS WITHOUT MERIT AND COMPLAINT COUNSEL SHOULD BE COMPELLED TO PRODUCE COMPLETE ANSWERS OR BE PRECLUDED FROM RAISING ADDITIONAL BASES OR THEORIES AT TRIAL

In responding to what it labels "contention" interrogatories calling for the description and bases of its contentions, Complaint Counsel interposed a blanket reservation of rights:

> To the extent an interrogatory asks for "each basis" in a response, our response to such an interrogatory is not intended to be exhaustive or to be admissions that other facts or bases are not supportive or relevant.

See Response at 2.

During the June 2 telephone call, Complaint Counsel argued that so-called contention interrogatories are premature at this time. However, Section 3.35 of the FTC's Procedures and Rules of Practice explicitly authorizes contention interrogatories:

> An interrogatory otherwise proper is not necessarily objectionable merely because an answer to the interrogatory involves an opinion or contention that relates to fact or the application of law to fact . . . .

16 C.F.R. § 3.35(b)(2). Described as a "useful discovery device in Federal Trade Commission adjudicatory proceedings," In re Flowers Industry, Inc., 1981 FTC LEXIS 110 (October 7, 1981), contention interrogatories assist respondents by providing them with a "current roadmap of where th[e] case is headed." Id. at *3 (rejecting Complaint Counsel's excuses for not answering contention interrogatories).

Moreover, contention interrogatories serve the useful purpose of narrowing the scope of issues to be tried -- which respondents need to do in order to know how to focus their efforts in the four months that remain until the close of fact discovery. It is for this reason that responses to contention interrogatories are considered to be an important part of pretrial preparation.

In this case, Andrx propounded 16 reasonable and narrow contention interrogatories[2] designed to elicit Complaint Counsel's contentions with respect to such basic issues as "anti-competitive effect" caused by the 1997 Stipulation (Interrogatory No. 1); the "definition and scope of the market (or markets) for pharmaceutical products that allegedly or actually compete with, may be substituted for, or otherwise provide an alternative for Cardizem CD and/or Cartia XT" (Interrogatory No. 8); and whether any other entity "would have entered the market with a generic version of Cardizem CD in the absence of the 1997 Stipulation." (interrogatory no. 15). Complaint Counsel should be required to provide answers in full.

Complaint Counsel's reservation of rights essentially guts the utility of Andrx's contention interrogatories. Andrx served these interrogatories in order to understand the case that Complaint Counsel intends to try so that it can, in turn, formulate a focused defense. Without complete responses, there is a genuine threat that Andrx and the other respondents will be surprised at trial by Complaint Counsel's case, and there simply is insufficient time allocated for discovery to enable Andrx to prepare for unexpected contentions.

---

[2] See Interrogatory Nos. 1, 3, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20.

Accordingly, Complaint Counsel should be compelled either immediately to supplement its responses to answer Andrx's interrogatories fully or be precluded, at trial, from proceeding on bases or theories not disclosed in its current responses.

II.

COMPLAINT COUNSEL SHOULD BE COMPELLED TO RESPOND TO THOSE OF ANDRX'S INTERROGATORIES RELATING TO AGREEMENTS IN OTHER PATENT LITIGATIONS

Andrx propounded interrogatories relating to other transactions or agreements in other patent litigations. Such information is highly germane to this action. For example, it is relevant to Complaint Counsel's case-in-chief insofar as general industry practices are relevant to a rule of reason analysis. The existence of agreements similar to the HMR/Andrx Stipulation in the brand name/generic context would rebut Complaint Counsel's assertion that, under a rule of reason analysis, the stipulation here violates the antitrust laws. Specifically, the other agreements will demonstrate that, in the legal and regulatory context in which generic pharmaceutical manufacturers operate, these deals are appropriate and, indeed, pro-competitive. The other agreements will also demonstrate that the FTC has approved deals containing similar features.

Indeed, Complaint Counsel has conceded the relevance of this information by itself requesting identical information from Andrx. In its First Request for the Production of Documents and Things, Complaint Counsel requested the production of "each settlement of any patent infringement action to which Andrx is or was a party" and "each licensing agreement and joint

development agreement to which Andrx is or was a party." See Complaint Counsel's First Request for Production of Documents, Specification Nos. 16, 17. That Complaint Counsel has itself requested such documents in this proceeding renders any argument by Complaint Counsel that such information is "beyond the scope of discovery" extremely hollow.

To obtain information about other similar transactions or settlements, Andrx propounded the following two interrogatories.

> Interrogatory No. 5: Identify each other settlement or partial settlement of patent litigation, concerning which the FTC is aware, involving an innovator or brand-name pharmaceutical company and a generic company that involved any form of: payment from a brand-name company to the generic company; or licensing and/or royalty arrangement between the brand-name company and the generic company.
>
> Interrogatory No. 6: For each settlement or partial settlement of a patent litigation identified in interrogatory no. 5, describe in detail each basis for concluding whether or not the settlement is or was an unfair method of competition or unfair or deceptive act or practice in or affecting commerce, as such terms are used in § 5(b) of the FTC act.

See Interrogatories.[3]

Notwithstanding the obvious (and conceded) relevance of this information, Complaint Counsel refused to provide this information, invoking a full array of confidentiality and privilege objections, including objections based upon the confidentiality accorded materials submitted to the Commission, the deliberative process privilege and the work product doctrine. See Responses at 11-12. As set forth at length at pages 14-22 of Andrx's Motion to Compel

[3] In addition, Complaint Counsel also sought information about other agreements from Andrx during the pre-complaint investigation. Indeed, Andrx's interrogatory No. 5 is verbatim the same as a request set forth in a pre-complaint Civil Investigation Demand (CID) directed at Andrx.

Documents, these objections are either inapplicable or not articulated with sufficient specificity to justify Complaint Counsel's refusal to respond.

III.

COMPLAINT COUNSEL SHOULD BE COMPELLED TO EXPLAIN WHY THIS PROCEEDING IS "IN THE INTEREST OF THE PUBLIC

In Interrogatory No. 4, Andrx requests that Complaint Counsel:

> Describe in detail each basis, if any, for concluding that it appears that the Action is in the interest of the public, as such terms are used in Section 5(b) of the FTC act, 15 U.S.C. § 45.

Andrx propounded this interrogatory because it believes that this proceeding was not commenced "in the interest of the public" and therefore, was brought in violation of statute. Andrx has interposed an affirmative defense premised upon this statutory deficiency, and Andrx's affirmative defense remains viable until such time as this Court strikes it from Andrx's answer -- a course of action Andrx believes to be inappropriate based upon the controlling case law. See Memorandum in Opposition to Complaint Counsel's Motion to Strike Andrx's Affirmative Defenses, at 26-31.

In explaining its objection to the interrogatory, Complaint Counsel argued that it did not know what was in the "heads of the Commissioners" when the Commission made its determination on public interest. However, that argument misses the point. Discovery, whether through interrogatories or otherwise, is routinely directed to the understanding or state of mind of a party. If Complaint Counsel takes the position it represents the Commission as a party, then it certainly has sufficient information available to it to set forth the bases

the Commission's determination. Indeed, the rules expressly provide for Complaint Counsel to disclose:

> all documents, data compilation, and tangible things in the possession, custody, or control of the Commission . . . relevant to the allegations of the Commission's complaint, to the proposal relief, or to the defenses of the respondent. (Emphasis added.)

16 C.F.R § 3.31(b)(2). Surely the information provided or available to the Commission in connection with its public interest determination fits that description -- it is relevant to Andrx's defense that there was no basis for the finding of public interest.

If, however, Complaint Counsel takes the contrary position that the Commission is not the party it represents, then no privilege attaches to documents or other information transmitted to the Commission and now accessible to Complaint Counsel. As a result, Andrx at the very least should be provided with all information the Commission has available to it when it made its determination on public interest.

To escape from its disclosure obligations, Complaint Counsel takes the position that the information the FTC staff provided to the Commission includes privileged information available to Complaint Counsel, but exempt from discovery. The case law is to the contrary, recognizing not only that Complaint Counsel, in its role as prosecutor, is distinct from the Commission and that therefore no privilege attaches to information available to both, see e.g. Champion Spark Plug, 1980 FTC LEXIS 200, *8, but also that the deliberative

process privilege upon which Complaint Counsel relies does not apply in situations, such as here, which involve allegations of governmental misconduct. See Texaco Puerto Rico v. Department of Consumer Affairs, 60 F.3d 867, 885 (1st Cir. 1995) (refusing to apply deliberative process privilege given allegations of government misconduct); In Re Sealed Case, 121 F.3d 729, 746 (D.C. Cir. 1997) ("[deliberative process] privilege disappears altogether when there is any reason to believe government misconduct occurred"); Alexander v. FBI, 186 F.R.D. 154, 164 (D.D.C. 1999) (same); Bank of Dearborn v. Saxon, 244 F. Sup. 394, 402 (E.D. Mich. 1965), aff'd, 377 F.2d 496 (6th Cir. 1967) (rejecting claim of deliberative process privilege given prima facie showing of government misconduct). Andrx is entitled, for example, to information tending to suggest that the Commission's decision to proceed against Andrx was based upon communications from or concerning Andrx's competitor, Biovail, information concerning the widespread publicly surrounding the 1997 Stipulation and inquiries from any other outside source (i.e., Congress or the press.) Put simply, information available to the Commission should be made available to Andrx, which is otherwise prejudiced in its ability to challenge the bases for the Commission's public interest determination.

