

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION



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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

**ORDER ON SCHERING-PLOUGH'S MOTION TO QUASH
AND UPSHER-SMITH'S MOTION TO QUASH**

I.

Respondent Andrx Corporation ("Andrx"), served third party subpoenas *duces tecum* and *ad testificandum* on Upsher-Smith Laboratories, Inc. ("Upsher") and on Schering-Plough Corporation ("Schering") seeking the production of documents and the designation of a company representative to testify regarding those documents. On August 16, 2000, Upsher filed a motion to quash the subpoenas served on it by Andrx. On August 24, 2000, Schering filed a motion to quash the subpoenas served on it by Andrx. Andrx responded to the motions filed by Upsher and Schering ("the Companies") in one opposition, filed on September 5, 2000 ("Andrx Opposition").

On September 6, 2000, Upsher filed a request for oral argument on its motion to quash. On September 26, 2000, Schering filed a request for oral argument on its motion to quash. Upsher's and Schering's requests for oral argument are DENIED.

II.

Although the subpoenas initially called for six broad categories, Andrx has stated that it is willing to accept the following two categories: (1) agreements entered into by the Companies

“that contain provisions similar to the ancillary provisions at issue here”; and (2) “any related communications with the FTC.” Andrx Opposition at 3. The movants argue generally (1) that the information sought by the subpoenas is irrelevant to the issues raised in this proceeding; (2) that the information sought is confidential and that no adequate showing of need has been made; and (3) that the protective order does not adequately safeguard their confidential information. For the reasons set forth below, the motions to quash are GRANTED in part and DENIED in part.

III.

Discovery sought in a proceeding before the Commission must be “reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defense of any respondent.” 16 C.F.R. § 3.31(c)(1). *Federal Trade Commission v. Anderson*, 631 F.2d 741,745 (D.C. Cir. 1979). Discovery may be limited if the burden and expense of the proposed discovery outweigh its likely benefit. 16 C.F.R. § 3.31(c)(1)(iii). Pursuant to Rule 3.31(d)(1), the Administrative Law Judge may deny discovery or make any order which justice requires to protect a party or other person from annoyance, embarrassment, oppression, or undue burden or expense. 16 C.F.R. § 3.31(d)(1). Thus, if the documents sought by Andrx are relevant to the subject matter of this action, the subpoenas should be enforced unless the documents are privileged or the subpoenas are unreasonable, oppressive, annoying, or embarrassing.

The Complaint asserts that Hoechst Marion Roussel, Inc. (“Hoechst MRI”) manufactures and sells Cardizem CD and that Andrx developed a generic or bioequivalent version of Cardizem CD. Complaint ¶¶ 1, 5. The Complaint asserts that Hoechst MRI and Carderm Capital L.P. filed a lawsuit against Andrx alleging infringement of a Cardizem CD patent. Complaint ¶ 18. The Complaint further asserts that Respondents entered into a Stipulation and Agreement on September 24, 1997 (“Stipulation”) through which Respondents agreed that Andrx would not enter the market with the generic version of Cardizem CD until other conditions were met. Complaint ¶ 23. The Complaint also alleges that the Stipulation had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition and consumers by preventing or discouraging the entry of competition in the form of generic versions of Cardizem CD into the relevant market. Complaint ¶ 29.

To rebut the charge that the Stipulation is anticompetitive, Andrx seeks to show 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.” Andrx Opposition at 8; Answer of Andrx ¶ 12. In the Order on Complaint Counsel’s Motion to Strike, entered September 14, 2000, a portion of Andrx’s Twelfth Defense, that the FTC acted unlawfully and arbitrarily in singling out Andrx for prosecution, was stricken. Andrx’s other assertions in its Twelfth Defense, that other companies in the industry have entered into agreements with similar restraints, remain. If other brand-name pharmaceutical manufacturers have entered into agreements with generic

pharmaceutical manufacturers that are similar to the challenged Stipulation, such agreements are relevant to Andrx's defense. However, Andrx's defense that the FTC acted arbitrarily in selecting Andrx for prosecution has been stricken as legally immaterial. Accordingly, evidence of communications between other pharmaceutical manufacturers and the FTC regarding their own agreements is not relevant. *See In re Kroger Co.*, 1977 FTC LEXIS 55, *4-5 (Oct. 27, 1977).

