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

TO: The Honorable D. Michael Chappell
Administrative Law Judge

COMPLAINT COUNSEL'S OPPOSITION TO ANDRX'S MOTION TO COMPEL INTERROGATORIES

In its June 5, 2000 Motion to Compel Interrogatories or to Preclude, Andrx seeks an order requiring complaint counsel to:

1. Provide more complete responses to Andrx's sixteen contention interrogatories, or in the alternative, be precluded from proceeding at trial on any bases beyond those set forth in our answers;

2. Identify the existence of, and the FTC's privileged internal analyses of, unrelated, nonpublic Commission investigations into patent settlement agreements to which neither Andrx, Hoechst, nor Carderm is a party; and

3. Explain the Commission's reason to believe that this proceeding is in the public interest.

As set forth in detail below, we oppose Andrx's motion in its entirety. First, just because Andrx is permitted under the Commission's rules of practice to propound contention interrogatories, does not mean that it is entitled to force us to adopt definitive factual and legal

positions prior to the completion -- much less the commencement -- of discovery in this matter. Second, by requesting information about the FTC's nonpublic investigations into other unrelated patent settlement agreements, and by seeking to probe the Commission's deliberative process in making the determination that this action is in the public interest, Andrx improperly seeks information that is (1) irrelevant to this proceeding; (2) protected by statutes and regulations governing the confidentiality of nonpublic information; and (3) subject to many well-established privileges. Accordingly, Andrx's motion to compel should be denied in its entirety.

I. Andrx's Motion to Compel More Complete Answers to Its Contention Interrogatories Is Premature and Without Merit

Less than one month into discovery, Andrx issued sixteen contention interrogatories to complaint counsel seeking to discover each factual and legal basis for the FTC's case.[1]

Although contention interrogatories are permitted under the Commission's rules of practice, they generally are reserved until closer to the completion of discovery. As the Commission's rules explicitly recognize: "the Administrative Law Judge may order that [contention interrogatories] need not be answered until after designated discovery has been completed or until a pre-trial conference or other later time."[2] Courts too routinely defer a

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[1] In its interrogatories, Andrx asks us to "describe in detail" each anticompetitive effect stemming from the Hoechst-Andrx agreement (Interrogatory No. 1); each basis for concluding the respondents have used an unfair method of competition (Interrogatory No. 3); each basis for concluding that a relevant product market for assessing respondents' anticompetitive conduct is once-a-day diltiazem (Interrogatory No. 7); each basis for concluding Andrx would have entered the market sooner but for its agreement with Hoechst (Interrogatory No. 14); each basis for concluding that Hoechst and Andrx acted with specific intent that Hoechst monopolize the relevant market (Interrogatory No. 16); or the subject matter of the testimony of each witness (including expert witnesses) on whom we intend to rely (Interrogatory Nos. 21 and 22).

[2] 16 C.F.R. § 3.35(b)(2).

party's obligation to respond to contention interrogatories until closer to the end of discovery.[3] The reason for this is simple: contention interrogatories are supposed to narrow the issues for trial. This goal, however, is not accomplished by trying to lock a party into positions before the party has had the opportunity to fully develop its factual and legal theories through discovery. As one court has put it: "fairness dictates that parties not be forced to prematurely take a position, which would produce an artificial narrowing of the issues, instead of an informed paring down."[4]

Despite the fact that Andrx's sixteen contention interrogatories are objectionable as premature, we provided a 30-page response to the interrogatories, putting forth in detail, our "present concept of the theor[ies] of the case."[5] A review of our responses demonstrates that we have provided Andrx with a "current roadmap of where the case is headed."[6] For example, in Interrogatory No. 7, Andrx asked us to "describe in detail each basis" for concluding that "[a] relevant product market for assessing respondents' anticompetitive conduct is once-a-day diltiazem." In responding to this interrogatory, we put forth our present factual bases for concluding the relevant market is once-a-day diltiazem, including the following:

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[3] *See McCarthy v. Paine Webber Group, Inc.*, 168 F.R.D. 448, 450 (D. Conn. 1996) (order denying the response of contention interrogatories because discovery is ongoing); *Braun Medical Inc. v. Abbott Laboratories,* 155 F.R.D. 525, 527 (E.D. Pa. 1994) (order refusing to require a response to contention interrogatories prior to the completion of discovery); *Convergent Technologies Secs. Litig.*, 108 F.R.D. 328, 336 (N.D. Cal. 1985) (order refusing to require a response to contention interrogatories prior to substantial completion of discovery).

