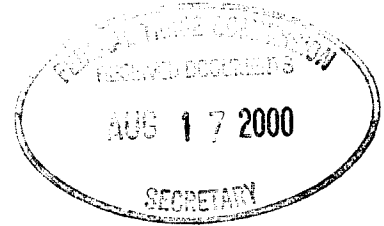


UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION



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In the Matter of )  
 )  
 )  
HOECHST MARION ROUSELL, INC., )  
a corporation, )  
 )  
CARDERM CAPITAL L.P., )  
a limited partnership, )  
 )  
and )  
 )  
ANDRX CORPORATION, )  
a corporation. )  
\_\_\_\_\_

Docket No. 9293

**UPSHER-SMITH'S MOTION TO QUASH THIRD-PARTY  
SUBPOENAE BY ANDRX CORPORATION**

Pursuant to Rule 3.34(c) of the Federal Trade Commission's Rules of Practice, non-party Upsher-Smith Laboratories, Inc. ("Upsher-Smith") hereby moves to quash subpoenae duces tecum and ad testificandum issued by Andrx Corporation to Upsher-Smith. The grounds for this motion are set forth in the enclosed Memorandum in Support of Motion to Quash and Affidavit of Mark S. Robbins.

Dated: 8/16/00

\_\_\_\_\_  
OPPENHEIMER WOLFF & DONNELLY LLP

Edward F. Fox                      Atty. Reg. No.: 3132X  
Gary Hansen                      Atty. Reg. No.: 40617  
Dawn Van Tassel                 Atty. Reg. No.: 297525

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*Attorneys for Upsher-Smith Laboratories, Inc.*

**UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION**

In the Matter of	)	
	)	
HOECHST MARION ROUSELL, INC.,	)	
a corporation,	)	
	)	
CARDERM CAPITAL L.P.,	)	
a limited partnership,	)	Docket No. 9293
	)	
and	)	
	)	
ANDRX CORPORATION,	)	
a corporation.	)	
	)	

**MEMORANDUM OF UPSHER-SMITH LABORATORIES, INC.,  
IN SUPPORT OF MOTION TO QUASH THIRD PARTY SUBPOENAE  
BY ANDRX CORPORATION**

**FACTS**<sup>1</sup>

Andrx Corporation (“Andrx”) is a party to this action by the Federal Trade Commission (“FTC”). The action relates solely to certain agreements entered into between Andrx and Hoechst Marion Rousell (“Hoechst”) related to Hoechst’s branded drug Cardizem CD and Andrx’s generic bioequivalent. Upsher-Smith Laboratories, Inc. (“Upsher-Smith”) is a small Minnesota-based pharmaceutical company in the business of developing and marketing generic bioequivalent versions of branded drugs. However, Upsher-Smith has not developed and is not developing a generic bioequivalent to Cardizem CD and has no knowledge or information related to the agreements between Andrx and Hoechst or to the development and marketing of Cardizem CD or its equivalents.

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<sup>1</sup> Unless otherwise noted, the facts set out in this Memorandum are supported by the Affidavit of Mark S. Robbins.

On the other hand, Upsher-Smith is a direct competitor of Andrx in the development and marketing of other generic drugs, including particularly a generic bioequivalent of a branded product known as K-Dur. K-Dur is a microencapsulated potassium supplement used to treat a condition known as hypokalemia, or potassium depletion, often caused by the use of diuretics. This product bears no relationship whatsoever to Cardizem CD, which is a widely prescribed drug for the treatment of hypertension (high blood pressure) and angina (coronary/chest pain). While information regarding K-Dur and the status of Upsher-Smith's efforts to develop a generic version of that product are entirely irrelevant to this proceeding, it is extremely sensitive information which could severely damage Upsher-Smith in the market place if it fell into the hands of a direct competitor such as Andrx. This information would be valuable and helpful to Andrx's own active efforts to develop and launch a generic version of K-Dur in direct competition with Upsher-Smith.

Andrx has served two third party subpoenas on Upsher-Smith seeking the production of documents and the designation of a company representative to testify regarding those documents at a deposition in New York City.

The subpoena seeks six categories of documents<sup>2</sup>:

**Request No. 1. Copies of all settlement agreements pertaining to patent litigation with a brand name pharmaceutical company.**

Upsher-Smith has entered into one such settlement agreement. However, that settlement agreement relates exclusively to Upsher-Smith's generic version of K-Dur, not to Cardizem CD, and is confidential by its terms. The settlement is the result of a patent infringement suit by Key Pharmaceutical, the innovator of its branded product, K-Dur. The production of the settlement

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<sup>2</sup> For purposes of brevity, the requests are paraphrased, not quoted verbatim. Copies of the subpoenas are Exhibits A and B to the Affidavit of Mark S. Robbins.

agreement would have no bearing on the Andrx's activities with respect to Cardizem; whereas, the contents of that document as it relates to Upsher-Smith's product and launch plans would be damaging to Upsher-Smith if it came into the possession of Andrx, a direct competitor in the development of another generic version of K-Dur.

**Request No. 2. All "operative agreements" involved in the settlement agreements identified in response to Request No. 1.**

This request is vague and ambiguous, and Upsher-Smith has no knowledge of what Andrx means by the undefined term, "operative agreements." Nevertheless, based on Upsher-Smith's interpretation of this request, the only pertinent document would be the settlement agreement with Key referenced in response to Request No. 1.