Schering is a manufacturer of brand-name drugs. Upsher is a manufacturer of generic bioequivalent versions of branded drugs and is a competitor of Andrx. Information in the files of competing companies is frequently crucial in proceedings such as this one. *See Service Liquor Distributors, Inc. v. Calvert Distillers Corp.*, 16 F.R.D. 507, 509 (S.D.N.Y. 1954) (“[I]n an action under the antitrust laws, based upon an alleged abuse of competition, a competitor’s business records, where good cause has been shown, are not only not immune from inquiry, but they are precisely the source of the most relevant evidence.”). *Accord United States v. Lever Bros. Co.*, 193 F. Supp. 254, 257 (S.D.N.Y. 1961).

Andrx asserts that - using a rule of reason analysis - the reasonableness of the Stipulation should be assessed in the context of the norms and practices in dealings between generic and brand-name pharmaceutical companies. Andrx Opposition at 1-2. Upsher insists that other companies’ agreements are not relevant, especially to the analysis of a *per se* violation, and that because the District Court for the Eastern District of Michigan found that the Stipulation constitutes a *per se* violation of Sherman Act § 1, other agreements are not relevant in this proceeding. Complaint Counsel, in its Statement of the Case filed September 13, 2000, has stated explicitly that it intends to prove not only that the Stipulation is illegal *per se*, but also that the Stipulation constitutes an unreasonable restraint of trade under the rule of reason. Complaint Counsel’s Statement of the Case at 9. In light of this representation, any responsive agreements are relevant to the allegations of the complaint or defenses of the respondents if they are relevant to a rule of reason analysis.

Under a rule of reason analysis, to determine whether a restraint suppresses competition, “the court must ordinarily consider the facts peculiar to the business to which the restraint is applied. . . .” *Chicago Board of Trade v. United States*, 246 U.S. 231, 244 (1918) (holding that the district court erred in striking from the answer allegations concerning the history and purpose of the challenged rule and in excluding evidence on that subject). *See also National Soc’y of Prof’l Engrs. v. United States*, 435 U.S. 679, 692 (1978) (competitive effects “can only be evaluated by analyzing the facts peculiar to the business, the history of the restraint, and the reasons why it was imposed”); *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997). Discovery is often “necessary to make a determination as to the reasonableness of the defendants’ activities under the more lenient, but more fact intensive Rule of Reason.” *CSR Ltd. v. Federal Insurance Co.*, 40 F. Supp. 2d 559, 565 (D.N.J. 1998). *See also Canterbury Liquors & Pantry v. Sullivan, et al.*, 16 F. Supp. 2d 41, 46 (D. Mass. 1998) (“If the plaintiffs do not prevail on their claims of a *per se* violation, discovery and further litigation will be necessary with regard to their rule of reason claim.”).

In *United States v. Serta Assocs., Inc.*, 29 F.R.D. 136 (N.D. Ill. 1961), on which Upsher relies, the defendant sought to prove the “reasonableness” of its conduct by demonstrating similar activities undertaken by its competitor. Though the court quashed the subpoena on the grounds that the activities of the competitor did not appear to be relevant, it did so relying on the government’s assertions that the complaint’s charges were of *per se* violations. *Id.* at 138. By contrast, in the instant case, the government has expressly stated it intends to prove the Stipulation is illegal under the rule of reason. Accordingly, Andrx is entitled to discovery relevant to the “reasonableness” of its conduct.

At this stage of the proceeding, it is not necessary to determine which mode of analysis will ultimately be employed in evaluating Respondents’ activities. *See CSR Ltd.*, 40 F. Supp. 2d at 565. Further, holding that the material sought by the subpoenas is relevant to the issues of the case does not indicate that any evidence so produced will be admissible at the trial or, if admissible, what its effect will be.

IV.

Having determined that agreements entered into between brand-name pharmaceutical manufacturers and generic pharmaceutical manufacturers in settlement of patent disputes involving brand-name drugs are relevant, it follows that they must be produced unless the documents are privileged, or enforcement of the subpoena would be unreasonable, oppressive, annoying or embarrassing. Although claims of confidentiality have been asserted, no claim of privilege has been asserted for any responsive agreements and no absolute privilege protects any such agreements from disclosure in discovery proceedings.

