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

FEDERAL TRADE COMMISSION, Plaintiff, v. CEPHALON, INC., Defendant.	Civil Action No. 08-cv-2141 (MSG)

PLAINTIFF FEDERAL TRADE COMMISSION'S
MEMORANDUM IN OPPOSITION TO CEPHALON'S MOTION TO COMPEL

The Federal Trade Commission has cited various publicly-available empirical studies in legal briefs submitted in this Court and others. It has used statistics from these studies to attack the legal argument that Cephalon has advocated in this case. Cephalon now moves to compel the FTC to produce all documents related to two empirical studies of the pharmaceutical industry published by the FTC, one in 2002 and the other in 2010. The documents at issue are a voluminous set of materials that concern scores of other pharmaceutical companies, litigating other patent disputes, concerning other drugs. Cephalon concedes that these materials are "unrelated" to the investigation that gave rise to this case and are "irrelevant" to proof of adjudicative facts in this case.[1]

Cephalon nonetheless claims that – absent production of all of this admittedly irrelevant material – the FTC is not entitled to make any reference to the statistics contained in these studies. It thus asks this Court to preclude the FTC (by way of a required stipulation) from "offer[ing] the studies into evidence or otherwise rely[ing] on them in any manner in this

[1] Letter from Mark A. Ford to Bradley S. Albert (Oct. 28, 2010), Exh. A to Albert Decl.; Ceph. Mem. at 5 n. 4.

litigation." Ceph. Mem. at 1, 8. One aspect of Cephalon's request is easily disposed of: The FTC has no intention to offer the two studies into evidence and hereby stipulates that it will not seek to do so.

But Cephalon seeks far more. It asserts that reliance on the studies in question "in any filing or expert report" would be improper and further that federal civil discovery "principles" entitle it to the materials it seeks. Ceph. Mem. at 1, 5. Neither proposition is correct.

First, reliance on extra-record empirical studies for so-called "legislative facts," that is, facts that "have relevance to legal reasoning,"[2] is a well-established practice in federal courts. For example, the Supreme Court cited repeatedly to an FTC study of internet wine sales in *Granholm v. Heald*, 544 U.S. 460, 466-68, 490-92 (2003). And, at least two federal courts have already relied on the very FTC study that Cephalon claims may not be relied upon here.[3] In none of these cases were the underlying study materials disclosed. It is likewise proper for an expert to consider the FTC studies, as part of a survey of the relevant literature. As required under Federal Rule of Civil Procedure 26, all expert reports will disclose any reliance on these studies and any other materials considered in forming an opinion.

Second, Cephalon offers no legal support for its assertion that civil discovery rules or principles require the production it seeks to compel. As is discussed below, the cases it relies on concern discovery relevant to adjudicative facts – not legislative facts, whose relevance goes to legal reasoning rather than the facts of the parties' particular case. And Cephalon's claim (Ceph.

---

[2] Fed. R. Evid. 201 advisory committee's note.

[3] *See Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 604 F.3d 98, 108 n. 17 (2d. Cir. 2010) (citing statistic regarding the litigation success rate for generic patent challengers); *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 900 (7th Cir. 2004) (citing data on the outcome of a subset of Hatch-Waxman cases).

Mem. at 4) that the FTC has "by extension" cited the 2002 FTC study to support its allegation that Cephalon likely would not have prevailed in its patent suit is manifestly false. In short, Cephalon has failed to demonstrate that the discovery it seeks to compel is relevant within the meaning of Rule 26(b)(1).

Finally, Cephalon's claim that the FTC unfairly seeks to hide behind "a veil of secrecy" is particularly inapt. Ceph. Mem. at 6. The vast majority of the material that Cephalon requests contains confidential business information submitted to the FTC by pharmaceutical companies that are not parties to this litigation. This information is subject to special statutory protections enacted by Congress to enable the FTC to conduct empirical studies and to assure FTC review of all Hatch-Waxman patent settlements. Cephalon's failure to establish the relevance of its requested discovery is thus particularly significant here, because its request implicates the statutorily-protected confidentiality interests of roughly 100 non-parties.

I. BACKGROUND

The two FTC studies at issue were not created for this (or any other) litigation. They are merely two of the many industry reports and empirical analyses that the agency has published over the years.