[4] *Ziemack v. Centel Corp.*, No. 92-C3551, 1995 U.S. Dist. LEXIS 18192 at *5 n.3 (N.D. Ill December 6, 1995).

[5] *Flowers Industries*, FTC Dkt. No. 9148, 1981 FTC LEXIS 110 at *3 (October 7, 1981) (ALJ Timony).

[6] *Id.*

- 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.

Apparently this response is not satisfactory to Andrx. Why? Because we have left open the possibility that we may seek to introduce at trial additional bases for concluding the relevant market is once-a-day diltiazem that are learned in the course of discovery.

Similarly, Andrx objects to all of our responses to its contention interrogatories not because they are incomplete, but because they are "couched with language reserving the right to modify [the] contentions at some later point."[7] But, the issues raised in Andrx's contention interrogatories are all issues upon which we are entitled to conduct discovery, and for which we are currently seeking discovery. We have issued document requests to the respondents, and we intend to take depositions, to further develop factual information relevant to the very issues addressed by Andrx's contention interrogatories. In addition, our economic expert is still in the process of sifting through the information collected to date and will rely on documents, information, and transcripts from the on-going discovery in formulating his opinions, writing his report, and testifying. Thus, prior to the completion of discovery, it is not possible for us to know each and every way in which our factual and legal theories may be further developed.

Taken to it logical conclusion, Andrx's insistence that complaint counsel provide each and every basis for our legal positions at this time -- or risk being precluded from doing so later -- either is intended to deny us the right to conduct any meaningful discovery in this proceeding,

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[7] Andrx's Motion to Compel Interrog. at 2.

or is intended to preclude us from using the product of our discovery efforts. In either case, such a result contradicts the many provisions of the FTC's rules of practice granting complaint counsel the right to conduct and use discovery equal to that of respondents.[8]

II. Respondent Andrx Is Not Entitled to Information from Unrelated, Nonpublic Commission Investigations

By its interrogatories number 5 and 6, Andrx seeks information concerning unrelated patent settlement agreements that are currently subject to non-public Commission investigations that do not involve Andrx, Hoechst, or Carderm. Andrx argues that, because agreements similar to the Hoechst-Andrx Stipulation and Agreement at issue in this case have become "industry-wide practice," it is entitled to know the identity of, and the FTC's privileged internal analyses of, each of these agreements that has been, or is being, investigated by the Commission.

Although Andrx may be right that agreements by which a brand-name pharmaceutical manufacturer pays a generic pharmaceutical company to stay out of the market (like the agreement at issue here) have become more prevalent, complaint counsel does not intend, nor have we considered, using either the existence of, or the FTC's analysis of, other such agreements to challenge the legality of the Hoechst-Andrx agreement. Commission

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[8] *See, e.g.,* 16 C.F.R. §§ 3.31-3.35. Should Andrx eventually show that it actually is entitled to a more detailed response to certain of its contention interrogatories, the proper way to deal with this would be to require complaint counsel to supplement the responses at the end of the discovery period. As a number of courts have ruled, "parties should not be bound by [contention interrogatory] answers, if in the interim between the time of the answers and the trial, they obtain by subsequent investigation new or additional facts." *McElroy v. United Airlines,* Inc., 21 F.R.D. 100, 102 (W.D. Mo.1957). *See also Thomas & Betts*, No. 93-C4017, 1996 U.S. Dist. LEXIS 4494 at *8 (N.D. Ill.1996) (ordering that a party must answer interrogatories with whatever information is currently available but also may augment responses at a later date).

investigations into other such settlements is irrelevant as well as protected from disclosure by many privileges and statutory and regulatory confidentiality provisions.