The Companies vigorously contend that the documents are highly confidential and extremely sensitive and that the disclosure of this information to Andrx will result in irreparable injury. Upsher asserts that the party seeking to discover documents that disclose trade secrets or confidential information, must make a showing not only that the documents are relevant, but also that the party has a specific need for those documents in preparing for trial. Upsher Brief at 11 *citing Pioneer Hi-Bred Int’l Inc. v. Holden’s Found. Seeds, Inc.*, 105 F.R.D. 76, 82 (N.D. Ind. 1985); *Guardian Life Ins. Co. v. Service Corp. Int’l*, 1989 WL 3496 (E.D. Pa. Jan. 17, 1989). Andrx has demonstrated such need.

The Commission’s Rules of Practice do not specifically protect trade secrets or confidential information from discovery. Section 6(f) of the Federal Trade Commission Act and Section 21(d)(2) of the Improvements Act (codified at 15 U.S.C. § 46(f) and 15 U.S.C. § 57b-2(b), respectively) limit the Commission’s ability to disclose confidential information to the public. They do not limit a litigant’s ability to obtain confidential information through discovery. *In re E.I. DuPont de Nemours & Co.*, 97 F.T.C. 116, 116 (Jan. 21, 1981) (These provisions do “not absolutely bar disclosure of business data as evidence in [FTC] adjudicatory proceedings.”).

Courts interpreting discovery sought under the Federal Rules of Civil Procedure have held that there is no immunity protecting the disclosure of trade secrets. *Federal Trade Commission v. J.E. Lonning*, 539 F.2d 202, 209-210 (D.C. Cir. 1976); *LeBaron v. Rohm and Hass Co.*, 441 F.2d 575, 577 (9th Cir. 1971) (“The fact that discovery might result in the disclosure of sensitive competitive information is not a basis for denying such discovery.”). *See also Federal Trade Commission v. Rockefeller, et al.*, 441 F. Supp. 234, 242 (S.D.N.Y. 1977), *aff’d* 591 F.2d 182 (2d Cir. 1979) (An objection to a subpoena on grounds that it seeks confidential information “poses no obstacle to enforcement.”). Although the Companies assert that the terms upon which they have settled patent disputes is extremely sensitive information which they would never voluntarily disclose outside the company, the burden on the Companies of production does not outweigh Andrx’s need for the documents. “Inconvenience to third parties may be outweighed by the public interest in seeking the truth in every litigated case.” *Covey Oil Co. v. Continental Oil Co.*, 340 F.2d 993, 999 (10th Cir. 1965) (denying motion to quash subpoenas served on competitors). In light of the limitations set forth below, enforcement of the subpoenas would not be unreasonable or oppressive.

V.

Pursuant to 16 C.F.R. § 3.31(d)(1), a protective order was entered in this case. That order has already been amended several times to further protect the interests of third parties. The provisions of the Second Amended Protective Order, entered August 7, 2000, adequately safeguard the confidential documents of third parties. However, due to the extremely sensitive nature of these documents, the Companies may negotiate with the parties to submit a request for limited modification to the Second Amended Protective Order. Further, the Companies may file applications for *in camera* treatment to prevent disclosure to the public of their confidential materials. Requirements and guidelines for filing applications for *in camera* treatment have been set forth in this case in the Order on Applications for *In Camera* Treatment and Modifying Scheduling Order, entered on September 19, 2000.

VI.


For the reasons set forth above, the Companies’ motions to quash the subpoenas are DENIED with respect to their own agreements that are between brand-name pharmaceutical manufacturers and generic pharmaceutical manufacturers in settlement of patent disputes involving brand-name drugs. The Companies are hereby ORDERED to produce any such agreements. However, the Companies or other third parties producing such agreements may redact proprietary information including, but not limited to, the following: trade secrets, formularies, and cost and profit data.

In the alternative to producing redacted agreements, the Companies may negotiate with Andrx and Complaint Counsel to formulate stipulations that sufficiently describe any such agreements entered into by the Companies.

In all other respects, the motions to quash of Upsher and Schering are GRANTED.

The Companies shall comply with this order within seven business days.

ORDERED:



D. Michael Chappell
Administrative Law Judge

Date: October 4, 2000