## UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION



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# ORDER ON AETNA'S MOTION FOR A PROTECTIVE ORDER AND AVENTIS' MOTION TO ENFORCE SUBPOENA SERVED ON AETNA

I.

Respondent Aventis Pharmaceuticals, Inc. ("Aventis"), formerly known as Hoechst Marion Roussel, Inc., served a third party subpoena on Aetna U.S. Healthcare, Inc. ("Aetna"). This subpoena ("Aetna subpoena") is the subject of two pending motions.

The first motion is Aventis' Motion to Enforce Compliance With The Subpoena Served on Aetna, filed on September 20, 2000 ("Aventis' Motion to Enforce"). Aetna responded by filing its Opposition to Aventis' Motion to Enforce Compliance ("Opposition to Motion to Enforce") on September 28, 2000. Aventis filed a motion for leave to respond to Aetna's Opposition and its Reply to Aetna's Memorandum in Opposition to Aventis' Motion to Enforce ("Reply in Support of Motion to Enforce") on October 5, 2000.

Aventis' motion for leave to respond is GRANTED. As set forth below, Aventis' Motion to Enforce is DENIED WITHOUT PREJUDICE.

The second motion regarding the Aetna Subpoena is Aetna's Motion for a Protective Order ("Motion for Protective Order"), filed on September 25, 2000. Aventis did not respond to the Motion for Protective Order. Instead, Aventis asserted in its Reply in Support of Motion to Enforce that Aetna's Motion for Protective Order is "not a filing recognized by FTC practice rules" and that the arguments that Aetna made in its Motion for Protective Order are the same

arguments as Aetna made in its Opposition to Motion to Enforce. For these reasons, Aventis asserts, it was not responding to Aetna's Motion for Protective Order, unless requested by the Court.

Aventis has adequately briefed and argued the issues raised in Aetna's Motion for Protective Order through Aventis' Motion to Enforce and through Aventis' Reply in Support of Motion to Enforce. Accordingly, a response by Aventis to Aetna's Motion for Protective Order is not necessary. Although Aetna's objections to the subpoena would have been more appropriately presented in a motion to quash the subpoena pursuant to Commission Rule 3.34(c), as a non-party, Aetna will not be penalized for filing its objections in the form of a motion for a protective order.

On October 11, 2000, Aetna filed its Request That This Court Enter Its Motion for a Protective Order Given Respondent Aventis' Lack of Opposition. That request is DENIED. As described in detail below, Aetna's Motion for Protective Order is GRANTED in part and DENIED in part.

П.

Aetna seeks a protective order to avoid further compliance with the subpoena on grounds that (1) it has already produced all relevant, non-privileged documents; (2) other documents sought by the subpoena are not relevant to this proceeding; and (3) the information sought is confidential and no adequate showing of need has been made. Aventis wants Aetna to fully comply with its subpoena, asserting that the information sought is both relevant and essential for Aventis' defense in this case.

Aventis states that its subpoena seeks, in summary, documents from Aetna relating to Aetna's drug classifications studies and determinations, formularies, market-share incentive contracts with manufacturers, documents reflecting substitutability judgments and studies, and other information necessary to determine the proper scope of any relevant product market that includes Cardizem® CD or generic versions of Cardizem® CD. Aventis asserts that it needs these documents from Aetna (as well as from other third party payor health insurance providers) in order to arrive at a proper relevant market definition. Aventis also asserts that this information is essential to allow Aventis to defend this case; to demonstrate that the relevant product market allegations set forth in the Complaint are overly narrow; and to permit Aventis to prove that the relevant market in this case is, at a minimum, the market for calcium channel blockers. In addition, Aventis maintains that it needs information from Aetna in order to prepare for the testimony of Mr. Jackson, Vice President of Pharmacy and Head of Clinical Pharmaceutical Management for Aetna, who has been identified by Complaint Counsel as a potential witness in this case.

Aetna asserts that the information is not relevant, that the information is readily available from other sources, that much of the information constitutes valuable trade secrets and or

confidential material, and that the subpoena poses an undue burden on Aetna. Aetna relies on the ruling made by the U.S. District Court for the Eastern District of Michigan denying Aventis' motion to compel discovery from Aetna on the grounds that the relevancy of the requested documents to the definition of the relevant market was speculative and even if relevant, Aventis had not shown sufficient need for trade secrets. Aetna contends that it would be more appropriate for Aventis to obtain some of the information requested from medical research centers or pharmaceutical marketers or researchers than from it, a third party payor health insurance provider. Aetna further maintains that Aventis does not need additional documents from it to prepare for the testimony of Mr. Jackson because Aventis already has all the documents that Aetna produced to the FTC.

