UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of

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

and

ANDRX CORPORATION, a corporation.

DOCKET NO. 9293

RESPONDENT ANDRX CORPORATION'S MEMORANDUM IN OPPOSITION TO UPSHER-SMITH'S MOTION TO QUASH THIRD-PARTY SUBPOENAE BY ANDRX CORPORATION AND IN OPPOSITION TO SCHERING-PLOUGH'S MOTION TO QUASH

Pursuant to § 3.22 of the Federal Trade Commission's Rules of Practice, Respondent Andrx Corporation ("Andrx") respectfully submits this memorandum in opposition to Upsher-Smith's Motion to Quash Subpoenae by Andrx Corporation (dated August 16, 2000) and Schering-Plough Corporation's Motion to Quash (dated August 24, 2000)[1].

Preliminary Statement

As this Court is aware, this proceeding is one that, from both Complaint Counsel's and Respondents' perspectives, falls squarely within the parameters of situations warranting a "rule of reason" analysis.[2] As such, evidence of the reasonableness of the Stipulation and Agreement at issue (the "HMR/Andrx Stipulation") should be assessed in the context of the norms and

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[1] Andrx technically served a subpoena on Key Pharmaceuticals, a division of Schering Corporation and, as respondents understand it, a counter-party to an agreement about which Andrx seeks information.

[2] See, generally, the FTC's Release by Richard G. Parker, Director Bureau of Competition, Federal Trade Commission, March 16, 2000; and, generally, Transcript of Initial Pretrial Conference, April 24, 2000, at pp. 11, 21, and 37.

practices in dealings between generic and brand pharmaceutical companies. As the United States Supreme Court stated in State Oil Co. v. Khan, 522 U.S. 3 (1997):

> most antitrust claims are analyzed under a "rule of reason," according to which the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect (emphasis added). Id. at 10.

To that end, respondents have sought to develop a meaningful factual record evidencing, in circumstances analogous or otherwise relevant here, dealings between other generic and brand pharmaceutical companies. In particular, Andrx has served subpoenae on movants Upsher and Schering, along with approximately nine other third parties, who respondents believe entered into agreements bearing similarity to the ancillary provisions of the HMR/Andrx Stipulation -- the very provisions that Complaint Counsel takes out of context and challenges, in this proceeding, as anti-competitive. The other agreements obtained from third parties will bear directly on a rule of reason analysis, and will ultimately show that the HMR/Andrx Agreement was, in fact, pro-competitive and the so-called "restraints" are the type of ancillary provisions generally understood in the industry as being appropriate.[3]

Other parties have agreed to produce responsive agreements, including, among others, Bayer Corporation and Abbott Laboratories. Indeed, this Court ruled that Complaint Counsel, at least at this point, did not need to

[3] The provisions in question are no more than "ancillary restraints" subject to a rule of reason analysis. E.g., United States v. Addyston Pipe & Steel Co., 85 F. 271 (6th Cir. 1898).

produce all other responsive agreements in its possession "since Andrx may discover such agreements" directly from third parties, such as Upsher and Schering. See Order on Respondent Andrx's Motion to Compel Complaint Counsel to Respond to Interrogatories (dated April 16, 2000) (at p.2). In fulfilling its meet and confer obligations, Andrx has sought to accommodate Upsher and Schering and narrowed the subpoenae, at least as an initial matter, to calling simply for the agreement(s) entered into by Upsher or Schering that contain provisions similar to the ancillary provisions at issue here, together with any related communications with the FTC. The suggestion that Andrx is pressing "six categories of documents" (Upsher Mem. at 2) is misleading since the subpoenae now have been limited to the actual agreement(s) and related FTC communications -- as movants concede (see Schering Mem. at 3).

