IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION,	:	CIVIL ACTION
Plaintiff,	:	
v.	:	No. 2:08-cv-2141
CEPHALON, INC.,	:	
Defendant.	:	

DEFENDANT CEPHALON, INC.'S MOTION TO COMPEL PRODUCTION OF DOCUMENTS FROM PLAINTIFF FEDERAL TRADE COMMISSION

Defendant Cephalon, Inc. hereby moves the Court for an order requiring Plaintiff Federal Trade Commission (1) to produce documents and things in response to Cephalon, Inc.'s Requests for Production 10 and 11 or (2) to stipulate that it will not seek to offer into evidence or otherwise rely in any manner on the studies *Generic Drug Entry Prior to Patent Expiration: An FTC Study* or *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*. The grounds for this motion and proposed Order are set forth in the accompanying memorandum of law, which is incorporated herein.

Respectfully submitted,

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Dated: December 22, 2010

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FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION,	:	CIVIL ACTION
Plaintiff,	:	
v.	:	No. 2:08-cv-2141
CEPHALON, INC.,	:	
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DEFENDANT CEPHALON, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION TO COMPEL PRODUCTION OF DOCUMENTS FROM PLAINTIFF FEDERAL TRADE COMMISSION

Throughout this litigation, and in other cases challenging Hatch-Waxman settlements, the Federal Trade Commission (FTC) and the private plaintiffs have repeatedly cited the FTC's conclusions from studies it conducted of brand-generic litigation and settlements. Although Cephalon believes those studies are inadmissible and should not be relied upon in any filing or expert report, it is evident that the FTC and other plaintiffs will continue to do so.[1] Accordingly, Cephalon seeks discovery concerning the analyses, source materials, and other documents relating to these studies in order to be in a position to respond to any use of the studies in motion practice and to be able to cross-examine experts or other witnesses relying upon them. The FTC, however, refuses to produce a single underlying document, relying on meritless relevance, confidentiality, and burden objections. Cephalon therefore moves for an order compelling the FTC to produce forthwith the documents underlying the studies, or to stipulate that it will not seek to offer the studies into evidence or otherwise rely on them in any manner in this litigation.

[1] Cephalon offered to withdraw all requests relating to these studies if the FTC and other plaintiffs in the consolidated actions would stipulate that they and their experts would not rely on the studies in any way. The FTC did not accept that proposal.

I. Factual Background

Cephalon's Requests for Production ("RFPs") 10 and 11 (attached as Exhibit 1 to Ford Declaration) seek:

> [10] All documents concerning the FTC study "Generic Drug Entry Prior to Patent Expiration," dated July 2002 [hereinafter, the "2002 Study"], including without limitation drafts; supporting data and analyses; notes; memoranda; worksheets and workbooks; all documents concerning contributions to the report by the Food and Drug Administration; and all other documents on which the Commission or authors relied in reaching the conclusions set forth in the study.
>
> [11] All documents concerning the FTC study "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions," dated January 2010 [hereinafter, the "2010 Study"], including without limitation drafts; supporting data and analyses; notes; memoranda; worksheets and workbooks; all other documents concerning the calculations and analysis of the Bureau of Competition, Bureau of Economics, and Office of Policy Planning described in the study methodology; and all other documents relied upon by the Commission or authors in reaching the conclusions set forth in the study.

Despite its initial response that it would produce at least some responsive documents,[2] the FTC stated in a November 4, 2010 letter that it did not intend to produce any documents at all in response to these requests because it unilaterally determined that the materials were not relevant. *See* Exhibit 3 to Ford Decl., Letter from Bradley Albert, Esq. to Mark A. Ford, Esq. (Nov. 4, 2010). Moreover, during the meet-and-confer process, the FTC objected for the first time on the grounds that the RFPs require production of third-parties' confidential settlement agreements. *See* Exhibit 4 to Ford Decl., Letter from Bradley Albert, Esq., to Mark A. Ford, Esq. (Dec. 7, 2010).