Nor is there any justification for not providing the requested information because respondents' affirmative defenses pertaining to the public interest determination are subject to a motion to strike. These affirmative defenses remain in the case, and the FTC's Rules of Practice do not grant Complaint Counsel a stay of discovery pending the resolution of its motion to

strike. Accordingly, Complaint Counsel should be compelled to answer fully to interrogatory No. 4, or at least produce the documents made available to the Commission, within ten days.

CONCLUSION

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

Dated: New York, New York
June 5, 2000

Respectfully Submitted,

SOLOMON, ZAUDERER, ELLENHORN,
FRISCHER & SHARP

By: 

Louis M. Solomon
Hal S. Shaftel
Jonathan D. Lupkin
Sharon M. Sash
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New York, New York 10111
(212) 956-3700

Counsel for Respondent Andrx Corporation

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of

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

and

ANDRX CORPORATION, a corporation.

DOCKET NO. 9293

[PROPOSED] ORDER

The motion of Respondent Andrx Corporation for an Order (1) overruling Complaint Counsel's objections and assertions of purported privileges to Andrx Corporation's First Set of Interrogatories dated April 17, 2000; and (2) requiring Complaint Counsel to provide complete responses to Andrx's interrogatories within ten (10) days hereof and be precluded at trial from proceeding on bases either inconsistent with, or in addition to, those set forth in those answers is hereby GRANTED.

Dated: June _____, 2000

_____
D. Michael Chappell
Administrative Law Judge

CERTIFICATE OF SERVICE

I, JONATHAN D. LUPKIN, HEREBY CERTIFY THAT ON JUNE 5, 2000, I CAUSED A COPY OF RESPONDENT ANDRX'S MOTION TO COMPEL COMPLAINT COUNSEL TO RESPOND TO INTERROGATORIES OR TO PRECLUDE TO BE SERVED UPON THE FOLLOWING PERSONS BY HAND:

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

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

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

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

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

Jonathan D. Lupkin

UNITED STATES OF AMERICA

BEFORE FEDERAL TRADE COMMISSION

In the Matter of

HOECHST MARION ROUSSEL, INC., a corporation,

CARDERM CAPITAL L.P., a limited partnership,

and

ANDRX CORPORATION, a corporation.

Docket No. 9293

DECLARATION OF JONATHAN D. LUPKIN

Jonathan D. Lupkin, pursuant to 28 U.S.C. § 1764, declares as follows:

1. I am associated with the firm of Solomon, Zauderer, Ellenhorn, Frischer & Sharp, counsel for respondent Andrx Corporation ("Andrx"). I submit this declaration in order to place certain documents before the Court and pursuant to 16 C.F.R. 3.22(f).

2. Annexed hereto as Exhibit A is a copy of Andrx's First Set of Interrogatories (served April 17, 2000) (the "Interrogatories").

3. Annexed hereto as Exhibit B is a copy of Complaint Counsel's Responses and Objections to Respondent Andrx Corporation's First Set of Interrogatories (the "Interrogatory Responses").

4. As counsel for Andrx, I, along with my colleague, Hal Shaftel, conferred with Complaint Counsel, pursuant to 16 C.F.R. § 3.22(f), in an effort in good faith to resolve by agreement the disputes concerning Complaint Counsel's Interrogatory Responses. During our conversations, and as set out more fully below, the parties were only able to reach agreement on one issue.

5. On the afternoon of June 3, 2000 Mr. Shaftel and I spoke with Bradley S. Albert and Markus Meier of the FTC. At that time, we explained our concerns with respect to several deficiencies in the Interrogatory Responses. Specifically, we noted that the Interrogatory Responses were deficient in, among other respects, that : (1) Complaint Counsel improperly purported to reserve the right to augment or modify its responses to the 16 contention interrogatories propounded pursuant to 16 C.F.R. §3.35(b)(2); (2) Complaint Counsel refused to respond to interrogatory nos. 5 and 6, which call for information concerning deals similar to the 1997 Stipulation; (3) Complaint Counsel refused to respond to interrogatory no. 4, which calls for the bases upon which the Commission concluded that commencement of this proceeding was "in the public interest," as required by statute; and (4) Complaint Counsel refused to respond to interrogatory no. 2, which calls for, among other things, the identities of those individuals contacted by the Commission in connection with its investigation of Andrx.

6. With respect to Andrx's contention interrogatories (item (1) above), Complaint Counsel indicated that they were premature, notwithstanding the fact that the Commission staff has been investigating the 1997 Stipulation for

over two years. Mr. Shaftel and I explained to Messrs. Albert and Marcus that given the extremely short time frame allotted for the completion of discovery, Andrx must understand the scope of the case against which it must defend so that it can conduct effective and efficient discovery. Complaint Counsel refused to change its position in response to Andrx's protestations.

7. With respect to Andrx's interrogatories concerning other deals and the bases upon which the Commission concluded that this proceeding was commenced "in the public interest" (items (2) and (3) above, Complaint Counsel declined to modify its position that the information called for by these interrogatories was privileged and confidential.

8. The parties did reach a resolution with respect to interrogatory no. 2, which calls for, among other things, the identities of those to whom Commission staff spoke during its investigation, including the identities of various doctors apparently contacted with respect to the market for calcium channel blockers. As Mr. Shaftel and I pointed out during the call, the FTC's Rules of Practice required Complaint Counsel, as part of its initial disclosures, to provide the name, address and phone number, if known, of each person likely to have discoverable information. 16 CFR § 3.31(b)(1).

9. In a subsequent conversation on June 2, Andrx indicated that while it did not concede the validity of any purported privilege covering these doctors, it would agree to a compromise whereby Complaint Counsel would provide promptly to Andrx the names of all those individuals the Commission staff communicated with in connection with its pre-complaint investigation,

excluding the doctors, and Complaint Counsel will not call these doctors as either fact or expert witnesses at trial.

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

Executed in New York, New York, on June 5, 2000

JONATHAN D. LUPKIN

Exhibit A

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of

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

and

ANDRX CORPORATION, a corporation.

Docket No. 9293

RESPONDENT ANDRX CORPORATION'S FIRST SET OF INTERROGATORIES

Pursuant to §3.35 of the Commission's Rules of Practice, respondent Andrx Corporation hereby requests that the FTC, by its Staff Counsel, respond to the following interrogatories within thirty (30) days, in accordance with the Definitions and Instructions set forth in the accompanying Appendix.

INTERROGATORIES

Interrogatory No. 1

Describe in detail each anticompetitive effect, if any, the FTC contends was the result of or caused by, directly or indirectly, the alleged anticompetitive conduct of respondents, as set forth in the Complaint, including, without limitation, any actual increase in price, restriction on output, foreclosure of entry into the market, or any other consequence.

Interrogatory No. 2

Identify each person, by name and address, with whom the FTC communicated in connection with any investigation concerning Andrx or the 1997

Stipulation; and, for each such person, describe in detail the substance of any information the FTC ascertained from the person.

Interrogatory No. 3

Describe in detail each basis, if any, for concluding that respondents have used or have been using any unfair method of competition or unfair or deceptive act or practice in or affecting commerce, as such terms are issued in Section 5(b) of the FTC Act, 15 U.S.C. § 45.

Interrogatory No. 4

Describe in detail each basis, if any, for concluding that it appears that the Action is in the interest of the public, as such terms are used in Section 5(b) of the FTC Act, 15 U.S.C. § 45.

Interrogatory No. 5

Identify each other settlement or partial settlement of patent litigation, concerning which the FTC is aware, involving an innovator or brand name pharmaceutical company, and a generic company, that involved any form of:

(a) payment from a brand name company to the generic company; or

(b) licensing and/or royalty arrangement between the brand name company and the generic company.

Interrogatory No. 6

For each settlement or partial settlement of a patent litigation identified in Interrogatory No. 5 above, describe in detail each basis for concluding whether or not the settlement is or was an unfair method of competition or unfair or deceptive act or practice in or affecting commerce, as such terms are used in Section 5(b) of the FTC Act.

Interrogatory No. 7

Describe in detail each basis, if any, for your allegation in paragraph 12 of the Complaint that "[a] relevant product market for assessing respondents' anticompetitive conduct is once-a-day diltiazim", and identify, for that alleged market, the number of wholesalers; amount of annual sales by wholesalers to retailers; number of retailers; and amount of annual sales by retailers to individual consumers.

Interrogatory No. 8

Describe in detail the definition and scope of the market (or markets) for calcium channel blockers, ace inhibitors and beta blockers, including, without limitation, the identity of any pharmaceutical products that allegedly or actually competes with, may be substituted for, or otherwise provide an alternative for Cardizem CD and/or Cartia XT.

Interrogatory No. 9

For entities or individuals who purchased Cardizem CD, including wholesalers, retailers and individual consumers, identify the extent, if any, that prices paid were artificially inflated or otherwise exceeded what the prices otherwise would have been by reason of defendants' alleged anticompetitive conduct, and describe in detail the basis for your contention; how this amount was calculated; any formula used in making the calculation; the sources of any data; and state all facts and assumptions on which you base such answer.

Interrogatory No. 10

Describe in detail the relationship, if any, which you contend exists between (a) the degree to which, if any, the prices paid for Cardizem CD by wholesalers or retailers were higher than they would have been in the absence of defendants' alleged

anticompetitive conduct, and (b) the degree to which, if any, the prices paid by individual consumers for Cardizem CD exceeded what they otherwise would have been.