In particular, we are aware of, and Upsher and Schering acknowledge, a specific agreement between those two companies involving the prescription pharmaceutical called K-Dur. Upsher, similar to Andrx here, was the first to file a paragraph IV ANDA preliminary to any introduction of a generic version of K-Dur, and was sued by the patent holder Key Pharmaceuticals (an affiliate of Schering). Upsher received FDA approval in November 1998. ESI Lederle was the second to file a paragraph IV ANDA, was sued by Key for patent infringement and, in May 1999, received tentative approval of its ANDA, to become final upon the expiration of Upsher's statutory exclusivity period. However, pursuant to settlement agreements, the terms of which have not been disclosed, Key dismissed its patent litigation against each of these companies.

Upsher thereafter still did not bring its ANDA product to market, and because the dismissal of the litigation was not a result that would trigger the commencement of Upsher's exclusivity period under 21 U.S.C. § 355(j)(5)(B)(iv)(II), the exclusivity period did not begin to run. It appears these settlement agreements potentially have had effects on the introduction of a generic product into the marketplace. Andrx has filed a paragraph IV ANDA for this product as well.

I.

Discovery is Broad under the FTC's Rules of Practice

Under the FTC's own Rules of Practice, Rule 3.31(c)(1), the scope of discovery is broad so as to allow for the development of a full factual record:

> Parties may obtain discovery to the extent that it may be reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defenses of any respondent. Such information may include the existence, description, nature, custody, condition and location of any books, documents, or other tangible things and the identity and location of persons having any knowledge of any discoverable matter. Information may not be withheld from discovery on grounds that the information will be inadmissible at the hearing if the information sought appears reasonably calculated to lead to the discovery of admissible evidence.

Likewise, under the Federal Rules of Civil Procedure, which routinely are referenced as guidance in FTC proceedings, "[t]he burden is on the party resisting discovery to clarify and explain precisely why its objections are proper." Obiajulu v. City of Rochester, 166 F.R.D. 293, 295 (W.D.N.Y. 1996). Thus,

> A party opposing a discovery request cannot make conclusory allegations that a request is irrelevant, immaterial, unduly burdensome or overly broad. Instead the party resisting discovery must show specifically how each discovery request is irrelevant, immaterial, unduly burdensome or overly broad. Id.

Not only do the FTC's Rules of Practice provide for broad, liberal interpretations of the relevancy of discovery requests, but the discovery Andrx seeks from Upsher and Schering is specific and tailored. What Andrx seeks is a particular agreement entered into by those companies, along with discrete communications, if any, with the FTC regarding the agreement. There is no conceivable issue of burden here. Beyond that, third parties such as Upsher and Schering do not have a legitimate ground to object to discovery on relevancy grounds. As one federal court noted in a case where the non-party FBI sought to quash a subpoena duces tecum:

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

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

Neither Upsher nor Schering can, or have, claimed that the documents Andrx seeks somehow are privileged or the production will create any undue burden -- because they seriously cannot make any such assertion. As for relevance, third parties such as Schering or Upsher do not have a proper basis to dispute the issue; nonetheless, the relevance to this proceeding of the K-Dur agreement is clear-cut.

II.

Under Any Objective Assessment, Evidence of Other Agreements and Discovery Pertaining to Industry Practice Is Appropriate and Highly Relevant to This Proceeding

There is no question that the K-Dur agreement and the related documents being sought from Upsher and Schering are relevant to this proceeding. In fact, this Court already recognized that respondents could obtain discovery from third parties concerning other agreements in its Order on Respondent Andrx's Motion to Compel Complaint Counsel to Respond to Interrogatories (dated August 18, 2000) (at p.2.):

> Andrx has not made the requisite showing at this stage of the litigation since Andrx may discover such agreements or information from sources other than from the FTC's confidential files (emphasis added). See Seeburg Bus Corp., 70 F.T.C. 1809, 1812-13 (Oct 25, 1966).