The 2002 Study outlines the FTC's opposition to Hatch-Waxman settlements based on "documents and information from brand-name and generic drug manufacturers" that the FTC

[2] The FTC's initial response to RFP 10 and 11, dated July 1, 2010, read: "The FTC objects to this request as overly broad, unduly burdensome, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. The FTC also objects to this request to the extent it calls for public documents readily available to Cephalon. Subject to and without waiving the general and specific objections, the FTC will produce any non-privileged documents, not previously produced, responsive to this request." Exhibit 2 to Ford Decl., Plaintiff Federal Trade Commission's Objections and Responses to Defendant Cephalon, Inc.'s First Set of Requests for Production of Documents and Things (July 1, 2010).

obtained via subpoena. FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, ii (July 2002). The FTC's analysis of these documents resulted in the comprehensive 129-page study that has been cited in this and other litigations. The 2010 Study summarizes the key arguments the FTC levies in opposition to Hatch-Waxman settlements, including that "[b]rand-name pharmaceutical companies have found a wide variety of techniques through which to compensate generics for delaying their entry." FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, 5 (January 2010). The FTC explicitly cites the 2002 Study on the outcome of brand-generic patent litigation in its Complaint and motion to dismiss briefing. Pl. FTC's First Am. Compl. ¶ 25 (Aug. 12, 2009) (Dkt. No. 40); *see also* Pl. FTC's Mem. in Opp. to Def. Cephalon's Mot. to Dismiss at 21 (Sept. 14, 2009) (Dkt. No. 45).[3] And while the 2010 Study was not released until after briefing was complete on the motions to dismiss, in a letter to the Court, the FTC referenced a speech by FTC Chairman Jon Leibowitz that previewed the findings of the 2010 Study. *See* Exhibit 5 to Ford Decl., Letter from Markus Meier to Court at 2 n.1 (Oct. 14, 2009). Moreover, the FTC repeatedly discussed the 2010 Study in a recent brief to the Eleventh Circuit, seeking to overturn the district court's order adopting the scope-of-the-patent test. *See* Br. for Pl.-Appellant at 34-35, 51, *Federal Trade Comm'n v. Watson Pharms, Inc.*, No. 10-12729 (11th Cir. July 26, 2010).

[3] The private plaintiffs have already expressed their intent to rely on the FTC studies. *See* Tr. of St. Conf. at 49:10-12 (Jul. 28, 2009) (Dkt. No. 39) (counsel for direct purchasers: "[C]ertain studies that the FTC has done in the Hatch-Waxman context bear on this case…."). Indeed, after the Court criticized plaintiffs for attaching the 2002 Study to their initial opposition to the motion to dismiss, *see id.* at 48-49, the Direct Purchasers proceeded to incorporate the study's findings into the allegations of their Amended Complaint. Second Cons. Am. Compl. ¶ 84, *King Drug Co. of Florence, Inc., et al. v. Cephalon, Inc., et al*., No. 06-cv-1797 (E.D. Pa. Aug. 10, 2009) (Dkt. No. 193). Pharmacies Rite Aid, CVS, Brooks, and Eckerd (the "Rite Aid Plaintiffs") also relied on the 2002 Study in their complaint to support their assertion that "Cephalon was no doubt aware that [] as a general matter … it most likely would not be able to keep the Generic Defendants off the market solely by using its patent." Compl. ¶ 72, *Rite Aid Corp., et al. v. Cephalon, Inc., et al.*, No. 09-cv-03820 (E.D. Pa. Aug. 20, 2009) (Dkt. No. 1). The End Payor class similarly invoked the study in its brief opposing Cephalon's motion to dismiss. End Payor Pls.' Mem. of Law in Opp'n to Def. Cephalon's Mot. to Dismiss End-Payor Pls.' Compl. at 24, *Vista Healthplan, Inc., et al. v. Cephalon, Inc., et al.*, No. 06-cv-1833 (E.D. Pa. Sept. 18, 2009) (Dkt. No. 92).

II. Argument

None of the principal objections advanced by the FTC – relevance, confidentiality, or undue burden – justifies withholding the documents underlying the studies.