A. The FTC's Congressional Mandate to Conduct Studies of Industry-Wide Competition Issues

When Congress created the FTC in 1914, it envisioned that the agency would fulfill an important role in gathering, analyzing, and reporting information about American industry, apart from its role as a law enforcement agency. *See, e.g.,* F.M. Scherer, *Sunlight and Sunset at the Federal Trade Commission*, 42 Admin. L. Rev. 461, 461 (1990) ("A principal element of the Commission's original mission was to collect and disseminate information about the functioning

of American industry.").[4] As a result, Congress granted the agency not only investigatory authority necessary to prosecute individual violations of law, but also broad authority to compel the production of data and information not directly related to any law enforcement investigation. This authority gives the agency a unique capacity to conduct "systematic, institutional study of real-world industries and activities" that "modern academic research in industrial organization rarely undertakes."[5]

The FTC has conducted in-depth analyses of a wide variety of industries, including petroleum, electric power, carbonated soft drinks, tobacco, and telecommunications.[6] Since the 1970s, the agency has been active in analyzing competition issues in the pharmaceutical

---

[4] *See also* Timothy J. Muris, *More Than Law Enforcement: The FTC's Many Tools – A Conversation with Tim Muris and Bob Pitofsky*, 72 Antitrust L.J. 773, 773 (2005), *available at* http://www.law.gmu.edu/assets/files/publications/working_papers/06-23.pdf ("When Woodrow Wilson and Congress created the FTC in 1914, they wanted more than litigators and adjudicators.").

[5] Report of the American Bar Association Section of Antitrust Law, Special Committee To Study the Role of the Federal Trade Commission, 58 Antitrust L.J. 43, 103 (1989).

[6] *See The Petroleum Industry: Mergers, Structural Change, And Antitrust Enforcement* (August 2004), *available at* http://www.ftc.gov/os/2004/08/040813mergersinpetrolberpt.pdf; *Competition and Consumer Protection Perspectives on Electric Power Regulatory Reform* (2000), *available at* http://www.ftc.gov/be/v000009.shtm; *Transformation and Continuity: The U.S. Carbonated Soft Drink Bottling Industry and Antitrust Policy Since 1980* (1999), *available at* http://www.ftc.gov/reports/softdrink/softdrink.pdf; *Competition and the Financial Impact of the Proposed Tobacco Industry Settlement* (1997), *available at* http://www.ftc.gov/reports/tobacco/ndoc95.pdf; *Measurements of Market Power in Long Distance Telecommunications* (1995), *available at* http://www.ftc.gov/be/econrpt/232316.pdf. FTC Reports from 1996 to the present are available at http://www.ftc.gov/reports/index.shtm. The FTC Bureau of Economics has also published over 300 working papers on a broad range of competition and consumer protection issues, most of which are available at http://www.ftc.gov/be/econwork.shtm.

industry.[7] In addition to the two studies at issue here, in recent years the agency has published studies on so-called "authorized generics," follow-on biologic drug competition, and ownership of mail-order pharmacies by pharmacy benefit managers.[8] In many instances, the FTC has conducted such research at the direction of Congress.[9]

B. The 2002 Generic Drug Study

In July 2002, the FTC issued an empirical study analyzing generic drug competition under the Hatch-Waxman Act.[10] At the request of Representative Henry Waxman, one of the co-sponsors of the Hatch-Waxman Act, the FTC undertook a study of conduct by pharmaceutical

---

[7] *See, e.g., Staff Report on Drug Price Disclosure* (1975); *Sales, Promotion, and Product Differentiation in Two Prescription Drug Markets* (1977); *Staff Report on Drug Product Selection* (1979); *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* (1985); *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (1999), *available at* http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf.

[8] *See Authorized Generics: An Interim Report* (2009), *available at* http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf; *Emerging Health Care Issues: Follow-on Biologic Drug Competition* (2009), *available at* http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf; *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (2005), *available at* http://ftc.gov/be/healthcare/wp/10_Schmidt_Pharmacy_benefit_managers.pdf.

[9] In 2003, Congress directed the FTC to undertake a "Conflict of Interest Study" to examine "differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers." Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, § 110, 117 Stat. 2066, 2174 (2003) [hereinafter Medicare Modernization Act or MMA]. Several members of Congress requested the agency to study the effect of authorized generics on the pharmaceutical marketplace. *See* Letter from Hon. Henry A. Waxman, U.S. House of Representatives, to Deborah Platt Majoras, Chairman, Fed. Trade Comm'n (Sept. 13, 2005); Letter from Senators Charles Grassley, Patrick J. Leahy, and John D. Rockefeller IV to Deborah Platt Majoras, Chairman, Fed. Trade Comm'n (May 9, 2005).