**Request No. 3. Licensing Agreements and Joint Development Agreements involving payments from a brand name pharmaceutical company or licensing or royalty arrangements with a brand name pharmaceutical company.**

This is an ambiguous and overbroad request which appears to be directed at wholly irrelevant commercial relationships unrelated to patent litigation or to indirectly eliciting the terms of any settlement agreements which might be responsive to Request No. 1.<sup>3</sup>

**Request No. 4. Documents relating to agreements between Upsher-Smith and Key Pharmaceuticals relating to K-Dur.**

This is a reference to documents related to the negotiation and performance of the confidential settlement agreement identified in response to Request No. 1. Again, the action the FTC has brought against Andrx relates to the generic version of Cardizem CD, not K-Dur, a

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<sup>3</sup> It is not surprising that the generalized language of the subpoenae are vague and overbroad since Upsher-Smith understands that Andrx has issued approximately 80 such subpoenae to other companies. Here, however, the subpoenae are aimed at capturing documents which are irrelevant to this proceeding but could be extremely helpful in allowing Andrx to position itself to successfully compete with Upsher-Smith in developing and launching Andrx's own generic version of K-Dur.

totally unrelated drug. Upsher-Smith has no information or documents related to a generic bioequivalent of Cardizem CD, and the release to Andrx of information related to the development and marketing of a generic version of K-Dur would be very damaging to Upsher-Smith while assisting Andrx's efforts to market a directly competitive product.

**Request No. 5. Any communications between Upsher-Smith and the FTC regarding the agreements referenced in Requests 1 through 4.**

Upsher-Smith has not had any communications with the FTC regarding Cardizem CD or the Andrx proceeding. If the FTC has requested or received information from Upsher-Smith in the context of K-Dur or any other investigation or action of the FTC, that investigation and any information provided by Upsher-Smith would be confidential as the subject of a non-public investigation. Indeed, Andrx has already posed this same request to the FTC, which the FTC has opposed on those grounds and others.<sup>4</sup>

**Request No. 6. Documents related to any decision not to market a pharmaceutical product in the context of actual or threatened patent litigation.**

This is yet another reference to the settlement of patent litigation involving Upsher-Smith's development of a generic version of K-Dur. The terms of the resolution of that matter are contained in the confidential settlement agreement with Key. Upsher-Smith has not been involved in any other patent litigation.

This is not Andrx's first attempt to obtain the information encompassed by these subpoenae. Its discovery demands on the FTC included a request encompassing all FTC files from January 1, 1993, forward, related to any "settlement or partial settlement of patent litigation."<sup>5</sup> Clearly, this request covered any communication between the FTC and Upsher-

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<sup>4</sup> Complaint Counsel's Opposition to Respondents' Motion to Compel, June 23, 2000 ("Complaint Counsel's Opposition"), pages 20-25.

<sup>5</sup> Complaint Counsel's Opposition, page 20.

Smith, if there was any such communication, relative to the confidential settlement of the patent litigation regarding Upsher-Smith's generic version of K-Dur. The FTC opposed Andrx's request on the grounds that the documents 1) were irrelevant to the proceeding against Andrx and 2) were protected by many privileges and statutory provisions.<sup>6</sup> That issue was the subject of an August 3, 2000, motion hearing and a decision is pending.<sup>7</sup>

The August 3, 2000, hearing also addressed the FTC's motion to strike certain defenses asserted by Andrx.<sup>8</sup> Among those defenses was a defense based on the theory of selective prosecution.<sup>9</sup> Apparently, Andrx hopes to avoid the FTC's enforcement action if it can establish that the FTC is proceeding against it on facts similar to situations where it has not proceeded against others. A decision is also pending on the FTC's motion to strike that defense.

Upsher-Smith has attempted to confer with counsel for Andrx as required by FTC Rule of Practice for Adjudicative Proceedings 3.22(f). Upsher-Smith suggested in that letter that the subpoenae be withdrawn until after a ruling is issued on Andrx's motion to compel discovery against the FTC and the FTC's motion to strike defenses, since those same issues are presented in this motion to quash the subpoenae served upon Upsher-Smith. Andrx's counsel has not yet responded to its request for a telephone conference, or to a subsequent voice mail message again requesting a telephone conference.

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<sup>6</sup> Id. at 20-25.

<sup>7</sup> Order setting hearings on Motions, July 14, 2000.

<sup>8</sup> Id.

<sup>9</sup> Answer of Andrx Corporation, ¶ 51.

## ARGUMENT

### **I. The Third Party Subpoenae Seek Documents Which are not Relevant to this Proceeding.**

The scope of discovery in a proceeding before the Commission is required by Rule 3.31(c)(1), to be “reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defense of any respondent.” Andrx has requested documents regarding settlements of patent litigation, licensing agreements and contracts Upsher-Smith may have entered into regarding its generic bioequivalent of the potassium chloride supplement, K-Dur. None of these requests can reasonably be expected to yield information relevant to Andrx’s conduct with regard to Cardizem CD, a completely distinct, unrelated drug. This action centers only on Andrx’s alleged violations of the Sherman Act in its handling of a patent infringement suit involving Cardizem CD. Upsher-Smith has no Cardizem CD generic bioequivalent and no plans to develop such a drug. Upsher-Smith has no documents or information in its possession in any way relevant to a dispute involving Cardizem CD.