A. Information from other nonpublic Commission investigations into settlement agreements is irrelevant to this proceeding

The Commission rules of practice make clear that discovery is limited to "the extent it may be reasonably expected to yield information relevant to the allegations of the complaint, of the proposed relief, or to the defenses of any respondent."[9] Contrary to Andrx's arguments, the existence of, as well as the privileged internal FTC analyses of, other patent settlement agreements is irrelevant to whether Andrx and Hoechst violated the antitrust laws, and the discovery of similar types of information has consistently been denied by administrative law judges at the FTC.[10] Whether the Hoechst-Andrx agreement is the only such agreement or whether it is the hundredth, does not change its illegality. Just as a price-fixing agreement is no less pernicious because of the existence of other price-fixing agreements, the existence of other patent settlement agreements that include non-compete provisions has no bearing on the legality of the agreement at issue here.[11] And, to the extent that such information is relevant at all, the

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[9] 16 C.F.R. § 3.31(c)(1).

[10] *See, e.g., The Kroger Co.*, FTC Dkt. No. 9102, 1977 FTC LEXIS 55 at *4-5 (October 27, 1977) (denying discovery of the FTC's "prior proceedings, including formal proceedings, investigations, compliance proceedings, and proposed rulemaking proceedings" as beyond the scope of legitimate discovery and denying discovery of the FTC's pending investigations because of the absence of showing good cause); *Sterling Drug, Inc.*, FTC Dkt. No. 8919, 1976 FTC LEXIS 460 at *7-8 (March 17, 1976) (same).

[11] Indeed, antitrust law is filled with examples of cases where the illegal behavior was practiced by a majority of, or the entire, industry. *See e.g., Indiana Federation of Dentists*, 476 U.S. 447 (1986); *NCAA v. Board of Regents of the University of Oklahoma*, 468 U.S. 85 (1984); *American Medical Ass'n v. FTC*, 638 F.2d 443 (2d Cir 1980) *aff'd per curium by an equally divided court,* 455 U.S. 676 (1982); *National Society of Professional Engineers v. United States*,

Commission has held that "testimony concerning the ubiquity and value of challenged practices [can] be readily obtained from other industry members or experts."[12]

Andrx mistakenly argues that we have "conceded the relevance" of other settlement agreements by requesting from Andrx other such agreements to which it is a party. Unlike Andrx's all-encompassing interrogatory, however, our document request is carefully targeted to the parties in this case, and our request is clearly relevant to a number of issues in this litigation, including Andrx's intent and knowledge in entering such agreements, the terms Andrx typically includes in such agreements, and Andrx's alleged defenses for entering such agreements.

B. Numerous confidentiality provisions and privileges protect information from other nonpublic Commission investigations of settlement agreements

Aside from its irrelevancy, the existence of other nonpublic FTC investigations into such settlement agreements, as well as the FTC's privileged internal conclusions and analyses of these agreements, is shielded from discovery under statutory and regulatory confidentiality provisions,[13] the attorney-client and work product privileges, the investigatory files privilege (which protects against forced disclosure of information gleaned from investigatory files, that could reveal confidential investigative targets, deter witnesses from sharing necessary information for fear of being revealed, and prematurely reveal investigation results),[14] and the

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435 U.S. 679 (1978).

[12] *Chock Full O' Nuts*, 82 F.T.C. 747, 748 (March 2, 1973).

[13] *See, e.g.*, 15 U.S.C. § 57b-2(c) and 2(f). *See also* 16 C.F.R. § 4.10.