Interrogatory No. 11

Describe in detail the relationship, if any, which the FTC contends exists, between the price(s) of a brand name pharmaceutical product and the price of one or more generic versions of such a product.

Interrogatory No. 12

Does the FTC contend that the alleged anticompetitive conduct, as set forth in the Complaint, constitutes, either in whole or in part, a "per se" violation of any laws; if so, describe in detail each basis, if any, for such a contention.

Interrogatory No. 13

Does the FTC contend that the alleged anticompetitive conduct, as set forth in the Complaint, constitutes, either in whole or in part, a violation of any laws based on a "rule of reason" analysis; if so, describe in detail each basis, if any, for such a contention.

Interrogatory No. 14

Describe in detail each basis, if any, for concluding that Andrx would have entered the market with a generic version of Cardizem CD in the absence of the 1997 Stipulation.

Interrogatory No. 15

Describe in detail each basis, if any, for concluding that some person other than respondents herein, whether Biovail, Faulding, or another person, would have

entered the market with a generic version of Cardizem CD in the absence of the 1997 Stipulation.

Interrogatory No. 16

Describe in detail each basis, if any, for the allegation made in paragraph 38 of the Complaint that "Hoechst MRI, Cardizem and Andrx acted with the specific intent that Hoechst MRI monopolize the relevant market."

Interrogatory No. 17

Describe in detail each basis, if any, for the allegation made in paragraph 29 of the Complaint that "[t]he acts and practices of the respondents as herein alleged have had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and injure competition and consumers," including, without limitation, explain the meaning of "tendency or capacity" as used in the allegation.

Interrogatory No. 18

Describe in detail each basis, if any, for the allegation in paragraph 31 of the Complaint that "[t]he purpose and intended effect of the $10 million quarterly payments from Hoechst MRI to Andrx during the term of the Stipulation and Agreement was to provide an incentive for Andrx to refrain both from entering the relevant market, and from taking any steps . . . to permit or facilitate the entry of any other generic manufacturer."

Interrogatory No. 19

Describe in detail each basis, if any, for the allegations in paragraph 35 of the Complaint that "[a]lthough the Stipulation and Agreement provided Andrx with the

option of selling a generic version of Cardizem CD pursuant to a license from Hoechst MRI at a future date, this did not offset the anticompetitive efforts."

Interrogatory No. 20

Describe in detail each basis, if any, for concluding that any of the parties to the Florida Patent Action undertook to delay the resolution of that action.

Interrogatory No. 21

With respect to each person whose testimony as an expert witness the FTC intends to or may adduce or rely on in this action (in person or by affidavit, report or declaration), identify such expert and describe in detail his or her expert testimony, including, without limitation:

(a) The subject matter of the testimony of such expert witness, and the substance of the facts and opinions to which the expert is expected to testify and a summary of the grounds for each opinion.

(b) The area of the witness' expertise, and the qualifications of such witness establishing him or her as an expert, including without limitation his/her knowledge, skill, experience, training or education relating to the subject of the testimony.

Interrogatory No. 22

With respect to each person whose testimony as a non-expert witness the FTC intends to or may adduce or rely on in this action (in person or by affidavit,

report or declaration), identify such person and describe in detail his or her expected testimony, including, without limitation, the subject matter of the testimony.

Dated: April 17, 2000

SOLOMON, ZAUDERER, ELLENHORN
FRISCHER & SHARP

By: _____

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Attorney for Respondent
Andrx Pharmaceuticals, Inc.

APPENDIX OF DEFINITIONS AND INSTRUCTIONS TO ANDRX'S FIRST SET OF INTERROGATORIES

1. The term "FTC" shall refer to, either collectively or separately as the case may be to make the scope of the request as broad as permissible, the Federal Trade Commission, the Commissioners, staff members, employees, or agents, including, without limitation, the staff involved in the Bureau of Competition or Bureau of Economics.

2. The term "Action" shall mean the Federal Trade Commission adjudicative proceeding, Docket No. 9293.

3. The term "Complaint" means the FTC Complaint dated March 16, 2000, issued in connection with this Action.

4. The term "FTC Staff" shall mean any FTC attorney or other staff connected with this Action.

5. The term "Andrx" shall mean respondent Andrx Corporation and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.

6. The term "HMR" shall mean respondent Hoeschst Marion Roussel and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.

7. The term "Biovail" shall refer to Biovail Corporation International, and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, consultants (including public relations consultants and Anne George, John Grimaldi, Michael Sitrick, Steven Seiler or Sitrick and Company), controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.

8. The term "Faulding" shall refer to Faulding Inc. and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.

9. The "Florida Patent Action" shall refer to the action captioned Hoechst Marion Roussel, Inc. v. Andrx Pharmaceuticals, No. 96-06121, which was commenced in the United States District Court for the Southern District of Florida.

10. The term "September 1997 Stipulation" shall refer to the Stipulation, dated September 24, 1997, between Andrx and HMR.

11. The term Cardizem CD means the diltiazem formulation sold under that name.

12. The term "person" shall mean any natural person, firm, partnership, corporation, incorporated association, organization, joint venture, cooperative, governmental body or other form of legal entity.

13. The term "concerning" means related to, referring to, describing, evidencing or constituting.

14. The term "describe in detail" as used herein means: describe fully by reference to underlying facts, rather than by reference to ultimate facts or conclusions of fact or law; provide full information with respect to: (i) time; (ii) place; and (iii) manner; provide all applicable information required by the word "identify"; and provide a precise calculation of all numerical information requested.

15. If it is claimed that information responsive to any interrogatory 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 information, state: (a) the reason for withholding it or other information relating to it; (b) the author of the documents; if the information is embodied in a document; (c) each individual to whom the original or a copy of the document was sent; (d) all persons present at or participating in the oral communication; (e) the date of the documents or oral communication; (f) the general subject matter of the document or oral communication; and (g) 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.

16. The term "identify", when used in reference to a natural person, shall mean to state the person's (a) full name, present or last known residence and business address(es) and telephone number(s); (b) present or last known employer(s), place of employment and job title, if any; and (c) the nature (including job title, if any) and dates of any affiliation, by employment or otherwise, with any party to this litigation. Once a

natural person has been identified properly, it shall be sufficient thereafter when identifying that same person to state the name only.

17. When used in reference to a person other than a natural person, "identify" shall mean (a) to state its name; (b) to describe its nature (*e.g.*, corporation, partnership, etc.); (c) to state the location of its principal place of business; and (d) to identify the person or persons employed by such entity whose actions on behalf of the entity are responsive to the interrogatory. Once a person other than a natural person has been identified properly, it shall be sufficient thereafter when identifying that same person to state the name only.

18. The term "identify" when used with respect to a documents or documents shall mean (a) the specify the nature or type of the document (*e.g.*, letter, memorandum, etc.); (b) to state the date, if any, appearing on the documents, or if non, the date such documents was prepared or received; (c) to describe in general the subject matter of the documents with sufficient particularity so as to enable such document to be precisely identified; (d) if the documents is longer than three pages, to describe the portion of the documents responsive to the interrogatory; (e) to identify each person who wrote, signed (or authorized the signature of), dictated, or otherwise participated in the preparation of the documents; (f) to identify any addressee thereof, and, if known, each person to who the documents was distributed; (g) to state whether the documents has been produced during the course of the documents production in this section and, if it has not, to state the source of the documents and the reason or reasons for not producing such document; (h) if the document has been produced during the course of this action, to provide the documented identification number of the documents; (i) to state the present

physical location of the document; and (j) to identify each person having possession, custody or control of the documents, and information sufficient to locate the document.

19. The term "identify" or "identification", when used with respect to the identification of facts, acts, events, occurrences, meetings, telephone conferences, or communications, means to describe with particularity the fact, act, event, occurrence, meeting, telephone conference, or communication in question, including, but not limited to: (a) identifying any participants in the fact, act, event, occurrence, meeting, telephone conference, or communication; (b) identifying any witnesses to the fact, act, event, occurrence, meeting, telephone conference, or communication; (c) stating the date(s) on which the fact, act, event, occurrence, meeting, telephone conference, or communication took place; (d) stating the location(s) at which the fact, act, event, occurrence, meeting, telephone conference, or communication took place; and (e) providing a description of the substance of the fact, act, event, occurrence, meeting, telephone conference, or communication.

20. Unless otherwise stated, the use of a verb in any tense shall be construed as the use of the verb in all other tenses as necessary to bring within the scope of the interrogatory responses which might otherwise be construed outside its scope.

21. The singular includes the plural and vice versa; the words "and" and "or" shall be both conjunctive and disjunctive; the word "all" means "any and all"; the word "any" means "any and all"; the word "including" means "including without limitation"; the word "he" or any other masculine pronoun includes any individual regardless of sex.

22. 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, without limitation, the following information: date of disposal, manner of disposal, reason for disposal, person authorizing the disposal and person disposing of the document.

23. Insofar as any of the requested information discloses Andrx's confidential business information, the information should only be disclosed subject to an appropriate protective order covering confidentially, which Andrx is prepared to have adopted in this proceeding.

24. The FTC should supplement, amend or correct as promptly as practicable the disclosures and responses to these requests, on a continuing basis, to the extent it ascertains any additional responsive information.