1. *Relevance*. There is little doubt that the FTC and private plaintiffs will seek to use the 2002 and 2010 Studies. As noted above, the FTC cites the 2002 Study for the proposition that "the risk that the patentee will fail in its attempt to exclude [generic competitors] is substantial" and therefore, by extension, Cephalon would likely not have been successful in the patent litigation with the generics. FTC's Mem. in Opp. to Def. Cephalon's Mot. to Dismiss at 21. Private plaintiffs have also invoked the Studies to support the claims in their Complaints and briefing. *See, e.g.,* First Cons. Am. Compl. ¶ 84, *King Drug Co. of Florence, Inc., et al. v. Cephalon, Inc., et al*., No. 06-cv-1797 (E.D. Pa. Aug. 10, 2009) (Dkt. No. 193); Compl. ¶ 72, *Rite Aid Corp., et al. v. Cephalon, Inc., et al.*, No. 09-cv-03820 (E.D. Pa. Aug. 20, 2009) (Dkt. No. 1); End Payor Pls.' Mem. of Law in Opp'n to Def. Cephalon's Mot. to Dismiss End-Payor Pls.' Compl. at 24, *Vista Healthplan, Inc., et al. v. Cephalon, Inc., et al.*, No. 06-cv-1833 (E.D. Pa. Sept. 18, 2009) (Dkt. No. 92).

The FTC cannot, on the one hand, rely on the conclusions of its own studies and, on the other hand, refuse to provide any discovery concerning those studies on the ground that the requested materials are irrelevant. While Cephalon will certainly oppose the admissibility and

use of the studies,[4] the FTC has taken the affirmative step to place the studies at issue in this case, and the Court has not yet ruled on their admissibility. Therefore, given that the scope of discovery is defined by the *claims* in a case, the FTC's relevance objection is without merit. *See Pettyjohn v. Goodyear Tire & Rubber Co.*, No. Civ. A. 91-2681, 1992 WL 94895, at *8 (E.D. Pa. Apr. 20, 1992) (defendants have a right to discover the basis of plaintiffs claim against them, as this is the purpose of discovery); *see also Muhl v. Tiber Holding Corp.*, No. Civ. A. 95-5284, 1997 WL 13680, at *3 (E.D. Pa. Jan. 9, 1997) (defendant is entitled to all documents upon which plaintiff relies to support claims in complaint). Indeed, the fundamental principles of fairness that underlie federal civil discovery entitle Cephalon to obtain the underlying materials to scrutinize the studies' conclusions and to be in a position to respond to their use in motion practice and to cross-examine any witnesses who rely on them. *See Segal v. Strausser Enterprises, Inc.*, No. 07-4647, 2010 WL 3946284, at *3 (E.D. Pa. Oct. 7, 2010) (party has right to test liability theory; need not rely solely on other party's submissions to do so).

2. *Confidentiality*. The FTC claims that the Hatch-Waxman settlement agreements that inform the conclusions in its 2010 Study are confidential business documents protected from disclosure by the provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA"), which generally requires that pharmaceutical companies submit certain patent settlements to the FTC. Pub. L. No. 108-173 § 1112, 117 Stat. 2006 (2003). As an initial

[4] The Court has adopted the scope of the patent test. *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 528 (E.D. Pa. 2010). Accordingly, any reliance by the FTC or other plaintiffs on the 2010 Study to suggest that another test would be more appropriate would be irrelevant. *See* 2010 Study at 1, 11 n.3 (arguing that courts adopting the scope of the patent test have misapplied the antitrust law to Hatch-Waxman settlements). The FTC and other plaintiffs also generally invoke the studies to support the proposition that, in patent litigation, a generic drug manufacturer is more likely to prevail than its branded counterpart. *See, e.g.,* Pl. FTC's First Am. Compl. ¶ 25 (citing 2002 Study for proposition that "when cases were litigated to a decision on the merits, the generics prevailed in cases involving 73 percent of the challenged drug products); Second Cons. Am. Compl. ¶ 84, *King Drug Co. of Florence, Inc., et al. v. Cephalon, Inc., et al*., No. 06-cv-1797 (E.D. Pa. Aug. 10, 2009) (Dkt. No. 193) (citing same statistic). But these general observations as to the outcome of other patent litigations have no bearing on the likely outcome of patent litigation between Cephalon and the Generic Defendants, and cannot possibly be used to prove that Cephalon's patent was "weak" or that Cephalon would have lost the underlying patent case. Finally, unsupported statistics about the alleged costs of Hatch-Waxman settlements to consumers is likely only to confuse and prejudice the jury. For these reasons and others, neither the studies themselves nor expert testimony relying on them would be admissible at trial.

matter, those settlement documents are just a subset of the materials requested concerning the studies. Moreover, even as to the settlements themselves, the MMA does not relieve the FTC of the obligation to produce them. While the MMA generally exempts the agreements from disclosure under FOIA, it expressly *authorizes* disclosure where – such as here – the "information or documentary material ... may be relevant to any administrative or judicial action or proceeding." *Id.* at § 1114.