#### 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 Commission 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 Aventis are relevant to the subject matter of this action, the subpoena should be complied with unless the documents are privileged or the subpoena is unreasonable, oppressive, annoying, or embarrassing.

Ascertaining a restraint's competitive effects ordinarily requires a definition of the relevant market and an analysis of the restraint's effect on competition within that market. <u>See</u>, <u>e.g.</u>, <u>Times-Picayune Publ'g Co. v. United States</u>, 345 U.S. 594, 613 (1953); <u>United States v. Columbia Steel Co.</u>, 334 U.S. 495, 527 (1948).

The Complaint alleges that Respondents entered into a Stipulation and Agreement on September 24, 1997, that had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition and consumers by preventing or discouraging the entry of competition in the form of generic versions of Cardizem® CD into the relevant market. Complaint ¶ 29. The Complaint further alleges:

a relevant product market for assessing respondents' anticompetitive conduct is once-a-day diltiazem. Diltiazem belongs to a group of drugs known as "calcium channel blockers," and is used principally to treat high blood pressure (hypertension) and to decrease the occurrence of chronic chest pain ("angina"). Once a day diltiazem is a time-release version of diltiazem, in capsule form, that is designed to be taken once every 24 hours.

Other calcium channel blockers are not acceptable substitutes for diltiazem for several reasons, including, *inter alia*, the differences in efficacy and side effects, and the risks associated with switching patients from one calcium channel blocker to another. In addition, narrower relevant product markets may be contained within the market for once-a-day diltiazem products.

### Complaint ¶ 12.

Aventis disputes Complaint Counsel's relevant product definition. Aventis Answer ¶ 12. Aventis contends that the relevant product market is, at a minimum, the market for a class of anti-hypertension products known as calcium channel blockers. In order to arrive at a proper relevant market definition, Aventis maintains, information in the hands of third-party payor health insurance providers, such as Aetna, is essential. Aventis further asserts that materials in the possession of Aetna and other third party payors, such as formularies, treatment and substitution studies, prescribing guidelines, reimbursement guidelines, and marketing contracts, are relevant indicators of the substitutability of pharmaceutical products, and of which products manufacturers view as being in direct competition.

Documents which are probative in defining the relevant product market are relevant to the disputed issues in this case. Aventis has demonstrated that many of the requested documents are relevant.

## IV.

Aetna asserts also that its documents are highly confidential and extremely sensitive and that the disclosure of this information to Aventis will result in irreparable injury. Aetna maintains 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.

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 (9<sup>th</sup> Cir. 1971) ("The fact that discovery might result in the

disclosure of sensitive competitive information is not a basis for denying such discovery."). <u>See also Federal Trade Commission v. Rockefeller</u>, 441 F. Supp. 234, 242 (S.D.N.Y. 1977), <u>aff'd 591 F.2d 182 (2d Cir. 1979)</u> (An objection to a subpoena on grounds that it seeks confidential information "poses no obstacle to enforcement."). However, federal courts have held that "[w]here a discovery request seeks confidential commercial information such as a trade secret, 'the burden is on the party seeking discovery to establish that the information is sufficiently relevant and necessary to his case to outweigh the harm disclosure would cause to the person from whom he is seeking the information." *In re Brand Name Prescription Drugs Antitrust Litig.*, 1994 U.S. Dist. LEXIS 17278, \*3 (N.D. Ill. 1994) (<u>quoting</u> 8 C. Wright & A. Miller, Federal Practice and Procedure § 2043 at 301-02 (1970)).

Although the materials requested may contain sensitive commercial information, the burden of production on Aetna does not outweigh Aventis' need for certain relevant 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 (10<sup>th</sup> Cir. 1965) (denying motion to quash subpoenas served on competitors). Based upon the limitations to the subpoenaed information set forth below, enforcement of the subpoena would not be unreasonable or oppressive.

V.