25. 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. Plaintiff should answer each interrogatory separately and fully, unless it is objected to, in which event the reasons for the objections should be specifically and separately stated. The answers are to be signed by plaintiff and the objections, if any, are to be signed by the attorney(s) making them. Where a complete answer to a particular interrogatory is not possible, the interrogatory should be answered to the extent possible and a statement should be made indicating why only a partial answer is given.

26. With respect to any interrogatory calling for the identification or listing of documents, unless otherwise indicated, you may in lieu thereof, attach to your

answer a copy of such documents segregated separately for each answer, with an identification of the interrogatory or interrogatories (or portion thereof) to which they are submitted as being responsive. In the event you elect to attach documents rather than identify them in response to any interrogatory, the documents should be produced as they are kept in the usual course of business and clearly designated to reflect the individual (and, as appropriate, his or her job title), department (as appropriate) and entity from whose files each document was produced, the file from which each document was produced and the location of each such file.

27. Whenever an interrogatory, in whole or in part, calls for information already supplied by Complaint Counsel in answer to another one or more of these interrogatories, you need not repeat information already supplied, provided that you clearly indicate in your answer to the interrogatory (a) the portion of the interrogatory for which you have already supplied the information called for, and (b) the specific answer to the specific interrogatory (or subpart thereof) in which you have already supplied the information.

CERTIFICATE OF SERVICE

I, Hal S. Shaftel , hereby certify that on April 17, 2000, I caused a copy of Respondent Andrx Corporation's First Set of Interrogatories to be served upon the following persons by Federal Express:

Bradley S. Albert, Esq.
Federal Trade Commission
Room 3116
601 Pennsylvania Ave, N.W.

James M. Spears, Esq.
Shook, Hardy & Bacon, L.L.P
801 Pennsylvania Avenue, N.W.
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Markus H. Meier, Esq.
Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

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

Hal S. Shaftel

Exhibit B

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

COMPLAINT COUNSEL'S RESPONSES AND OBJECTIONS TO RESPONDENT ANDRX CORPORATION'S FIRST SET OF INTERROGATORIES

In accordance with section 3.35 of the Federal Trade Commission's Rules of Practice, 16 C.F.R. § 3.35, complaint counsel hereby respond to respondent Andrx Corporation's First Set of Interrogatories. The full text of each interrogatory is set out below, *in italics*, followed by our respective objections and responses. Our provision of a response to any interrogatory shall not constitute a waiver of any applicable objection, privilege, or other right.

General Objection

Complaint counsel has attempted to answer Andrx's First Set of Interrogatories as completely and accurately as is reasonably possible. Complaint counsel's answers, however, are subject to the following general objection to this entire set of interrogatories (and hence complaint counsel will not repeat this objection in each response):

Complaint counsel object to Andrx's First Set of Interrogatories to the extent that they are excessively broad and therefore are unreasonably burdensome. For example, the majority of the interrogatories request complaint counsel to describe in detail or identify "each basis" for our responses. To the extent an interrogatory asks for "each basis" in a response, our response to such an interrogatory is not intended to be exhaustive or to be admissions that other facts or bases are not supportive or relevant. Complaint counsel has, however, expended reasonable efforts to answer these interrogatories to the best of our abilities.

Responses and Specific Objections to Interrogatories

Complaint counsel object to each and every interrogatory on the basis of the general objection stated above. Without waiving this general objection (but without restating it in each and every response), complaint counsel provide the following answers:

Interrogatory No. 1
Describe in detail each anticompetitive effect, if any, the FTC contends was the result of or caused by, directly or indirectly, the alleged anticompetitive conduct of respondents, as set forth in the Complaint, including, without limitation, any actual increase in price, restriction on output, foreclosure of entry into the market, or any other consequence.

Response to Interrogatory No. 1

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 1 as premature to the extent it asks us to identify, prior to the completion of discovery, each anticompetitive effect that we will contend was the result of, or caused by, directly or indirectly, the alleged anticompetitive conduct of respondents. Complaint counsel further object to Interrogatory No. 1 as premature to the extent it seeks information prepared by an expert who may testify in this matter.

Subject to these objections, as far as complaint counsel is presently aware, the anticompetitive conduct of respondents had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition and consumers by preventing or discouraging the entry of competition in the form of generic versions of Cardizem CD into the relevant market, decreasing the output of generic Cardizem CD products, raising or stabilizing the prices of Cardizem CD, and eliminating or reducing consumer choice.

On September 24, 1997, respondents entered into the September 1997 Stipulation. Under this agreement, HMR, Carderm, and Andrx agreed among themselves that Andrx would not enter the market with the generic version of Cardizem CD covered by its Abbreviated New Drug Application (ANDA) until the earlier of (1) the entry of final judgment in the patent lawsuit, (2) Andrx obtaining a license from HMR under the terms and conditions specified in the September 1997 Stipulation, or (3) HMR providing notice that it intended to license a third party or sell its own bioequivalent or generic version of Cardizem CD. In the September 1997 Stipulation, Andrx also agreed – at HMR's insistence – to refrain from selling any other bioequivalent or generic version of Cardizem CD, regardless of whether such product would infringe HMR's or Carderm's patents. In addition, Andrx agreed not to withdraw its pending ANDA or to relinquish or otherwise compromise any right accruing under its ANDA, including its 180-day exclusivity right, until the entry of final judgment in the Florida Patent Action.

By prohibiting Andrx from commencing the commercial sale of not only the product subject to the patent infringement suit, but also of any bioequivalent or generic version of Cardizem CD during the term of the agreement, the September 1997 Stipulation had the purpose, as well as the intended or likely effect, of deterring Andrx from developing and selling any non-

infringing or potentially non-infringing version of its generic Cardizem CD product. By prohibiting Andrx from withdrawing its pending ANDA or relinquishing or otherwise compromising any right accruing under its ANDA, including its right to 180 days of generic market exclusivity, until the entry of final judgment in the patent lawsuit, the September 1997 Stipulation had the purpose, as well as the intended or likely effect, of deterring Andrx from relinquishing its eligibility to the 180-day period of exclusivity under the Hatch-Waxman Act.

Had the September 1997 Stipulation not been terminated in June 1999, it likely would have delayed entry by Andrx for a minimum of seven months, from June 1999 until January 2000, if not later. Even if Andrx had entered in January 2000 pursuant to paragraph 6 of the stipulation, the competitive significance of its entry would have been diminished by the requirements of paying licensing royalties to HMR. In addition, had the September 1997 Stipulation not been terminated in June 1999, it likely would have delayed entry by Faulding or Biovail for a minimum of seven months, from December 1999 until July 2000, if not later.

Interrogatory No. 2
Identify each person, by name and address, with whom the FTC communicated in connection with any investigation concerning Andrx or the 1997 Stipulation; and, for each such person, describe in detail the substance of any information the FTC ascertained from the person.

Response to Interrogatory No. 2

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 2 on the grounds that it calls for information protected by the work product doctrine. Complaint counsel further object to Interrogatory No. 2 on the grounds that it calls for information the disclosure of which would reveal the identity of confidential informants. Complaint counsel further object to Interrogatory No. 2 on the grounds that it calls for

information the disclosure of which would invade the deliberative process of the Commission. Complaint counsel further object to Interrogatory No. 2 on the basis that it calls for information acquired through compulsory process, or produced voluntarily in lieu of compulsory process, in investigations other than the Commission's investigation of the September 1997 Stipulation, FTC File Number 981-0368. All information learned in any investigation besides FTC File Number 981-0368 is privileged and confidential under 15 U.S.C. §§ 46(f), 57b-2(b), and 18a(h) as well as 16 C.F.R. § 4.10(d).

Subject to these objections, complaint counsel state that we communicated with insurance companies, managed care organizations, physicians, pharmaceutical manufacturers and sellers, state and federal government agencies, and group purchasing organizations. We discussed, among other things, issues relating to generic substitution of brand name pharmaceutical products, substitution among once-a-day diltiazem products, substitution between once-a-day diltiazem products and other calcium channel blocker ("CCB") products, substitution between once-a-day diltiazem products and other drug products that treat hypertension or angina, and the likely effects of the September 1997 Stipulation on the entry of generic Cardizem CD. From these discussions, we learned the following general information which supports our allegation that once-a-day diltiazem is a relevant product market in which to assess the likely or actual anticompetitive effects stemming from the September 1997 Stipulation:

- Cardizem CD and generic versions of Cardizem CD have been determined by the Food and Drug Administration to be bioequivalent, contain the same active pharmaceutical ingredient, and act similarly in the body, so that they are virtually identical in safety, efficacy, and side effects.

- Sales of generic versions of Cardizem CD come almost exclusively at Cardizem CD's expense, with little or no effect on other drugs approved for the treatment of hypertension or angina.

- Generic products tend to be significantly less expensive than their brand-name counterparts.

- Pharmacists may, and in some cases are required to, substitute generic versions of Cardizem CD for Cardizem CD without obtaining authorization from a physician. In contrast, pharmacists cannot substitute other drugs for Cardizem CD without obtaining authorization from a physician.

- Once-a-day diltiazem products cannot be reasonably substituted with products from other CCB product categories. Although all CCBs are indicated for the treatment of hypertension, the CCB class is a diverse group of drugs with different chemical structures and effects. CCBs typically are classified into three distinct categories: benzothiazepines (diltiazem), phenylalkylamines (verapamil), and dihydropyridines. Each of these categories of drugs contain different active pharmaceutical ingredients, may react differently in the body, or are associated with different side effects.