Thus, this Court expressly anticipated that the documents Andrx seeks, namely other agreements that may contain terms similar to the HMR/Andrx Stipulation at issue here, would be produced by third parties.[4] The Court's concern in its August 18 Order in not granting Andrx full access to those agreements within the FTC's files was specifically based upon governmental privileges that are not present with regard to Upsher, Schering or any private third parties. Indeed, respondents were denied access to other settlement agreements in the FTC staff's files because it was recognized that the agreements would be available from third parties, who would not be in a position to assert the kinds of privileges

[4] See also Order on Motions to Compel Discovery from Complaint Counsel filed by Andrx and by Aventis (dated August 18, 2000) (at p.6), which also recognized the discoverability of information about other settlements.

available to Complaint Counsel, and who could hardly assert that Andrx's narrowly tailored requests were in any way burdensome.

In the August 18 Order, this Court underscored the pertinence of other agreements by compelling Complaint Counsel to produce:

> other settlement agreements relating to patent litigation involving innovator and generic pharmaceutical companies of patent litigation that have come into the Commission's possession *only if* Complaint Counsel intends to rely on or refer to any such agreements in prosecuting its case *or if* any such agreements have been reviewed or relied upon by a testifying expert for Complaint Counsel.

Contrary to Upsher and Schering's self-serving arguments about relevance, Complaint Counsel itself has conceded the pertinence of information concerning other transactions. For example, Complaint Counsel has referred to agreements involving Abbott in its filings in this proceeding and produced, as part of its document production, two agreements between Abbott, Geneva Pharmaceuticals and Zenith Goldline. In the First Request for the Production of Documents and Things, Complaint Counsel requested that Andrx produce -- and the Court required it --"each settlement of any patent infringed action to which Andrx is or was a party" and "each licenses agreement and joint development agreement to which Andrx is or was a party. In addition, the FTC sought information about other agreements during the pre-Complaint investigation.

For Schering and Upsher to argue that the agreements have "no obvious relevance" (Schering Mem. at 1) reflects their obstructionist approach. The movants misstate the basis of the discovery, claiming it is designed to demonstrate that agreements similar to the HMR/Andrx Stipulation are "common"

and that Andrx was "arbitrarily singled out" (Schering Mem. at 2). While, in fact, the K-Dur agreement presumably will provide such evidence, the primary purpose of the discovery is not directed at the issue of selective enforcement. Rather, the more rudimentary purpose is to demonstrative that participants in other generic/brand deals have structured transactions containing so-called "ancillary restraints", which, when objectively reviewed, are ancillary provisions to agreements understood as actually enhancing generic competition.[5]

Here, the Court's August 18 Order expressly contemplates that the sources of the information being sought -- information that is crucial to this proceeding -- would be third parties such as Upsher and Schering.

III.

Neither Upsher Nor Schering Can Show Any Undue Burden

Andrx has identified the particular K-Dur agreement about which it seeks information. As discussed above, Andrx limited the scope of the discovery requests at issue to any responsive agreements themselves and communications with the FTC concerning the agreements. It simply is wrong for Schering to claim that Andrx seeks "a wide range of information relating to patent settlement agreements." Schering Mem. at 1. Upsher and Schering cannot claim that the narrowed requests being pressed are at all burdensome. Recognizing as much, Schering jumps to the scenario of the possibilities of "mini-trials" to determine if the other agreements are similar. However, there is no

[5] It obviously is not the role of Schering or Upsher to challenge the merits of the selective enforcement defense or prognosticate on the outcome. In any event, there is no stay of discovery pending Complaint Counsel's motion to strike and movants' assertions about the merits of this proceeding do not provide any basis for further delaying discovery.

genuine basis for forecasting the need for any further discovery -- let alone mini-trials or substantial additional discovery. The face of the agreements largely will speak for themselves. The claim that this discovery "no doubt" will result in "distracting collateral litigation" (Schering Mem. at 2) is not grounded in anything. Even assuming the need for any additional discovery, that possibility can be managed if and when the need for it arises. Thus, there is no genuine claim of undue burden that can be made by Upsher or Schering.

IV.