Perhaps Andrx is attempting to gather support for a rule-of-reason defense based upon activities in the generic drug market in general. If so, its defense is misguided. The court in a parallel Michigan class action against Andrx has already found that Andrx’s agreement with Hoechst constitutes a per se violation of Sherman Act § 1. In re Cardizem CD Antitrust Litig., 2000 WL 867676 (E.D. Mich., June 6, 2000). Evidence regarding the generic drug market generally or Upsher-Smith’s unrelated products specifically is, therefore, wholly irrelevant and inadmissible. The Supreme Court has held that evidence of reasonableness is irrelevant to evaluating agreements which constitute a per se violation of Section 1 of the Sherman Act; leading other courts to quash third-party subpoenae seeking information to establish a rule-of-reason defense in Section 1 cases. See United States v. Socony-Vacuum Oil Co., 310 U.S. 150

(1940) (holding that violations of Sherman Act § 1 are illegal per se, and evidence of reasonableness is irrelevant); United States v. Serta Assocs., Inc., 29 F.R.D. 136, 137 (N.D. Ill. 1961) (“It is not too apparent at this time that the activities and manner of operation of [the third party] will have any bearing upon the determination of the issue of the guilt or innocence of the instant defendant.”).

Andrx’s fishing expedition may also pertain to its assertion of a selective enforcement defense,<sup>10</sup> a defense the Commission has deemed irrelevant and inapplicable in FTC proceedings. See Moog Indus., Inc. v. F.T.C., 355 U.S. 411, 413, 78 S.Ct. 377 (holding that the Commission may selectively enforce, absent an abuse of discretion). Andrx’s requests are apparently calculated to discover whether Upsher-Smith is similarly situated to Andrx: that is, whether Upsher-Smith has entered into a settlement agreement regarding patent litigation over a generic drug other than Cardizem CD. It is improper for Andrx to seek information from a third party to support an irrelevant defense. See Outdoor World Corp., 1989 FTC Lexis 142 at \*2 (refusing to grant discovery of Commission files of competitors because “[t]his demand is irrelevant. ... the Commission may proceed against one party without acting against others similarly situated”).

Andrx’s defense of selective enforcement is already subject to a motion to dismiss, on which the Commission heard oral argument on August 3, 2000. Andrx’s subpoenae should be quashed for the same reasons Complaint Counsel has already enumerated in its motion to strike defenses.<sup>11</sup>

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<sup>10</sup> Answer of Andrx Corporation, ¶ 51.

<sup>11</sup> Complaint Counsel’s Opposition, pages, 20-25.



## II. The Subpoenae Seek Discovery of Confidential Communications Between Upsher-Smith and FTC.

The record does not reflect that there have been any communications between Upsher-Smith and the FTC. However, if there had been, those communications would be strictly confidential. See 15 U.S.C. 46(f); 15 U.S.C. 57b-2(b); 16 C.F.R. § 4.10(d).

Andrx has already requested precisely this same information from to the FTC, and the FTC has objected to that request. The grounds of the FTC's objections are set forth in Complaint Counsel's Opposition to Andrx's motion to compel.<sup>12</sup> The Administrative Law Judge apparently heard oral argument on this issue on August 3, 2000, and a decision is pending. The arguments made by Complaint Counsel in those motions apply with equal force here. The subpoenae issued to Upsher-Smith are simply an improper ploy to pursue a sweeping, hypothetical search for information which the FTC has already declined to produce. Until the Administrative Law Judge rules on the pending motions, there is no basis to allow Andrx to burden Upsher-Smith with precisely the same requests which the FTC itself has already deemed improper.

Andrx seeks to discover whether the Commission is conducting an investigation completely unrelated to Cardizem CD and, if so, the contents of that investigation. Andrx cannot obtain confidential information about non-public investigations through the Commission. See 15 U.S.C. 46(f); 15 U.S.C. 57b-2(b); 16 C.F.R. § 4.10(d). In an attempt to circumvent the Commission rules, Andrx now wishes to get this information through the back door from Upsher-Smith. Andrx cannot do indirectly what it cannot do directly. See, e.g., *McSurely v. McClellan*, 426 F.2d 664 (U.S. App. D.C. 1970) (denying discovery in a civil case to obtain information to be used in a criminal case); *Beard v. New York Cent. R. Co.*, 20 F.R.D. 607, 610

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<sup>12</sup> Id.

(D.C. Ohio 1957) (holding that a party may not institute proceedings in federal court to obtain discovery it could not otherwise obtain in a parallel state action).

Whether Upsher-Smith entered into a settlement agreement and whether that settlement has come under the Commission's scrutiny is not only irrelevant, but undiscoverable. See The Kroger Co., 1977 FTC Lexis 55 at \*4-5 (October 27, 1977) (holding that prior FTC proceedings are not within the scope of a legitimate discovery request and denying discovery of pending investigations for lack of good cause). Moreover, discovering what documents, if any, Upsher-Smith may have provided to the Commission violates the deliberative process privilege of the Commission by revealing which topics it is investigating. See Carl Zeiss Stiftung v. V.E.B. Carl Zeiss, 40 F.R.D. 318, 323-24 (denying discovery of governmental communications because the "rule forecloses investigation into the methods by which a decision is reached, the matters considered, the contributing influences, or the role played by the influence of others."). Andrx should not be permitted to make an end-run around the protections of the Commission's confidentiality rules by gathering equivalent information from third parties, especially since this information has nothing to do with Cardizem CD and does not remotely bear on the issues in this proceeding.

**III. The Subpoenae Seek Highly Confidential Information, the Disclosure of Which would be Extremely Damaging to Upsher-Smith.**

Though the information sought by the subpoenae has nothing to do with Cardizem CD or the pending action, it has everything to do with obtaining confidential competitive intelligence. Andrx and Upsher-Smith are competitors with respect to a generic version of K-Dur. Upsher-Smith has received ANDA approval of both its 10mEq and 20mEq generic versions and believes it stands first in line to market its products for an exclusive 180-day period under the Hatch-

Waxman Act. Andrx has also filed for ANDA approval of its generic version of K-Dur, and approval is pending, with action expected in the near future.