- Although immediate release and twice-daily formulations of diltiazem deliver the same active ingredient to the patient as once-a-day versions, they are not reasonable substitutes for several reasons. Primarily, the once-a-day formulation is superior to other formulations because it increases patient compliance. For a disease such as hypertension, compliance is critical to successful treatment. Non-compliance has an adverse effect on a patient's health, resulting in the inability to control blood pressure, which in turn increases stress on the arteries. The once-a-day formulation provides not only convenience and greater compliance, but also is believed to have greater therapeutic efficacy because of the more consistent level of the drug maintained in the patient's blood stream throughout a 24-hour period.

In support of this general information, complaint counsel refer Andrx to the documents submitted by Andrx in the pre-complaint investigation of this matter, as well as the documents we produced as part of our initial disclosures, including, but not limited to: Andrx 000922-000968; Andrx 004661-004671; Andrx 005164-005182; Andrx 008487-8523; HMRI Spec 10 001790; HMRI S17 001023; HMRI S18 000217-220; HMRI Spec 19 001790; HMRI S19 002732-002737; HMRI Spec 20 Stratemeier 00181-00190; and Astra Response to CID No. 3.

Interrogatory No. 3

Describe in detail each basis, if any, for concluding that respondents have used or have been using any unfair method of competition or unfair or deceptive act or practice in or affecting commerce, as such terms are issued in Section 5(b) of the FTC Act, 15 U.S.C. § 45.

Response to Interrogatory No. 3

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 3 as premature to the extent its asks us to describe in detail, prior to the completion of discovery, each basis for concluding that respondents have used or have been using any unfair method of competition or unfair or deceptive act or practice in or affecting commerce, as such terms are used in Section 5(b) of the FTC Act, 15 U.S.C. § 45. Complaint counsel further object to Interrogatory No. 3 on the grounds that it calls for a legal conclusion. Complaint counsel further object to Interrogatory No. 3 as premature to the extent it seeks information prepared by an expert who may testify in this matter.

Subject to these objections, as far as complaint counsel is presently aware, the following are bases for concluding that respondents have used or have been using such unfair method or unfair or deceptive act or practice.

First, respondents entered into an agreement – the September 1997 Stipulation – that had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition and consumers by preventing or discouraging the entry of competition in the form of generic versions of Cardizem CD into the relevant market by preventing or decreasing the output of generic Cardizem CD products, raising or stabilizing the prices of Cardizem CD, and eliminating or reducing consumer choice.

Beginning in late July 1997, representatives of HMR and Andrx engaged in discussions of a possible agreement, pursuant to which Andrx would agree to refrain from bringing a generic version of Cardizem CD to market for a specific period of time. On September 24, 1997, HMR, Carderm, and Andrx entered into their September 1997 Stipulation. Under the stipulation, HMR, Carderm, and Andrx agreed among themselves that Andrx would not enter the market with the generic version of Cardizem CD covered by its ANDA until the earlier of (1) the entry of final judgment in the Florida Patent Action, (2) Andrx obtaining a license from HMR under the terms and conditions specified in the September 1997 Stipulation, or (3) HMR providing notice that it intended to license a third party or sell its own bioequivalent or generic version of Cardizem CD. In the September 1997 Stipulation, Andrx also agreed – at HMR's insistence – to refrain from selling any other bioequivalent or generic version of Cardizem CD, regardless of whether such product would infringe HMR's or Carderm's patents. In addition, Andrx agreed not to withdraw its pending ANDA or to relinquish or otherwise compromise any right accruing under its ANDA, including its 180-day exclusivity right, until the entry of final judgment in the Florida Patent Action.

In exchange for Andrx's various agreements, HMR agreed to pay Andrx $10 million per quarter beginning upon final FDA approval of Andrx's ANDA (*i.e.*, once Andrx could otherwise market) and continuing until the occurrence of either (1), (2) or (3) described above in the preceding paragraph. The September 1997 Stipulation also provided that, should HMR lose the patent infringement suit, HMR would pay Andrx an additional $60 million per year for that same time period.

In the event Andrx breached any of its obligations under the September 1997 Stipulation, it was required to repay all amounts received. For example, if Andrx breached one of its obligations one year after receiving final FDA approval, it would be required to repay $40 million to HMR. In addition, by its terms, the September 1997 Stipulation would terminate in the event of a breach by Andrx, thus extinguishing any right of Andrx to receive an additional payment should it prevail in the patent lawsuit, or to exercise a license should it lose the lawsuit.

On July 9, 1998, the FDA granted final approval for Andrx's ANDA for a generic version of Cardizem CD. This approval permitted Andrx to begin the marketing and sale of its generic version of Cardizem CD immediately. In accordance with the terms of the September 1997 Stipulation, Andrx did not begin commercial sale of its generic product. As a result, pursuant to the terms of the stipulation, HMR began making quarterly payments of $10 million to Andrx.

In short, the September 1997 Stipulation was an agreement between competitors or potential competitors, whereby one party to the agreement was paid by the other not to compete. In light of Andrx's right to 180 days of marketing exclusivity and Andrx's agreement not to relinquish this right, the September 1997 Stipulation also acted to block entry from all potential forms of generic competition.

Second, HMR, Andrx, and Carderm acted with the specific intent that HMR monopolize the relevant market. The respondents implemented a plan calculated to exclude competitors or potential competitors from the market. They designed an agreement that was structured specifically to forestall the entry of generic competition to Cardizem CD. Both HMR and Andrx acted consistent with their obligations under the September 1997 Stipulation. For instance, consistent with the agreement, Andrx did not market its generic version of Cardizem CD upon

final FDA approval, in return for which HMR paid to Andrx $10 million per quarter. Moreover, HMR introduced to the agreement certain additional restrictive provisions. For instance, HMR insisted that the agreement include restraints on Andrx's ability (i) to market any generic version of Cardizem CD or (ii) to relinquish its right to 180 days of market exclusivity. Andrx knew – or should have known – that the September 1997 Stipulation would perpetuate HMR's monopoly power in the relevant market.

At the same time it was negotiating the September 1997 Stipulation, HMR also attempted to negotiate an agreement with Biovail. Shortly after Biovail filed an ANDA to market a generic version of Cardizem CD, HMR offered to pay Biovail to refrain from marketing a generic version of Cardizem CD until at least July 1999.

Complaint counsel refer Andrx to the documents submitted by Andrx in the pre-complaint investigation of this matter, as well as the documents we produced as part of our initial disclosures, including, but not limited to: August 10, 1997 correspondence from James M. Spears to Lou Solomon (the correspondence does not have Bates numbers); Andrx 01385-01675; Andrx 004291-004300; Andrx 004307-004308; Andrx 004344-004346; Andrx 004351-004352; Andrx 004358-004360; Andrx 004362-004365; Andrx 004369-004376; Andrx 004382-004384; Andrx 004403-004407; Andrx 04389-04392; Andrx 04397-04399; Andrx 004411-004414; Andrx 004418-004419; HMRI S8 000014-000023; GADS030661-030665; GADS030666-030680; and BVL0000001-0008080.

Interrogatory No. 4

Describe in detail each basis, if any, for concluding that it appears that the Action is in the interest of the public, as such terms are used in Section 5(b) of the FTC Act, 15 U.S.C. § 45.

Response to Interrogatory No. 4

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 4 on the grounds that it calls for information the disclosure of which would invade the deliberative process of the Commission. Complaint counsel further object to Interrogatory No. 4 on the grounds that it calls for information beyond the scope of discovery.

> It has long been settled that the adequacy of the Commission's "reason to believe" a violation of law has occurred and its belief that a proceeding to stop it would be in the "public interest" are matters that go to the mental processes of the Commissioners and will not be reviewed by the courts. Once the Commission has resolved these questions and issued a complaint, the issue to be litigated is not the adequacy of the Commission's pre-complaint information or the diligence of its study of the material in question but whether the alleged violation has in fact occurred. *Exxon Corp.*, 83 F.T.C. 1759, 1760 (Order Denying Reconsideration, June 4, 1974)

Interrogatory No. 5
Identify each other settlement or partial settlement of patent litigation, concerning which the FTC is aware, involving an innovator or brand name pharmaceutical company, and a generic company, that involved any form of: payment from a brand name company to the generic company; or licensing and/or royalty arrangement between the brand name company and the generic company.

Response to Interrogatory No. 5

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 5 on the grounds that it calls for information beyond the scope of discovery. Complaint counsel further object to Interrogatory No. 5 on the grounds that it calls for information which is protected by the work product doctrine. Complaint counsel further object to Interrogatory No. 5 on the grounds that it calls for information the disclosure of which would invade the deliberative process of the Commission. Complaint counsel further object to Interrogatory No. 5 on the grounds that the information is protected under the law enforcement investigatory file privilege. Complaint counsel further object to Interrogatory No. 5 on the basis

that is calls for information acquired through compulsory process, or produced voluntarily in lieu of compulsory process, in investigations other than the Commission's investigation of the September 1997 Stipulation, File Number 981-0368. All information learned in any investigation besides FTC File Number 981-0368 is privileged and confidential under 15 U.S.C. §§ 46(f), 57b-2(b), and 18a(h) as well as 16 C.F.R. § 4.10(d).