The Operative Protective Order Provides Fully Adequate Safeguards for Any Confidentiality Concerns

Upsher and Schering attempt to obscure the issue of producing the K-Dur agreement by claiming that it contains alleged trade secrets and, as purported competitors of Andrx, they somehow would be "damaged" by the production of the K-Dur Agreement. Upsher Mem. 9; Schering Mem at p. 7.[6] These vague, speculative concerns about trade secrets are insufficient to block discovery. There is no specific, concrete showing of any genuine prejudice, by affidavit or otherwise -- nor is there any basis whatsoever for such a showing. Other companies have agreed to produce settlement agreements responsive to the discovery requests at issue, finding that the confidentiality safeguards in place are satisfactory.

[6] Schering's counsel refers only to the May 8, 2000 Protective Order, and not to the Second Amended Protective Order dated August 7, 2000.

Movants' arguments about confidentiality are simply a red-herring: this Court has put in place a carefully structured Protective Order, which, in fact, has been modified twice to provide more than ample protections for any legitimate confidentiality concerns a third party possibly might have. As modified, the Protective Order includes a classification of documents subject solely to "Attorneys Eyes Only" review. Indeed, despite Andrx's own concerns that the scope of the amended protective order might be too restrictive, Andrx consented to its modification, specifically to provide additional safeguards to third parties, and to facilitate the discovery process in light of the extremely tight discovery schedule in this proceeding. That is why there is an "Attorneys Eyes Only" provision built into the second amended Protective Order, precisely to avoid the argument that trade secrets might be exposed to potential competitors.

Movants further contend that "nothing in the protective order here would prevent Schering's patent settlement agreements, as a result of having been turned over to Respondents, from being produced in other proceedings." Schering Mem. at 7. However, that speculation about potential discovery in some other case is not a basis for denying discovery here. In any event, the documents at issue will be subject to discovery in other matters -- and movants will retain the ability to object to such discovery -- regardless of whether or not the documents are produced in this proceeding. The relevance of the material to any other case can be addressed in the context of that case; however, the material will be potentially subject to discovery in another case even if not produced here.

V.

Upsher's Reference to the Michigan Decision Should be Disregarded

As a last-ditch effort to avoid their having to produce the K-Dur agreement, Upsher refers to a decision in the Multidistrict Litigation, in which Andrx and HMR are parties, pending in U.S. District Court for the Eastern District of Michigan. While that decision found the HMR/Andrx Stipulation to be a "per se" violation of the Sherman Act §1, Upsher Mem. at 6, it is a single decision taken out of context by movants here.[7] Not only is the Michigan court's decision neither binding nor controlling in this proceeding, but it is at this moment being challenged: the very district court judge who entered that opinion has now certified it for interlocutory appeal to the Sixth Circuit. Furthermore, Complaint Counsel has never agreed to treat this case solely on a "per se" basis and not seek to challenge it based upon a rule of reason analysis. Upsher and Schering, both third-parties to this proceeding, should not therefore dictate the terms under which discovery should proceed.

[7] Upsher-Smith conveniently ignores the decision of the U.S. District Court for the District of Columbia in Andrx v. Friedman, 83 F.Supp.2d 179, 185-86 (D.C. 2000), which determined that the HMR/Andrx Stipulation was not anticompetitive.

CONCLUSION

For the foregoing reasons, Andrx respectfully requests that the motions to quash the subpoenae directed at Upsher-Smith and Schering-Plough should be denied in all respects.

Dated: New York, New York
September 5, 2000

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Peter M. Todaro, hereby certify that on September 5, 2000, I caused to be served upon the following persons, by hand delivery, the following document: Respondent Andrx Corporation's Memorandum In Opposition To Upsher-Smith's Motion To Quash Third-Party Subpoenae By Andrx Corporation And In Opposition To Schering-Plough's Motion To Quash:

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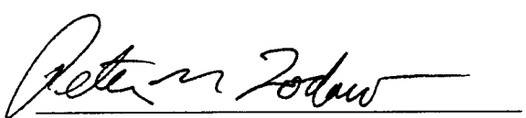

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