Upsher-Smith would be gravely harmed if Andrx were to learn if and when Upsher-Smith intends to launch its generic version of K-Dur. This intelligence would provide Andrx with key information to posture its own marketing plans in a way that is most likely to minimize the advantage Upsher-Smith would otherwise have as a result of its market exclusivity rights.

The Second Amended Protective Order does not adequately protect Upsher-Smith. Though it purports to limit access to certain documents to outside counsel and experts and witnesses not employed in the industry, it anticipates disclosure to other experts and witnesses.<sup>13</sup> It anticipates that the documents may be used during the proceedings itself, without exclusion of Andrx witnesses, employees, and in-house counsel.<sup>14</sup> With trial of this matter set for December, 2000, this loophole is a very real threat to the confidentiality that is essential to Upsher-Smith. Even if the Protective Order was more tightly drafted, the risk of intentional or inadvertent disclosure is increased geometrically when sensitive trade secret and confidential information is released outside of Upsher-Smith to a direct competitor.

Being proactive with an expansive protective order is no justification for allowing otherwise unduly intrusive, irrelevant and impermissible discovery against unrelated third parties. A protective order is intended to preserve the confidentiality of otherwise pertinent information; not to allow the disclosure of irrelevant data or information otherwise shielded from discovery. If Andrx's subpoenae are enforced, the threshold tests of reasonableness and relevance will be tossed out the window in favor of an unlimited free-for-all to obtain virtually

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<sup>13</sup> Second Amended Protective Order, ¶¶ 2(b), 4.

<sup>14</sup> Second Amended Protective Order, ¶ 2(f).

any type of information from any source for any reason, all because a protective order will supposedly protect the confidential information from a release that could be devastating to Upsher-Smith. Without some reasonable showing of relevance and need, the mere existence of a broad protective order provides no basis to allow Andrx's subpoenae to be launched against scores of companies in the pharmaceutical industry.

To discover documents that disclose trade secrets or confidential information, the party moving for discovery must make a showing that the documents sought are relevant to the issues involved in the litigation and that the party has a specific need for those documents in preparing for trial. See Pioneer Hi-Breed Int'l Inc. v. Holden's Foundation Seeds, Inc., 105 F.R.D. 76, 82 (N.D. Ind. 1985); Guardian Life Ins. Co. of Amer. v. Service Corp. Int'l, 12 U.S.P.Q.2d 1128, 1989 WL 3496 at \*3 (E.D. Pa. Jan. 17, 1989) (recognizing that courts may curb discovery to prevent disclosure of trade secrets or confidential business information). Andrx has not come close to making that showing, particularly given the dubious relevance of its requests, as shown above.

The party seeking discovery has an even higher burden when it requests information from a third party. See Barrie v. Barrie, 457 A.2d 76, 82 (N.J. Super. 1983). "As to business records, courts have been most reluctant to force a nonparty competitor to divulge confidential information." Id. The Administrative Law Judge should weigh the need for the information against the harm that disclosure would cause to Upsher-Smith. See Pioneer Hi-Breed, 105 F.R.D. at 83. This balance weighs strongly against disclosure of highly confidential competitive information to a direct competitor, particularly when its claimed relevance is in conjunction with legally questionable defenses.

#### **IV. The Subpoenae May be an Attempt to Conduct Improper Pre-Litigation Discovery.**

Andrx's true motivation in serving subpoenae on Upsher-Smith may be to gather ammunition to support a lawsuit of its own to interfere with Upsher-Smith's launch of its generic version of K-Dur. "A court should deny a discovery request when its purpose is to gather information for use in proceedings other than the pending suit." Westmoreland v. CBS, Inc., 584 F. Supp. 1206, 1213 (D. D.C. 1984), rev'd on other grounds, 770 F.2d 1168 (U.S. App. D.C. 1985) (internal quotation marks omitted).

Because it was the first to file for ANDA approval of its generic bioequivalent to K-Dur, Upsher-Smith is entitled to enjoy a 180-day exclusivity period on the market. Andrx is seeking its own approval to market a generic bioequivalent to K-Dur. If Andrx could conceive an argument that would deprive Upsher-Smith of this 180-day exclusivity period or otherwise disrupt Upsher-Smith's marketing plans, it would be able to improve its own position in the market place. This would be very financially beneficial to Andrx and equally detrimental to Upsher-Smith. These are not idle concerns since Andrx has already made unsuccessful overtures to license Upsher-Smith's rights in its generic version of K-Dur and Andrx has also made direct inquiries about when Upsher-Smith intends to launch that product.

From the tenor of the document requests, it appears that Andrx may be more interested in obtaining information upon which to challenge or interfere with Upsher-Smith's product launch than in obtaining information relevant to this action. This would be an abuse of the discovery process. Discovery may not be used merely to circumvent limitations on discovery in another proceeding or, as in this case, to attempt to use discovery in one action to cobble together a theory of recovery in a yet unfiled lawsuit. See Wilk v. American Medical Ass'n, 635 F.2d 1295, 1300 (7<sup>th</sup> Cir. 1980). See also 6 Wright & Miller, Federal Practice and Procedure § 2040 at 528. ("The courts do not permit the discovery procedures in federal civil actions to be used merely as

a device to obtain evidence for use in some other proceeding in which discovery is less extensive.”). The Commission should prevent Andrx from abusing the discovery process in this manner.