[10] Fed. Trade Comm'n, *Generic Drug Entry Prior to Patent Expiration* (2002) [hereinafter "2002 Study"], *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

companies that may delay generic drug competition. 2002 Study at 1. The 2002 generic drug study has been widely cited and has influenced regulatory and legislative developments.[11] In 2003, Congress adopted several of the study's policy recommendations in the Medicare Modernization Act ("MMA").[12]

To collect the information necessary to conduct the requested study, the FTC issued special orders pursuant to section 6(b) of the FTC Act, 15 U.S.C. § 46(b), requesting detailed information from 28 brand-name companies and 52 generic companies, covering Paragraph IV certifications filed between January 1, 1992 and January 1, 2001, for a total of 104 separate brand-name products.[13] The documents, data, and other material from the 2002 study include complete narrative responses, copies of agreements, financial data, and additional background and summary information submitted by the 80 companies that received special orders. These materials also include numerous internal FTC documents and spreadsheets cataloguing, summarizing, and analyzing the information submitted by these 80 drug companies; copies of Orange Book patent listings relating to each contested patent; copies of correspondence between the FTC and the FDA regarding non-public information; and other confidential materials.

---

[11] *See* Muris, *supra* note 4, at 777 (explaining that the 2002 study "received a highly public endorsement from the President, induced regulatory reforms at the Food and Drug Administration (FDA), and inspired legislative amendments to the Hatch-Waxman Act").

[12] Medicare Modernization Act, § 1112, 117 Stat. at 2461-62.

[13] These special orders required the companies to provide the results of patent litigation, including any settlement agreements; information regarding patents listed in the FDA's Orange Book; relevant sales data; and other competitively sensitive information. *See* 2002 Study at 10-11 (describing special order process), Appendix C (listing New Drug Applications reviewed), Appendix D (listing companies who received special orders), Appendix E (listing information requested in the special orders).

C. The 2010 Study

One of the changes that Congress included in the MMA was a new notification provision requiring drug companies to file certain agreements with the FTC and the Department of Justice. MMA § 1112, 117 Stat. at 2461-63. Drug companies settling Hatch-Waxman patent litigation must file the settlement agreement and all related agreements within ten business days of their execution. MMA § 1113, 117 Stat. at 2463. The MMA filing requirement allows the FTC and the Department of Justice to investigate Hatch-Waxman settlement agreements that might otherwise escape review. In addition, since the notification provision took effect, the FTC has issued annual reports with summary statistics regarding the agreements that have been filed.[14]

In January 2010, the FTC published a study that presents summary statistics based on all patent settlement agreements filed with the FTC between January 1, 2004, and September 30, 2009.[15] Like the 2002 study, this 2010 study includes policy recommendations for Congress. The 2010 study is based on over 425 agreements involving over 110 companies. In addition to the documents submitted by these companies, the underlying study materials include documents and spreadsheets created by the FTC cataloguing the agreements by date, length of delay, brand-name companies involved, generic companies involved, first-filer, Paragraph IV certification, ANDA date, entry date, patent expiration, and other data points, as well as confidential information obtained from the FDA regarding patent listings and ANDA applications.

---

[14] *See, e.g.*, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2008*, *available at* http://www.ftc.gov/os/2010/01/100113mpdim2003rpt.pdf.

[15] Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010) [hereinafter "2010 study"], *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

II. ARGUMENT

A. Cephalon Has Not Established That the Materials It Seeks Are Relevant

Rule 26(b)(1) provides that a party may obtain discovery as to matters that are "relevant to any party's claim or defense." Fed. R. Civ. P. 26(b)(1). "The rule requires the District Court, when considering a motion to compel, to determine whether the material sought is relevant to the 'subject matter of the litigation.'" *Katz v. Verizon Comms., Inc.*, Civ. A. No. 01-5627, 2002 WL 31356302, at *1 (E.D. Pa. Oct. 16, 2002) (internal citations omitted). *Accord Integrated Serv. Solutions, Inc. v. Rodman*, Civ. A. No. 07-3591, 2008 WL 4791654, at *4 (E.D. Pa. Nov. 3, 2008) (denying motion to compel for lack of relevance). The requested discovery thus must pertain to the factual issues actually before the court. *See Musarra v. Digital Dish, Inc.*, Civ. A. No. 05-CV-545, 2008 WL 4758699, at *4 (S.D. Ohio Oct. 30, 2008) (denying motion to compel for lack of relevance because plaintiffs failed to show how defendant's conduct toward several non-parties would provide insight into defendant's conduct toward plaintiffs).