[14] *See, e.g., In re Sealed Case*, 856 F.2d 268, 271-72 (D.C. Cir. 1988); *Black v. Sheraton Corp. of America*, 564 F.2d 531, 545-46 (D.C. Cir 1977).

deliberative process privilege (which protects against the disclosure of information gleaned from discussions and materials used by the Commission to make its decision).[15]

Providing Andrx access to the information sought in interrogatories 5 and 6 would undermine the Commission's ongoing, non-public, law enforcement activities by deterring witnesses from sharing necessary information and would interfere with the Commission's decisionmaking process by requiring the premature disclosure of the Commission's views on investigations that are not yet complete. For these reasons, the Commission and the courts have long held that one must show a "substantial need" to gain access to information protected by these privileges, and even upon such a showing have limited discovery to factual information.[16] Andrx has made no such showing here, stating only that "the other agreements will demonstrate that . . . these deals are appropriate and, indeed, procompetitive."[17] Such conjecture, without more, does not entitle Andrx to gain access to confidential, non-public and privileged information.

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[15] *See, e.g., NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 150-51 (1975); *Nat'l Wildlife Fed'n v. Forest Service*, 861 F.2d 1114, 1118-19 (9th Cir. 1988). This privilege is predicated on the recognition "that the quality of administrative decision-making would be seriously undermined if agencies were forced to operate in a fishbowl." *Dow Jones & Co. v. Dept. of Justice* 917 F.2d 571, 573 (D.C. Cir. 1990).

[16] 16 C.F.R. § 3.31(c)(3). S*ee also Schering Corporation*, FTC Dkt. No. 9232, 1990 FTC Lexis 133, at *2 (May 10, 1990)(production of factual information ordered only upon showing 'a substantial need for the materials in preparation of its case').

[17] Andrx's Motion to Compel Interrog. at 2.

III. Andrx Is Not Entitled to Discovery Concerning the Commission's "Reason to Believe" and "Public Interest" Determinations

Andrx's Interrogatory No. 4 is the latest maneuver in a string of tactics designed to derail this litigation from its proper course -- to determine whether Andrx and Hoechst violated the law by entering into an agreement not to compete. Through this interrogatory, Andrx improperly seeks discovery concerning the Commission's "reason to believe" that respondents' agreement not to compete violates the antitrust laws and, consequently, that bringing this action is in the "public interest." In essence, this interrogatory seeks to require complaint counsel to get into the head of each Commissioner and extract their thoughts at the moment they cast their vote in favor of issuing the complaint. Putting aside all the practical impossibilities as well as legal prohibitions to obtaining such information (such as the FTC's rules prohibiting communications between complaint counsel and the Commissioners once a complaint issues),[18] Andrx simply is not entitled to this information. The Commission's pre-complaint deliberations are irrelevant to this proceeding and are privileged.

A. The Commission's reason to believe and public interest determinations are irrelevant to this proceeding

As briefed in detail in our various filings regarding complaint counsel's motion to strike, the information Andrx seeks is irrelevant to this proceeding and is not discoverable under the FTC's rules of practice.[19] Both the Commission and the Supreme Court have recognized that once the Commission issues a complaint, the basis for issuing the complaint is irrelevant:

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[18] 16 C.F.R. § 4.7(b)(1).

[19] 16 C.F.R § 3.31(c)(1) (limiting discovery to the extent it may be reasonably expected to yield relevant information)

> 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.*[20]

Accordingly, Andrx's motion to compel an answer to this interrogatory should be denied as irrelevant.

B. The Commission's reason to believe and public policy determinations are protected from disclosure by numerous privileges

The information Andrx seeks through Interrogatory No. 4 is also protected by the deliberative process and work product privileges. Courts have long recognized that shielding agency decision-making processes benefits society by fostering well reasoned agency policy.[21] As the District of Columbia Circuit Court observed in *Montrose Chemical Corp v. Train,* "if internal agency discussions and memoranda were publicized, the Government would be forced to 'operate in a fishbowl'. . . thus inevitably inhibiting frank discussion essential to the development of carefully formulated, coherent agency policy."[22]

While the deliberative process privilege is more often asserted in the context of protecting the disclosure of sensitive documents, FTC administrative law judges have recognized that

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[20] *FTC v. Standard Oil Co. of California*, 449 U.S. 232, 235 n.5 (1980) (quoting *Exxon Corp.*, 83 F.T.C. 1759, 1760 (1974) (emphasis added)).