**CONCLUSION**

The Andrx subpoenae directed to Upsher-Smith seek information that is irrelevant to this proceeding and openly request disclosure of what would constitute protected and confidential communications with the FTC in unrelated (and entirely hypothetical) investigative proceedings. They also seek discovery of highly sensitive and confidential information, the release of which could be extremely prejudicial to Upsher-Smith, particularly in the hands of a direct competitor like Andrx. Finally, they seek information that could potentially be used to create some market disturbance or concoct some kind of claim against Upsher-Smith in a future separate action having nothing whatsoever to do with this FTC proceeding. For all of these reasons, the Andrx subpoenae to Upsher-Smith should be quashed.

Respectfully Submitted,

Dated: 8/16/00

OPPENHEIMER WOLFF & DONNELLY LLP



Edward F. Fox                      Atty. Reg. No. 3132X  
Gary Hansen                      Atty. Reg. No.: 40617  
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*Attorneys for Upsher-Smith Laboratories, Inc.*

**UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION**

In the Matter of	)	
	)	
HOECHST MARION ROUSELL, INC.,	)	
a corporation,	)	
	)	
CARDERM CAPITAL L.P.,	)	
a limited partnership,	)	Docket No. 9293
	)	
and	)	
	)	
ANDRX CORPORATION,	)	
a corporation.	)	
	)	

**AFFIDAVIT OF MARK S. ROBBINS PhD.**

Mark S. Robbins, PhD., being first duly sworn upon oath, deposes and says as follows:

1. Affiant is Vice President of Scientific Affairs at Upsher-Smith Laboratories, Inc., (“Upsher-Smith”) and submits this Affidavit in support of Upsher-Smith’s motion to quash two subpoenae issued to it by Andrx Corporation (“Andrx”). Copies of the subpoenae are attached to this Affidavit as Exhibits A and B. Affiant holds a doctorate in pharmacology and is also an attorney licensed to practice law in Minnesota.

2. Affiant is generally aware of the issues in the above-captioned action, understanding them to involve the brand name drug Cardizem CD, marketed by Hoechst Marion Rousell, Inc. (“Hoechst”), a bioequivalent generic version of Cardizem CD, developed by Andrx, and an agreement between Hoechst and Andrx resolving issues relating to the marketing of that generic product while patent litigation was pending. Upsher-Smith has not developed and is not developing a bioequivalent generic version of Cardizem CD, and has no documents or



information relating to that drug, to the issues in the patent litigation between Hoechst and Andrx, to the agreement reached by Hoechst and Andrx, or to this action.

3. Affiant has reviewed the description of documents sought by Andrx's subpoenae and provides the following information in response. (The requests are paraphrased, not quoted verbatim).

**Request No. 1. Copies of all settlement agreements pertaining to patent litigation with a brand name pharmaceutical company.**

The only responsive document is a confidential settlement agreement entered into between Upsher-Smith and Key Pharmaceuticals, Inc., a subsidiary of Schering-Plough Corp. (collectively, "Key") to resolve patent litigation instituted by Key with respect to Upsher-Smith's bioequivalent generic version of K-Dur, a potassium chloride supplement. There is no relationship whatsoever between this drug and Cardizem CD, the drug involved in the FTC's action against Andrx and Hoechst.

**Request No. 2. All "operative agreements" involved in the settlement agreements identified in response to Request No. 1.**

This request is vague and ambiguous. Affiant has no knowledge of what Andrx means by "operative agreements," the undefined term. Nevertheless, upon information and belief, the only document responsive to this request is the settlement agreement referenced in response to Request No. 1.

**Request No. 3. Licensing Agreements and Joint Development Agreements involving payments from a brand name pharmaceutical company or licensing or royalty arrangements with a brand name pharmaceutical company.**

This request is vague and ambiguous and appears to be directed at entirely unrelated and irrelevant commercial relationships or at indirectly uncovering the potential terms of the types of settlement agreements sought by Request No. 1.

**Request No. 4. Documents relating to agreements between Upsher-Smith and Key Pharmaceuticals relating to K-Dur.**

The only potentially responsive documents are those related to the settlement agreement with Key, resolving the patent litigation over Upsher-Smith's bioequivalent generic version of K-Dur. Upsher-Smith has no such documents related in any way to Cardizem CD or to the issues in this action.

**Request No. 5. Any communications between Upsher-Smith and the FTC regarding the agreements referenced in Requests 1 through 4.**

Upsher-Smith has not had any communication with the FTC regarding Cardizem CD, this action, or the investigation that preceded this action. It is Affiant's understanding that the fact of whether Upsher-Smith has had communications with the FTC regarding any other investigation or action is strictly confidential under federal law. If Upsher-Smith communicated with the FTC in such circumstances, it would have been with the understanding that the communications were protected by these requirements of confidentiality and other protections extended to information provided in response to a non-public FTC investigation. It would have been Upsher-Smith's understanding that any such information would not be subject to disclosure pursuant to subpoenas such as those served by Andrx, particularly when the request is such that it necessarily compels disclosure of whether the FTC is engaged in a non-public, confidential investigation.

**Request No. 6. Documents related to any decision not to market a pharmaceutical product in the context of actual or threatened patent litigation.**

Again, the only potentially responsive documents are those related to the settlement agreement that resolved the patent litigation between Upsher-Smith and Key regarding Upsher-Smith's generic version of K-Dur. Upsher-Smith has no such documents related in any way to Cardizem CD or to the issues in the current action.