Subject to these objections, complaint counsel states that we are aware of the September 1997 Stipulation.

Interrogatory No. 6
For each settlement or partial settlement of a patent litigation identified in Interrogatory No. 5 above, describe in detail each basis for concluding whether or not the settlement is or was an unfair method of competition or unfair or deceptive act or practice in or affecting commerce, as such terms are used in Section 5(b) of the FTC Act.

Response to Interrogatory No. 6

Complaint counsel refer Andrx to our response to Interrogatory No. 3.

Interrogatory No. 7
Describe in detail each basis, if any, for your allegation in paragraph 12 of the Complaint that "[a] relevant product market for assessing respondents' anticompetitive conduct is once-a-day diltiazim", and identify, for that alleged market, the number of wholesalers; amount of annual sales by wholesalers to retailers; number of retailers; and amount of annual sales by retailers to individual consumers.

Response to Interrogatory No. 7

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 7 as premature to the extent it asks us to identify, prior to the completion of discovery, each basis for concluding that "[a] relevant product market for assessing respondents' anticompetitive conduct is once-a-day diltiazem." Complaint counsel further object to Interrogatory No. 7 as premature to the extent it seeks information prepared by an expert who

may testify in this matter. Complaint counsel further object to Interrogatry No. 7 on the grounds that it calls for information of which neither complaint counsel nor the Commission is aware. Complaint counsel further object to Interrogatory No. 7 on the grounds that it places an unreasonable burden on us. We do not have the information to identify, for the alleged market, the number of wholesalers, amount of annual sales by wholesalers to retailers, number of retailers, and amount of annual sales by retailers to individual consumers. This information is more readily available to Andrx than to complaint counsel, as Andrx has greater access to data (such as IMS data) and other resources which would identify the relevant information sought.

Subject to these objections, complaint counsel states the following in support of our allegation that "[a] relevant product market for assessing respondents' anticompetitive conduct is once-a-day diltiazem."

- Cardizem CD and generic versions of Cardizem CD have been determined by the Food and Drug Administration to be bioequivalent, contain the same active pharmaceutical ingredient, and act similarly in the body, so that they are virtually identical in safety, efficacy, and side effects.

- Sales of generic versions of Cardizem CD come almost exclusively at Cardizem CD's expense, with little or no effect on other drugs approved for the treatment of hypertension or angina. For instance, both HMR and Andrx – prior to the entry of generic competition – expected that the introduction of generic Cardizem CD would have a significant and profound effect on the sales of Cardizem CD. HMR forecasted that a generic version of Cardizem CD would capture roughly 40% of Cardizem CD sales within the first year, and nearly 70% after two years. (See e.g., HMRI S18 000217-220 and HMRI S19 002733, 004661). Andrx forecasted generic penetration at 43.75% of Cardizem CD sales after one year, reaching 66.10% after two years. (See e.g., Andrx 000922-000968, 000953).

- Generic products tend to be significantly less expensive than their brand-name counterparts. For instance, Andrx forecasted that upon its launch of a generic version of Cardizem CD, it would price the product at a 28-40% discount off Cardizem CD. (See Andrx 000922-000968)

- Pharmacists may, and in some cases are required to, substitute generic versions of Cardizem CD for Cardizem CD without obtaining authorization from a physician. In contrast, pharmacists cannot substitute other drugs for Cardizem CD without obtaining authorization from a physician.

- Once-a-day diltiazem products cannot be reasonably substituted with products from other CCB product categories. Although all CCBs are indicated for the treatment of hypertension, the CCB class is a diverse group of drugs with different chemical structures and effects. CCBs typically are classified into three distinct categories: benzothiazepines (diltiazem), phenylalkylamines (verapamil), and dihydropyridines. Each of these categories of drugs contain different active pharmaceutical ingredients, may react differently in the body, or are associated with different side effects.

- Although immediate release and twice-daily formulations of diltiazem deliver the same active ingredient to the patient as once-a-day versions, they are not reasonable substitutes for several reasons. Primarily, the once-a-day formulation is superior to other formulations because it increases patient compliance. For a disease such as hypertension, compliance is critical to successful treatment. Non-compliance has an adverse effect on a patient's health, resulting in the inability to control blood pressure, which in turn increases stress on the arteries. The once-a-day formulation provides not only convenience and greater compliance, but also is believed to have greater therapeutic efficacy because of the more consistent level of the drug maintained in the patient's blood stream throughout a 24-hour period.

- Andrx alleged a relevant product market of diltiazem in its counterclaim to HMR's patent infringement suit. (See Andrx's answer in the Florida Patent Action)

Interrogatory No. 8

Describe in detail the definition and scope of the market (or markets) for calcium channel blockers, ace inhibitors and beta blockers, including, without limitation, the identity of any pharmaceutical products that allegedly or actually competes with, may be substituted for, or otherwise provide an alternative for Cardizem CD and/or Cartia XT.

Response to Interrogatory No. 8

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 8 as premature to the extent it asks us to describe, prior to the completion of discovery, the definition and scope of the market (or markets) for calcium channel blockers, ace inhibitors, and beta blockers. Complaint counsel further object to Interrogatory No. 8 on the

grounds that it asks for a legal conclusion. Complaint counsel further object to Interrogatory No. 8 as premature to the extent it seeks information prepared by an expert who may testify in this matter.

Subject to these objections, as far as complaint counsel is presently aware, the relevant product market, as alleged in the complaint, is no broader than once-a-day diltiazem products. In addition, narrower relevant product markets may be contained within the market for once-a-day diltiazem, including a market of Cardizem CD and generic or bioequivalent versions of Cardizem CD.

Once-a-day diltiazem products include the following brand-name products and all generic versions thereof: Cardizem CD, Dilacor XR, and Tiazac.

Other CCB products, which are not part of the once-a-day diltiazem market, include the following brand-name products and all generic versions thereof: Adalat CC, Cardene SR, Cardene, Dynacirc CR, Dynacirc, Norvasc, Plendil, Procardia XL, Procardia, Sular, Calan SR, Calan, Covera HS, Isoptin SR, Isoptin, Verelan PM, Verelan, Cardizem SR, and Cardizem.

Ace inhibitors, which are not part of the once-a-day diltiazem market, include the following brand-name products and all generic versions thereof: Accupril, Aceon, Altace, Capoten, Lotensin, Mavik, Monopril, Prinivil, Univasc, Vasotec, and Zestril.

Beta blockers, which are not part of the once-a-day diltiazem market, include the following brand-name products and all generic versions thereof: Betachron E-R, Blocadren, Corgard, Inderal, Kerlone, Lopressor, Tenormin, Toprol XL, and Zebeta.

Interrogatory No. 9

For entities or individuals who purchased Cardizem CD, including wholesalers, retailers and individual consumers, identify the extent, if any, that prices paid were artificially inflated or

otherwise exceeded what the prices otherwise would have been by reason of defendants' alleged anticompetitive conduct, and describe in detail the basis for your contention; how this amount was calculated; any formula used in making the calculation; the sources of any data; and state all facts and assumptions on which you base such answer.

Response to Interrogatory No. 9

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 9 on the grounds that it calls for information beyond the scope of discovery. Complaint counsel further object to Interrogatory No. 9 as premature to the extent it seeks information by an expert who may testify in this matter. Complaint counsel further object to Interrogatory No. 9 as premature to the extent its asks us to identify, prior to the completion of discovery, the extent, if any, that prices paid were artificially inflated or otherwise exceeded what the prices otherwise would have been by reason of respondents' alleged anticompetitive conduct.

Subject to these objections, the evidence indicates that Andrx would have priced its generic version of Cardizem CD, upon launching the product, at a 28-40% discount off the brand name product. (See Andrx 000922-000968).

The September 1997 Stipulation, at the time of its inception and execution, was likely to foreclose entry of – or raise barriers to – lower-cost generic versions of Cardizem CD, by reducing or eliminating Andrx's incentives to launch its original product, to develop and sell any non-infringing or potentially non-infringing version of its generic Cardizem CD product, and to relinquish or otherwise compromise its right to 180 days of market exclusivity. Indeed, had the parties not terminated the September 1997 Stipulation in June 1999, the agreement likely would have delayed Andrx's entry by at least seven months, if not substantially longer. As a result, this agreement, had it not been terminated under pressure from the Commission, was likely to

artificially inflate prices in the once-a-day diltiazem market by at least 28-40% (see Andrx 000922-000968), decrease the output of generic Cardizem CD products, and eliminate or reduce consumer choice.

Interrogatory No. 10

Describe in detail the relationship, if any, which you contend exists between (a) the degree to which, if any, the prices paid for Cardizem CD by wholesalers or retailers were higher than they would have been in the absence of defendants' alleged anticompetitive conduct, and (b) the degree to which, if any, the prices paid by individual consumers for Cardizem CD exceeded what they otherwise would have been.

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 10 on the grounds that it calls for information beyond the scope of discovery. Complaint counsel further object to Interrogatory No. 10 as premature to the extent it seeks information by an expert who may testify in this matter. Complaint counsel further object to Interrogatory No. 10 as premature to the extent it asks us to identify, prior to completion of discovery, each basis for detailing the relationship which we may contend between (a) the degree to which, if any, the prices paid for Cardizem CD by wholesalers or retailers were higher than they would have been in the absence of respondents' alleged anticompetitive conduct, and (b) the degree to which, if any, the prices paid by individual consumers for Cardizem CD exceeded what they otherwise would have been.