[21] *See, e.g., Kaiser Aluminum & Chemical Corp. v. United States*, 157 F. Supp. 939, 946 (Ct. Cl. 1958); *Environmental Protection Agency v. Mink*, 410 U.S. 73, 87 (1973). *Cf. Chock Full O'Nuts Corp.*, 82 F.T.C. 747 (1973) (order quashing subpoena duces tecum).

[22] 491 F.2d 63, 66 (D.C. Cir 1974).

interrogatories seeking information concerning the Commission's deliberative process also is inappropriate.

> [I]nterrogatories may not seek information not relevant to the subject matter of the case, or privileged information (including the pre-complaint investigation information, information related to the Commissions's administrative determination to issue the complaint and informant's privilege) . . . in the absence of requisite showing of justification.[23]

Andrx's interrogatories target precisely this type of information -- pre-complaint information concerning the Commission's administrative determination to issue the complaint. And, while it is true that the deliberative process is a qualified privilege, Andrx has not articulated -- and certainly has not shown in its motion to compel interrogatories -- the "compelling circumstances" required to gain access to the Commission's deliberations.[24]

In its efforts to pierce the deliberative process privilege, Andrx has repeatedly contended that government misconduct was afoot in bringing this action. The government misconduct exception to the deliberative process privilege, however, only applies in those cases where the "deliberative process itself [is] directly at issue" in the lawsuit.[25] Here, the alleged misconduct

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[23] *TK-7 Corp.*, FTC Dkt. No. 9224, 1990 FTC LEXIS 20 at *1 (March 9, 1990) (order denying respondents motion to determine the sufficiency of complaint counsel's answers and objections to respondent's second set of interrogatories).

[24] *Chock Full O' Nuts*, 82 F.T.C. at 748 (order quashing subpoena duces tecum).

[25] *Dominion Cogen, D.C., Inc. v. District of Columbia*, 878 F. Supp. 258, 268 (D.D.C. 1995). *See also In re Sealed Case*, 121 F.3d 729 (D.C. Cir. 1997) (involving allegations of whether the former Secretary of Agriculture improperly accepted gifts from individuals and organizations with business before the USDA); *Alexander v. FBI*, 186 F.R.D. 154 (D.D.C. 1999) (involving allegations that the FBI violated plaintiffs' privacy interests by improperly turning over FBI files to the White House); *Bank of Dearbourne v. Saxon*, 244 F. Supp 394 (E.D. MI 1965) (where allegations that the defendant violated Michigan law and that the Comptroller knowingly acquiesced and implemented the alleged violation, the court noted "the charge of. . . sham and subterfuge, [was] the gravamen of the complaint").

the preparation of its case."[29] To date, however, Andrx has failed to articulate any basis for concluding that it has "substantial need" for the information it seeks, nor has it shown how that information will assist it in preparing its defense. Thus, Andrx's motion to compel this information should be denied.

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For all these reasons, Andrx's motion to compel interrogatories should be denied in all respects.

Respectfully Submitted,

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Dated: June 19, 2000

[29] 16 C.F.R. § 3.31(c)(3); *Schering Corporation*, FTC Dkt. No. 9232, 1990 FTC Lexis 133, at *2 (May 10, 1990).

CERTIFICATE OF SERVICE

I, Robin Moore, hereby certify that on June 19, 2000, I caused a copy of the Complaint Counsel's Opposition to Respondent Andrx's Motion to Compel Interrogatories to be served upon the following persons via facsimile and overnight delivery.

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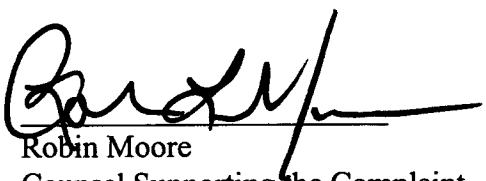

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