4. Key has marketed a 10 and 20 milliequivalent modified release potassium chloride tables under the brand name version of K-Dur. On November 20, 1998, Upsher-Smith received approval of its Abbreviated New Drug Application (“ANDA”) for a 20 milliequivalent modified release potassium chloride tablet, an “AB” rated version of K-Dur 20, a 20mEq tablet. On August 8, 2000, Upsher-Smith also received approval of its 10mEq modified release potassium chloride tablet “AB” rated to K-Dur 10, 10mEq tablet.

5. Andrx is a direct competitor of Upsher-Smith in the business of developing and marketing bioequivalent generic versions of brand name drugs. Andrx is also a likely direct competitor with respect to the development of a bioequivalent generic version of K-Dur, in both 10mEq and 20mEq dosages, because for approximately 12 months it has had a pending ANDA application for these products. Based on the average period of FDA consideration and the fact that other K-Dur generic equivalents have already been approved, the Andrx ANDA could be approved at any time, placing Andrx in imminent direct competition with Upsher-Smith.

6. The documents sought by Andrx’s subpoenae could provide Andrx with specific information about Upsher-Smith’s plans to launch and market its approved generic version of K-Dur including, in particular, the date(s) on which Upsher-Smith intends to enter the market with its product. Any such information is highly sensitive trade secret information that Upsher-Smith has held tightly within its own organization on an absolute need to know basis. If a competitor, particularly Andrx, obtained this information, it could anticipate Upsher-Smith’s marketing plans so as to be in a position to effectively thwart or otherwise compromise the effectiveness and success of Upsher-Smith’s product launch.

7. Upsher-Smith’s concerns are not academic or hypothetical. Andrx has made direct inquiries to Upsher-Smith about the status of Upsher-Smith’s modified release potassium

chloride products, including information as to when Upsher-Smith intends to launch its generic version of K-Dur.

8. Affiant has reviewed the recently approved Second Amended Protective Order that governs this action. Counsel for Andrx has represented in a letter to Upsher-Smith that this Order “removes any confidentiality reasons for not complying with the subpoena duces tecum.” Affiant disagrees. Upsher-Smith has been very careful to restrict the type of information sought by the subpoenae and described in this affidavit to those within the company and its agents and advisors on a strict need to know basis. The Second Amended Protective Order anticipates that the information will be shared with outside counsel for Andrx and the other parties and with expert witnesses and other witnesses not associated with a pharmaceutical company. Moreover, the Order contains a “due process savings clause” that contemplates that Andrx employees would be in attendance at a “trial of, or other proceedings in, this matter” at which documents could be offered and discussed, in spite of their designation under the Protective Order as “Restricted Confidential, Attorney Eyes Only.” Affiant understands that the trial of this matter is currently scheduled for December, 2000, which could pre-date Upsher-Smith’s launch and marketing plans for its generic version of K-Dur, which dramatically increases the likelihood of the release of Upsher-Smith’s trade secrets if the subpoenae are enforced.

9. Even if the Protective Order did not have those built in deficiencies, Affiant is very concerned about the possibility of some inadvertent or other disclosure in spite of the best efforts of outside counsel for Andrx, particularly since this action has apparently already involved the exchange of tens of thousands of documents and it may prove exceedingly difficult for counsel, experts, or other witnesses to recall where they learned certain facts and whether that information was defined by the Order as “Restricted Confidential, Attorney Eyes Only.” At any

rate, an agreement to maintain confidentiality is no justification for allowing the disclosure of the irrelevant, highly confidential information of a direct competitor that is not a party to this proceeding nor is it a basis to pierce the status of a potential non-public FTC investigation, the confidentiality of which is strictly protected by federal law.

Further Affiant Sayeth Not.

Dated: August 16, 2000

Mark S. Robbins  
Mark S. Robbins, PhD.

Signed and Sworn to Before Me  
this 16 day of August, 2000.

Terril L. Johnson  
Notary Public





# SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO  
 Upsher-Smith Laboratories, Inc.  
 By one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf concerning the subject matter of this action and/or of the subject matter of the documents described in Exhibit A.  
 14905 23<sup>rd</sup> Ave. N.  
 Plymouth, MN 55447

2. FROM  
  
**UNITED STATES OF AMERICA  
 FEDERAL TRADE COMMISSION**

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION  
 SOLOMON, ZAUDERER, ELLENHORN,  
 FRISCHER & SHARP  
 45 Rockefeller Plaza  
 New York, NY 10111  
 or at such other location as is mutually agreed upon.

4. MATERIAL WILL BE PRODUCED TO Notary Public  
 (at the request of Respondent  
 Andrx Corporation)

5. DATE AND TIME OF PRODUCTION OR INSPECTION  
  
**Aug. 30, 2000 at 10:30 a.m.**

6. SUBJECT OF PROCEEDING  
  
 In the matter of Hoechst Marion Roussel, Inc., et al.

7. MATERIAL TO BE PRODUCED  
  
**See Exhibit A**

8. ADMINISTRATIVE LAW JUDGE  
  
 The Honorable D. Michael Chappell  
  
 Federal Trade Commission  
 Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA  
  
 SOLOMON, ZAUDERER, ELLENHORN,  
 FRISCHER & SHARP  
 45 Rockefeller Plaza, 7<sup>th</sup> Floor  
 New York, NY 10111  
  
 Attorneys for Respondent Andrx Corporation

DATE ISSUED  
  
**30 JUN 2000**

SECRETARY'S SIGNATURE

### GENERAL INSTRUCTIONS

#### APPEARANCE

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

#### MOTION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any motion to limit or quash this subpoena be filed within the earlier of 10 days after service or the time for compliance. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission, accompanied by an affidavit of service of the document upon counsel listed in Item 9, and upon all other parties prescribed by the Rules of Practice.