Subject to these objections, complaint counsel state that the September 1997 Stipulation, at the time of its inception and execution, was likely to foreclose entry of – or raise barriers to – lower-cost generic versions of Cardizem CD. Indeed, had the parties not terminated the September 1997 Stipulation in June 1999, the agreement likely would have delayed Andrx's entry by at least seven months, if not substantially longer. As a result, this agreement, had it not

been terminated, was likely to artificially inflate prices in the once-a-day diltiazem market by at least 28-40% (See Andrx 000922-000968), decrease the output of generic Cardizem CD products, and eliminate or reduce consumer choice.

Complaint counsel refer Andrx to the documents submitted by Andrx in the pre-complaint investigation of this matter, as well as the documents we produced as part of our initial disclosures, including, but not limited to: Andrx 004661-004671; Andrx 005164-005182; Andrx 000922-000968; HMRI S19 002732-002737; and HMRI Spec 20 Stratemeier 00181-00190.

Interrogatory No. 11
Describe in detail the relationship, if any, which the FTC contends exists, between the price(s) of a brand name pharmaceutical product and the price of one or more generic versions of such a product.

Response to Interrogatory No. 11

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 11 on the grounds that it calls for information beyond the scope of discovery. Complaint counsel further object to Interrogatory No. 11 on the grounds that it is premature to the extent it seeks information prepared by an expert who may testify in this matter. Complaint counsel further object to Interrogatory No. 11 on the grounds that it is premature to the extent it seeks information concerning the relationship, prior to completion of discovery, between the price(s) of a brand name pharmaceutical product and the price of one or more generic versions of such a product.

Subject to these objections, as far as complaint counsel is presently aware, the prices of generic products are significantly lower than their brand-name counterparts. Andrx's own documents indicate that it projected that it would price its generic version of Cardizem CD, upon

launching the product, at a 28-40% discount off the brand name product. (See Andrx 000922-000968). See e.g., Roy Levy, "The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change," (March 1999) available on the Commission's web site (www.ftc.gov).

Interrogatory No. 12
Does the FTC contend that the alleged anticompetitive conduct, as set forth in the Complaint, constitutes, either in whole or in part, a "per se" violation of any laws; if so, describe in detail each basis, if any, for such a contention.

Response to Interrogatory No. 12

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 12 as premature to the extent it seeks, prior to completion of discovery, "each basis" that the alleged anticompetitive conduct, either in whole or in part, is illegal *per se*. Complaint counsel further object to Interrogatory No. 12 on the grounds that it calls for a legal conclusion.

Subject to these objections, as far as complaint counsel is presently aware, the September 1997 Stipulation is a market division or allocation and is *per se* illegal under Section 1 of the Sherman Act. It is a written agreement between competitors or potential competitors in which one party is paid by the other not to compete in the United States. The agreement is not justified by any countervailing efficiencies.

Interrogatory No. 13
Does the FTC contend that the alleged anticompetitive conduct, as set forth in the Complaint, constitutes, either in whole or in part, a violation of any laws based on a "rule of reason" analysis; if so, describe in detail each basis, if any, for such a contention.

Response to Interrogatory No. 13

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 13 as premature to the extent it seeks, prior to completion of discovery, "each basis" that the alleged anticompetitive conduct, either in whole or in part, is illegal based on a "rule of reason analysis." Complaint counsel further object to Interrogatory No. 13 on the grounds that it calls for a legal conclusion.

Subject to these objections, as far as complaint counsel is presently aware, the September 1997 Stipulation is illegal under a rule of reason analysis. The respondents entered into an agreement – the September 1997 Stipulation – that had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition and consumers by preventing or discouraging the entry of competition in the form of generic versions of Cardizem CD into the relevant market, decreasing the output of generic Cardizem CD products, raising or stabilizing the prices of Cardizem CD, and eliminating or reducing consumer choice. The September 1997 Stipulation has no countervailing pro-competitive justification. It does not contain any substantial efficiency enhancing integrations, nor does it enhance consumer welfare. The only benefits stemming from the stipulation were realized by HMR and Andrx: HMR was guaranteed that no generic competitors would challenge its Cardizem CD, and Andrx was paid $89 million in return for not entering, or facilitating entry into, the market.

Interrogatory No. 14

Describe in detail each basis, if any, for concluding that Andrx would have entered the market with a generic version of Cardizem CD in the absence of the 1997 Stipulation.

Response to Interrogatory No. 14

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 14 on the grounds that it calls for information beyond the scope of discovery. Complaint counsel further object to Interrogatory No. 14 as premature to the extent it seeks information by an expert who may testify in this matter. Complaint counsel further object to Interrogatory No. 14 on the grounds that it is premature to the extent it asks, prior to completion of discovery, for each basis for concluding that Andrx would have entered the market with a generic version of Cardizem CD in the absence of the September 1997 Stipulation.

Subject to these objections, complaint counsel refer Andrx to its own signed memorandum of law submitted to a court in the Florida Patent Action, in which Andrx states that it "intends to manufacture and sell its once-a-day diltiazem composition as soon as it receives FDA approval." (See HMRI S7 002984-003000, 002993) In the course of its patent litigation with HMR, Andrx consistently maintained that the generic version of Cardizem CD for which it filed an ANDA would not infringe any valid patent listed in the Orange Book claiming Cardizem CD. Complaint counsel refer Andrx to the documents submitted by Andrx in the pre-complaint investigation of this matter, as well as the documents we produced as part of our initial disclosures, including, but not limited to:

- Andrx's Notice of Certification of Non-Infringement of a Patent Under 21 C.F.R. § 314.95, HMRI S7 003129-3133;
- Andrx's Patent Certification and Exclusivity Statement, 2199-2200;
- January 17, 1996 Letter from David Gardner to the Office of Generic Drugs, 2068-2077;
- Protocol # AX-102596-1 To: Andrx Pharmaceuticals Inc. For: Manufacture of Diltiazem Capsules Once-Per-Day According to Patent No. 5,364,620, 007608-7613; 2068-2077;

- Andrx's Answer HMRI Spec 20 Hoskins 00230-00266;
- Memorandum of Law in Support of Defendant's Motion to Dismiss the Complaint for Lack of Subject Matter Jurisdiction, HMRI S7 001044-001062;
- Defendant's Motion for Summary Judgment on the Issue of Non-Infringement with Supporting Memorandum of Law, HMRI S7 001656-001678;
- Affidavit of Chih-Ming Chen in Support of Defendant's Motion for Summary Judgment on the Issue of Non-Infringement, HMRI S7 001599-001607; and
- Defendant's Reply Memorandum of Law in Support of its Motion for Summary Judgment on the Issue of Invalidity, HMRI S7 002803-002815).

Interrogatory No. 15

Describe in detail each basis, if any, for concluding that some person other than respondents herein, whether Biovail, Faulding, or another person, would have entered the market with a generic version of Cardizem CD in the absence of the 1997 Stipulation.

Response to Interrogatory No. 15

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 15 on the grounds that it calls for information beyond the scope of discovery. Complaint counsel further object to Interrogatory No. 15 on the grounds that it is premature to the extent its asks, prior to completion of discovery, for "each basis" concluding that some person other than respondents herein, whether Biovail, Faulding, or another person, would have entered the market with a generic version of Cardizem CD in the absence of the 1997 Stipulation.

Subject to these objections, as far as complaint counsel is presently aware, the September 1997 Stipulation had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition and consumers by preventing or discouraging the entry of competition in the form of generic versions of Cardizem CD into the relevant market, decreasing the output of generic Cardizem CD products, raising or stabilizing the prices of Cardizem CD,

and eliminating or reducing consumer choice. Under the September 1997 Stipulation, Andrx agreed not to market any generic version of Cardizem CD, regardless of whether the product infringed any of HMR's patents. In addition, Andrx agreed not to relinquish or otherwise compromise its right to 180 days of market exclusivity. By prohibiting Andrx from commencing the commercial sale of not only the product subject to the patent infringement suit, but also of any bioequivalent or generic version of Cardizem CD during the term of the agreement, the September 1997 Stipulation had the purpose, as well as the intended or likely effect, of deterring Andrx from developing and selling any non-infringing or potentially non-infringing version of its generic Cardizem CD product. Had the respondents not abandoned their agreement under pressure from the Commission, Andrx likely would not have marketed its product until January 2000 at the earliest, when it was eligible (but not required) to exercise a license. Even if Andrx had come to market in January 2000, neither Biovail nor Faulding would have been able to market their products until July 2000, after Andrx's exclusivity expired (which is six months after these parties actually came to market).

By prohibiting Andrx from withdrawing its pending ANDA or relinquishing or otherwise compromising any right accruing under its ANDA, including its right to 180 days of generic market exclusivity, until the entry of final judgment in the Florida Patent Action, the September 1997 Stipulation had the purpose, as well as the intended or likely effect, of deterring Andrx from relinquishing its eligibility for a 180-day period of exclusivity under the Hatch-Waxman Act. Had the respondents not abandoned their agreement under pressure from the Commission, Andrx likely would not have relinquished its 180-day exclusivity right. Accordingly, neither

Biovail nor Faulding would have been able to market their products until July 2000, after Andrx's exclusivity expired (which is six months after these parties actually came to market).