Moreover, any confidentiality concerns are addressed by the protective order already in place. The order allows the FTC to designate the settlements and other documents as Highly Confidential, thus limiting disclosure to the Court, outside counsel, and any expert witnesses or consultants retained by the parties, and prohibiting any use of the materials for reasons other than this litigation. Am. Stip. Protective Order ¶¶ 1(a)-(b), 2(a), 3 (Nov. 9, 2009, Dkt. No. 54); *see also ClubCom, LLC v. Captive Media, Inc.*, No. 07-CV-1462, 2009 WL 1885755, at *1 (W.D. Pa. June 30, 2009) (protective order addresses defendant's concern that production of agreements "would result in the disclosure of confidential competitive information").[5] In short, the FTC cannot have it both ways, by affirmatively relying on the studies' conclusions yet simultaneously cloaking the underlying documents in a veil of secrecy.

3. *Burden*. Finally, the FTC's argument that production of the requested documents would be an undue burden on the agency is without merit, particularly in light of the enormous

[5] The FTC's reliance on cases involving documents provided to the agency pursuant to the Hart Scott Rodino Act ("HSR") is misplaced, given the clear provision of the MMA authorizing disclosure. And the cases are not apposite even by analogy. In *General Motors Corp.*, 103 F.T.C. 58, 64 (1984), the FTC sought to disclose documents to the general public without redacting or otherwise protecting confidential business information. *Id.* In *Lieberman v. FTC*, 771 F.2d 32 (2d Cir. 1985) and *Mattox v. FTC*, 752 F.2d 116 (5th Cir. 1985), the court barred the release of confidential business information to states attorneys general for premerger enforcement because Congress envisaged that only the Department of Justice or the FTC should enjoin anticompetitive mergers. None of these cases is relevant to the present situation. Furthermore, as the FTC itself notes in correspondence, even the HSR exemption against disclosure "is lifted by the exception clause *to the extent such data actually is used by the Commission in administrative or judicial proceedings*." *General Motors Corp.*, 103 F.T.C. at 64 (emphasis added).

discovery demands that the FTC has placed on Cephalon in this litigation.[6] Indeed, the FTC has acknowledged in correspondence that it already has collected and reviewed much of the material requested in the Cephalon document requests at issue on this motion. As to the settlements themselves, the FTC's only claimed burden was to notify the parties to the agreements that they will be produced as part of this litigation. *See* Exhibit 4 to Ford Declaration. The FTC has already sent these letters. *See* Exhibit 6 to Ford Declaration, Letter from Bradley S. Albert, Esq., to Counsel (Dec. 20, 2010). If there is any remaining burden, it would be substantially outweighed by Cephalon's clear need for the materials to test the studies' conclusions and to be able to respond to use of the studies in motion practice or at trial. *D.E.J.S.A. v. Shooter*, No. Civ. A. 92-2953, 1993 WL 65816, at *1-2 (E.D. Pa. Mar. 9, 1993) (the party resisting discovery carries the burden of showing the request poses undue burden or oppression).

* * *

[6] Cephalon has produced just over a million pages in response to the plaintiffs' requests; the FTC, by contrast, has produced to Cephalon just over 20,000 pages, many of which were re-production of materials from third parties.

For all the foregoing reasons, Cephalon respectfully requests that the Court grant its motion to compel the production of documents and things in response to RFPs 10 and 11 and order the FTC to either (1) produce forthwith the documents underlying the studies or (2) stipulate that it will not seek to offer the studies into evidence or otherwise rely on them in any manner in this litigation.

Respectfully submitted,

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Dated: December 22, 2010

CERTIFICATE OF SERVICE

I certify that on the date set forth below the foregoing Defendant Cephalon, Inc.'s Motion to Compel Production of Documents from Plaintiff Federal Trade Commission, Memorandum in support, proposed Order, Declaration of Mark A. Ford, and Certification Pursuant to Local Rule Civ. P. 26.1(f) were electronically filed pursuant to the Court's CM/ECF system, and that the documents are available for downloading and viewing from the CM/ECF system. Notice of this filing will be sent to all counsel of record by operation of the CM/ECF system.

/s/ Nancy J. Gellman

Date: December 22, 2010