#### TRAVEL EXPENSES

The Commission's Rules of Practice require that fees and mileage be paid by the party that requested your appearance. You should present your claim to counsel listed in Item 9 for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from counsel listed in Item 9.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

**EXHIBIT A**

1. All documents sufficient to identify each settlement or partial settlement of patent litigation, concerning which your Company is aware, involving an innovator or brand name pharmaceutical company, and a generic company, that involved any form of:

- (a) payment from the brand name company to the generic company; or
- (b) licensing and/or royalty arrangement between the brand name company and the generic company.

2. All operative agreements involved in the settlements or partial settlements referenced in Request No. 1 above, together with any analyses of any such agreements.

3. Copies of all Licensing Agreements and Joint Development Agreements to which your Company is or was a party, that involved any form of:

- (a) payment from the brand name company to the generic company; or
- (b) licensing and/or royalty arrangement between the brand name company and the generic company.

4. All documents relating to any agreements or contracts between you and Key Pharmaceuticals concerning or relating to K-Dur.

5. All communications and documents which relate to communications between the Company and the FTC concerning any of the agreements referenced in Requests Nos. 1-4 above.

6. Documents concerning any decision, by your Company or any other, to market or not market a pharmaceutical product in the context of an actual or threatened patent litigation with respect to that product.



## DEFINITIONS AND INSTRUCTIONS

1. Unless otherwise stated, the requests herein refer to the time period of January 1, 1992 through present.
2. As used herein, the words "you" or "your," "your Company," or "the Company" shall mean the individual and/or entity to whom this subpoena was directed, and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of your 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.
3. As used herein, the terms "document" or "documents" or "documentation" include these terms as defined by 16 C.F.R. § 3.34(b) and, in addition, the original or drafts or any kind of written, printed, recorded or graphic matter or sound reproduction, however produced or reproduced, whether sent or received or neither, and all copies thereof which are different in any way from the original (whether by notation, indication of copies sent or received or otherwise) regardless of whether designated "Confidential," "Privileged" or otherwise and including, but not limited to, any correspondence, paper, book, account, drawing, agreement, contract, e-mail, handwritten notes, invoice, memorandum, telegram, object, opinion, purchase order, report, records, transcript, summary, study, survey recording of any telephone or other conversation, interviews or notes of any conference. The terms "document" or "documents" shall also include data stored, maintained or organized electronically or magnetically or through computer equipment, translated, if necessary, by you into reasonably usable form, and film impressions, magnetic tape and sound or mechanical productions of any kind or nature whatsoever.

4. Except for privileged materials, produce each responsive document in its entirety by including all attachments and all pages, regardless of whether they directly relate to the specified subject matter. Submit any appendix, table, or other attachment by either physically attaching it to the responsive document or clearly marking it to indicate the responsive document to which it corresponds. Except for privileged material, do not mask, cut, expunge, edit, or delete any responsive document or portion thereof in any manner.

5. As used herein, the connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope.

6. The response to each document production request is to be numbered in a manner consistent with these requests and is to be preceded by the specific request.

7. If any form of privilege or immunity is claimed as a ground for withholding a response, submit a written statement that describes the factual basis of the purported privilege or claim of immunity in sufficient detail to permit the court to adjudicate the validity of the claim.



# SUBPOENA AD TESTIFICANDUM

## Issued Pursuant to Rule 3.34(d)(1), 16 C.F.R. § 3.34(d)(1) (1997)

<p>1. TO</p> <p><b>Upsher-Smith Laboratories, Inc.</b>          By one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf concerning the subject matter of this action and/or of the subject matter of the documents described in Exhibit A.          14905 23<sup>rd</sup> Ave. N.          Plymouth, MN 55447</p>	<p>2. FROM</p> <p><b>UNITED STATES OF AMERICA          FEDERAL TRADE COMMISSION</b></p>
---	---

This subpoena requires you to appear and give testimony, at the date and time specified in Item 5, at the request of Counsel listed in Item 8, in the proceeding described in Item 6.

<p>3. PLACE OF HEARING</p> <p><b>SOLOMON, ZAUDERER, ELLENHORN,          FRISCHER &amp; SHARP</b>          45 Rockefeller Plaza          New York, NY 10111          or at such other location as is mutually agreed upon.</p>	<p>4. YOUR APPEARANCE WILL BE BEFORE</p> <p>Notary Public          (at the request of Respondent          Andrx Corporation)</p> <hr/> <p>5. DATE AND TIME OF HEARING OR DEPOSITION</p> <p><b>Aug. 30, 2000 at 10:30 a.m.</b></p>
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6. SUBJECT OF PROCEEDING

In the matter of Hoechst Marion Roussel, Inc., et al.

<p>7. ADMINISTRATIVE LAW JUDGE</p> <p>The Honorable D. Michael Chappell</p> <p>Federal Trade Commission          Washington, D.C. 20580</p>	<p>8. COUNSEL REQUESTING SUBPOENA</p> <p><b>SOLOMON, ZAUDERER, ELLENHORN,          FRISCHER &amp; SHARP</b>          45 Rockefeller Plaza, 7<sup>th</sup> Floor          New York, NY 10111</p> <p>Attorneys for Respondent Andrx Corporation</p>
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<p>DATE ISSUED</p> <p><b>26 JUN 2000</b></p>	<p>SECRETARY'S SIGNATURE</p> <p><i>Donald L. Clark</i></p>
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### GENERAL INSTRUCTIONS

#### APPEARANCE

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

#### MOTION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any motion to limit or quash this subpoena be filed within the earlier of 10 days after service or the time for compliance. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission, accompanied by an affidavit of service of the document upon counsel listed in Item 8, and upon all other parties prescribed by the Rules of Practice.