Interrogatory No. 16

Describe in detail each basis, if any, for the allegation made in paragraph 38 of the Complaint that "Hoechst MRI, Cardizem and Andrx acted with the specific intent that Hoechst MRI monopolize the relevant market."

Response to Interrogatory No. 16

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 16 as premature to the extent it asks us to identify, prior to the completion of discovery, each basis for concluding that HMR, Carderm, and Andrx acted with the specific intent that HMR monopolize the relevant market. Complaint counsel further object to Interrogatory No. 16 on the grounds that it calls for a legal conclusion. Complaint counsel further object that Interrogatory No. 16 does not accurately recite paragraph 38 of the complaint.

Subject to these objections, as far as complaint counsel is presently aware, HMR, Andrx, and Carderm acted with the specific intent that HMR monopolize the relevant market. The respondents implemented a plan calculated to exclude competitors or potential competitors from the market. They designed an agreement that was structured specifically to forestall the entry of generic competition to Cardizem CD.

Both HMR and Andrx acted consistent with their obligations under the September 1997 Stipulation. For instance, consistent with the agreement, Andrx did not market its generic version of Cardizem CD upon final FDA approval, in return for which HMR paid to Andrx $10

million per quarter. Moreover, HMR introduced to the agreement certain additional restrictive provisions. For instance, HMR insisted that the agreement include restraints on Andrx's ability (i) to market any generic version of Cardizem CD or (ii) to relinquish its right to 180 days of market exclusivity. Andrx knew – or should have known – that the September 1997 Stipulation would perpetuate HMR's monopoly power in the relevant market.

At the same time it was negotiating the September 1997 Stipulation, HMR also attempted to negotiate an agreement with Biovail. Shortly after Biovail filed an ANDA to market a generic version of Cardizem CD, HMR offered to pay Biovail to refrain from marketing a generic version of Cardizem CD until at least July 1999.

Complaint counsel refer Andrx to the documents submitted by Andrx in the pre-complaint investigation of this matter, as well as the documents we produced as part of our initial disclosures, including, but not limited to: August 10, 1997 correspondence from James M. Spears to Lou Solomon (the correspondence does not have bates numbers); Andrx 01385-01675; Andrx 004291-004300; Andrx 004307-004308; Andrx 004344-004346; Andrx 004351-004352; Andrx 004358-004360; Andrx 004362-004365; Andrx 004369-004376; Andrx 004382-004384; Andrx 004403-004407; Andrx 04389-04392; Andrx 04397-04399; Andrx 004411-004414; Andrx 004418-004419; HMRI S8 000014-000023; GADS030661-030665; GADS030666-030680; and BVL0000001-0008080.

Interrogatory No. 17

Describe in detail each basis, if any, for the allegation made in paragraph 29 of the Complaint that "[t]he acts and practices of the respondents as herein alleged have had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and injure competition and consumers," including, without limitation, explain the meaning of "tendency or capacity" as used in the allegation.

Response to Interrogatory No. 17

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 17 as premature to the extent its asks us to identify, prior to the completion of discovery, each basis for the allegation that "[t]he acts and practices of the respondents as herein alleged have had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and injure competition and consumers." Complaint counsel further object on the grounds that Interrogatory No. 17 calls for a legal conclusion, as the phrase "tendency or capacity" is defined in case law.

Subject to these objections, Complaint counsel refer Andrx to our response to Interrogatory No. 1.

Interrogatory No. 18

Describe in detail each basis, if any, for the allegation in paragraph 31 of the Complaint that "[t]he purpose and intended effect of the $10 million quarterly payments from Hoechst MRI to Andrx during the term of the Stipulation and Agreement was to provide an incentive for Andrx to refrain both from entering the relevant market, and from taking any steps . . . to permit or facilitate the entry of any other generic manufacturer."

Response to Interrogatory No. 18

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 18 as premature to the extent it seeks information by an expert who may testify in this matter. Complaint counsel further object to Interrogatory No. 18 as premature to the extent it asks us to identify, prior to the completion of discovery, each basis for the allegation that "[t]he purpose and intended effect of the $10 million quarterly payments from Hoechst MRI to Andrx during the term of the Stipulation and Agreement was to provide an incentive for Andrx to

refrain both from entering the relevant market, and from taking any steps . . . to permit or facilitate the entry of any other generic manufacturer."

Subject to these objections, as far as complaint counsel is presently aware, pursuant to the September 1997 Stipulation, Andrx agreed that it would not market the generic version of Cardizem at issue in the Florida Patent Action or any other generic version of Cardizem CD (even a non-infringing product). In addition, Andrx agreed that it would not relinquish or otherwise compromise its right to 180 days of market exclusivity. In return for these agreements, Andrx received non-refundable payments in the amount os $10 million a quarter. If Andrx failed to abide by any of these obligations, it would be required to repay all of the $10 million payments, forfeit any right to future $10 million payments, and forfeit any right to additional payments of up to $60 million per year (in the event Andrx prevailed in the Florida Patent Action). These penalty provisions created an incentive for Andrx to abide by its obligations under the September 1997 Stipulation and refrain from marketing a generic version of Cardizem CD or from relinquishing its right to exclusivity.

Interrogatory No. 19

Describe in detail each basis, if any, for the allegations in paragraph 35 of the Complaint that "[a]lthough the Stipulation and Agreement provided Andrx with the option of selling a generic version of Cardizem CD pursuant to a license from Hoechst MRI at a future date, this did not offset the anticompetitive efforts."

Response to Interrogatory No. 19

In addition to the general objection stated above, complaint counsel object to Interrogatory No. 19 as premature to the extent it asks us to describe, prior to the completion of discovery, each basis for the allegations in paragraph 35 of the Complaint that "[a]lthough the Stipulation and Agreement provided Andrx with the option of selling a generic version of

Cardizem CD pursuant to a license from Hoechst MRI at a future date, this did not offset the anticompetitive" effects. Complaint counsel further object to Interrogatory No. 19 as premature to the extent it seeks information by an expert who may testify in this matter.

Subject to these objections, as far as complaint counsel is presently aware, the licensing option within the September 1997 Stipulation did not offset the agreement's anticompetitive effects for several reasons. First, it is unclear whether Andrx would have exercised the licensing option. The September 1997 Stipulation did not require Andrx to exercise the license, and exercising the license would terminate future $10 million quarterly payments and would require the payment of substantial licensing fees.

Second, even if Andrx would have marketed a generic version of Cardizem CD pursuant to a license from HMR, it is likely that Andrx's marketing would have been delayed because of the September 1997 Stipulation. Under the agreement, barring a final resolution to the Florida Patent Action, the earliest HMR would have granted Andrx a license was January 2000 – approximately seven months after Andrx received final FDA approval to market a non-infringing generic version of Cardizem CD. Therefore, had HMR and Andrx not terminated the September 1997 Stipulation under pressure from the Commission, the licensing provision of the agreement would have delayed Andrx's launch by at least seven months.

Interrogatory No. 20
Describe in detail each basis, if any, for concluding that any of the parties to the Florida Patent Action undertook to delay the resolution of that action.

Response to Interrogatory No. 20

In addition to the general objections stated above, complaint counsel object to Interrogatory No. 20 on the grounds that it calls for information beyond the scope of discovery.

Complaint counsel further object to Interrogatory No. 20 as premature to extent it asks us to describe, prior to the completion of discovery, each basis for concluding that any of the parties to the Florida Patent Action undertook to delay the resolution of that action.

Subject to these objections, as far as complaint counsel is presently aware, neither HMR nor Andrx sought to delay the Florida Patent Action.

Interrogatory No. 21

With respect to each person whose testimony as an expert witness the FTC intends to or may adduce or rely on in this action (in person or by affidavit, report or declaration), identify such expert and describe in detail his or her expert testimony, including, without limitation: The subject matter of the testimony of such expert witness, and the substance of the facts and opinions to which the expert is expected to testify and a summary of the grounds for each opinion. The area of the witness' expertise, and the qualifications of such witness establishing him or her as an expert, including without limitation his/her knowledge, skill, experience, training or education relating to the subject of the testimony.

Response to Interrogatory No. 21

Complaint counsel object to Interrogatory No. 21 on the grounds that it calls for premature disclosure of information.

Consistent with the scheduling order in this matter, complaint counsel will provide respondents with an expert witness list by July 17, 2000. Complaint counsel will provide respondents with an expert report (or reports) by September 11, 2000, putting forth the opinion(s) to which the expert is expected to testify and summarizing the grounds for the opinion(s). At the time an expert is first listed as a witness by complaint counsel, we will provide to the respondents:

(a) materials fully describing or identifying the background and qualifications of the expert, lists of publications, and all prior cases in which the expert has testified or has been deposed; and

(b) transcripts of such testimony in the possession, custody, or control [illegible] party or the expert.

Interrogatory No. 22

With respect to each person whose testimony as a non-expert witness the FTC intends to or may adduce or rely on in this action (in person or by affidavit, report or declaration), identify such person and describe in detail his or her expected testimony, including, without limitation, the subject matter of the testimony.

Response to Interrogatory No. 22

Complaint counsel object to Interrogatory No. 22 on the grounds that it seeks [illegible] premature disclosure of information.

Consistent with the scheduling order in this matter, complaint counsel will provide respondents with a witness list (not including experts) by June 14, 2000. This witness list will include a description of the proposed testimony.

[illegible]

Markus H. Meier

[illegible]

Daniel A. Kotchen

[illegible]

Dated: May 15, 2000