Aventis' subpoena contains thirteen requests for documents. Aetna's Motion for Protective Order divides these requests into four categories: (1) information relating to Aetna's formularies; (2) information relating to scientific analyses of pharmaceutical products designed for treatment of hypertension and angina; (3) information relating to agreements between Aetna and Aventis' competitors regarding cardiovascular pharmaceutical products; and (4) information relating to analyses of the effect of the sale of generic versions of pharmaceuticals on sales price and market share of pioneering pharmaceutical products.

Aventis has demonstrated that parts of the discovery it seeks from Aetna are both relevant and essential, as set forth below. Thus, Aetna is not entitled to the blanket protective order it has requested to prohibit any further discovery of information from Aetna. However, parts of Aventis' thirteen document requests attached to the subpoena request information beyond the scope of permissible discovery in this case. Aetna need only produce the following documents:

- (1) pharmaceutical product formularies used in connection with any health benefit plan or prescription benefit plan, <u>but not</u> information regarding how formulary lists are created, determined, maintained, or utilized, or the identification of members of any committee that makes decisions regarding formularies;
- (2) scientific analyses of pharmaceutical products designed for the treatment of hypertension and angina, including any addressing the substitutability of one drug for another; and

(3) analyses of the effect of the sale of generic versions of pharmaceutical products designed for the treatment of hypertension and angina on sales price and market share of brand name pharmaceutical products designed for the treatment of hypertension and angina.

For each of these three categories, Aetna is not required to produce any attorney-client or work product privileged documents. In addition, Aetna may redact highly sensitive information such as cost and profit data from the materials Aetna does produce. Responsive documents shall be produced within ten days, or as otherwise agreed to by Aventis and Aetna.

In these respects, Aetna's Motion for Protective Order is GRANTED in part and DENIED in part.

#### VI.

A ruling on Aventis' Motion to Enforce would be premature at this time. Generally, motions for certification to the Commission to request court enforcement of a subpoena or order come after an order of an Administrative Law Judge on a motion to quash. <u>E.g.</u>, In re Trans Union Corp., 123 F.T.C. 840, 1997 FTC LEXIS 63 (March 12, 1997); In re American Family Publ., Inc., 1991 FTC LEXIS 2 (Jan. 7, 1991); In re Ford Motor Co., 1979 FTC LEXIS 99 (Nov. 14, 1979). The Commission's Rules of Practice state that "in instances where a nonparty fails to comply with a subpoena or order, the Administrative Law Judge shall certify to the Commission a request that court enforcement of the subpoena or order be sought." 16 C.F.R. § 3.38(c). This rule is derived from the Commission's organic statute which sets forth "in case of disobedience to a subpoena the Commission may invoke the aid of any court of the United States in requiring the attendance and testimony of witnesses and the production of documentary evidence." 15 U.S.C. § 49. <u>See also In re Market Dev. Corp.</u>, 95 F.T.C. 100, 1980 FTC LEXIS 162, \*244-45 (Jan. 15, 1980).

From the pleadings, it is not clear that Aetna has refused to comply with the subpoena. Aetna asserts that it has provided all relevant, non-privileged materials. Aventis disputes this. The dispute hinges principally on what material is relevant and whether Aventis has made a sufficient showing of need to access Aetna's "trade secrets." This order resolves that dispute and limits the scope of the requested information. If Aetna continues to withhold documents following the issuance of this order, Aventis may file a motion for certification to enforce this order, which will be considered expeditiously. Alternatively, Aventis may refile a motion to enforce compliance with its subpoena. Accordingly, at this time, Aventis' Motion to Enforce Compliance is DENIED WITHOUT PREJUDICE.

### VII.

Pursuant to 16 C.F.R. § 3.31(d)(1), a protective order governing confidential information was issued 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 protect the confidential documents of third parties through a number of safeguards, including provisions to limit disclosure of materials designated as "Restricted Confidential, Attorneys Eyes Only." Further, pursuant to the September 28, 2000 Order Denying Motion to Amend, Modify and Reissue the Protective Order Governing Discovery Materials, the parties, experts, or consultants shall not disclose any Confidential Discovery Materials or matters learned therefrom to competitors of Respondents, any other pharmaceutical company, any pharmacy benefits management company, any competitor of a third party which produced Confidential Discovery Material, or any entity that sells services or information to third party payors/insurers. And, in no event shall any party or third party be required to produce or otherwise divulge patient-identification or insured-identification information.

In addition, Aetna may file an application for *in camera* treatment to prevent disclosure to the public of its 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.

ORDERED.

Date: October 26, 2000

D Michael Chappell

Administrative Law Judge