#### TRAVEL EXPENSES

The Commission's Rules of Practice require that fees and mileage be paid by the party that requested your appearance. You should present your claim to Counsel listed in Item 8 for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from Counsel listed in Item 8.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

**UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION**

In the Matter of	)	
	)	
HOECHST MARION ROUSELL, INC.,	)	
a corporation,	)	
	)	
CARDERM CAPITAL L.P.,	)	
a limited partnership,	)	Docket No. 9293
	)	
and	)	
	)	
ANDRX CORPORATION,	)	
a corporation.	)	
	)	

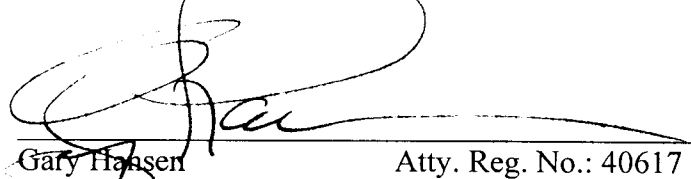
**STATEMENT PURSUANT TO RULE 3.22(f)**

I am an attorney with Oppenheimer, Wolff & Donnelly LLP, counsel for Upsher-Smith Laboratories, Inc., (“Upsher-Smith”) and submit this statement pursuant to Rule 3.22(f) of the Federal Trade Commission’s Rules of Practice in connection with the motion of non-party Upsher-Smith to quash subpoenae served upon it by Andrx Corporation (“Andrx”). On August 15, 2000, I wrote a letter setting forth concerns about the subpoenae to Hal Shaftel of Solomon, Zauderer, Ellenhorn, Frischer, & Sharp, counsel for Andrx, in a good faith effort to resolve by agreement the issues raised by Upsher-Smith’s motion. Among other things, the letter suggested that the subpoenae be withdrawn until such time as the Administrative Law Judge in this matter has ruled on related motions argued on August 3, 2000, and pertaining to the relevance of the documents sought by the subpoenae. I asked Mr. Shaftel to call me regarding the issues in the letter, but as of this time he has not. On August 16, 2000, I called Mr. Shaftel and was told he was in the office but unavailable. I left a voice mail message asking him to call me regarding Upsher-Smith’s concerns. As of this time, he has not returned my call. Because the deadline for

filing a motion to quash is extremely short, and in light of these efforts to communicate with counsel for Andrx, Upsher-Smith is filing its motion without having spoken to Andrx's counsel.

Dated: August 16, 2000

OPPENHEIMER WOLFF & DONNELLY LLP



Gary Hansen Atty. Reg. No.: 40617

Plaza VII Building, Suite 3300  
45 South Seventh Street  
Minneapolis, Minnesota 55402-1609  
Telephone: (612) 607-7000  
Facsimile: (612) 607-7100

*Attorneys for Upsher-Smith Laboratories, Inc.*

UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION

\_\_\_\_\_  
In the Matter of )  
 )  
HOECHST MARION ROUSELL, INC., )  
a corporation, )  
 )  
CARDERM CAPITAL L.P., )  
a limited partnership, )  
 )  
and )  
 )  
ANDRX CORPORATION, )  
a corporation. )  
\_\_\_\_\_ )

Docket No. 9293

**ORDER GRANTING UPSHER-SMITH'S MOTION  
TO QUASH THIRD PARTY SUBPOENAE  
BY ANDRX CORPORATION**

IT IS HEREBY ORDERED that Upsher-Smith's Motion to Quash Third Party Subpoenae by Andrx Corporation is hereby GRANTED, and those subpoenae are hereby quashed.

\_\_\_\_\_  
D. Michael Chappell  
Administrative Law Judge

Date: \_\_\_\_\_, 2000

**CERTIFICATE OF SERVICE**

I, Gary Hansen, hereby certify that on August 16, 2000, I caused a copy of Upsher-Smith Laboratories, Inc.'s, Motion to Quash Third Party Subpoenae by Andrx, and supporting papers, to be served upon the following persons via Federal Express:

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

Markus M. Meier  
Federal Trade Commission, Room 3114  
601 Pennsylvania Avenue NW  
Washington, D.C. 20580

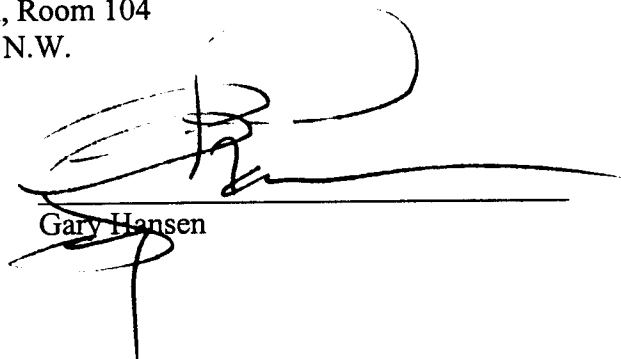
James M. Spears  
Shook, Hardy & Bacon LLP  
701 Pennsylvania Avenue NW  
Washington, D.C. 20004

Peter O. Safir  
Kleinfeld, Kaplan & Becker  
1140 19<sup>th</sup> Street NW  
Washington, D.C. 20036

and a copy sent Federal Express to:

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

Dated: August 16, 2000



Gary Hansen

Subscribed and Sworn to Before  
Me this 16<sup>th</sup> day of August, 2000.

  
NOTARY PUBLIC