Cephalon has not shown that the requested information meets this threshold standard of relevance. Indeed, Cephalon does not even contend that disclosure of these materials it seeks – agreements and related documents concerning hundreds of drugs that are not the subject of this litigation – would likely lead to the discovery of evidence proving or disproving the FTC's claim that Cephalon monopolized the market for Provigil. Instead, Cephalon asserts it is entitled to these materials as a matter of "fundamental principles of fairness" because the FTC has purportedly "place[d] the studies at issue in this case." Ceph. Mem. at 5. Cephalon wishes to: (1) "respond to [the FTC's] use [of the two studies] in motion practice"; and (2) "cross-examine any witnesses who rely on them." *Id.* None of this, however, serves to establish that the material Cephalon seeks is relevant, and thus a proper subject of discovery.

1. Citation to Empirical Studies on Pharmaceutical Settlement Practices Does Not Make the Details of Other Patent Cases Relevant to the Adjudicative Facts At Issue in this Case

There are "fundamental differences between adjudicative facts and legislative facts." Fed. R. Evid. 201,advisory committee's note. "Adjudicative facts are simply the facts of the particular case," while legislative facts "are those which have relevance to legal reasoning and the lawmaking process, whether in the formulation of a legal principle or ruling by a judge or court or in the enactment of a legislative body." *Id.* As Cephalon itself has observed in this case, "legislative facts" are "not specific to the case," but they may be relevant to legal reasoning and the formulation of legal rules. Cephalon's Reply Br. in Support of Mot. To Dismiss at 13 (June 20, 2008) (Dkt. No. 6). *See Bogosian v. Gulf Oil Corp.*, 561 F.2d 434, 457 (3d Cir. 1977) (Aldisert, J., dissenting) (stating that the legal and policy questions that may arise in case are distinct from the "kind of adjudicative facts which will be developed by discovery in a particular case concerning particular plaintiffs and defendants in a particular industry").

The FTC has not and will not seek to use the two studies at issue to prove adjudicative facts. Instead, the FTC has cited statistics from empirical studies as legislative facts. In this litigation, the FTC has referred to statistics on the overall success rate for patent challengers in pharmaceutical patent infringement cases in arguing that the legal rule Cephalon advocated in its motion to dismiss is inconsistent with Supreme Court patent cases:

> Treating a patentee's *unproven* "right to exclude" as an absolute entitlement to purchase a permanent injunction with monopoly profits is thus flatly inconsistent with these established Supreme Court principles. As the above cases make clear, the patent's potential power to exclude competitors is tempered by the risk that the patentee's arguments will not prevail in court. In pharmaceutical patent litigation, the risk that the patentee will fail

> in its attempt to exclude is substantial: the patentee loses in 70 percent of the cases, according to two studies.[16]

Contrary to Cephalon's claim (Ceph. Mem. at 4), the FTC has not used this statistic to argue "by extension" that Cephalon was likely to lose its Provigil patent case against the generic companies. As to this adjudicative fact, there is a wealth of evidence the FTC will introduce at trial to prove that Cephalon likely would not have prevailed in its patent case.

Cephalon also points to citations to the 2010 study in an FTC appellate brief filed in another circuit. This brief cites general industry statistics (concerning the effect of generic entry on sales of branded drugs and the average prices of generics relative to the branded drug), as well as estimates of the annual costs to consumers from exclusion payment settlements overall. These statistics were likewise used in making a legal argument – that the legal rule adopted by the district court ("that exclusion payment settlements are automatically lawful despite evidence at the time of settlement that the patent was invalid or not infringed") conflicts with the Supreme Court's teachings.[17]

Such use of extra-record empirical studies is consistent with federal courts' well-established practice of relying on legislative facts when resolving legal and policy issues. For example, in *Granholm v. Heald*, the Supreme Court referred several times to statistics and information concerning internet wine sales reported in an FTC study, ultimately striking down

---

[16] FTC Mem. in Opp. to Def. Cephalon's Mot. To Dismiss at 21 (Sept. 14, 2009) (Dkt. No. 45) (citing Paul Janicke & LiLan Ren, *Who Wins Patent Infringement Cases?* 34 AIPLA Q.J. 1, 20 (2006) and the 2002 Study at 19-20) (emphasis in original). The background section of the complaint in this case refers to the same empirical data from these two studies. FTC's First Am. Compl. ¶ 25 (Aug. 12, 2009) (Dkt. No. 40).

[17] *See* Brief of Appellant FTC at 33-35, 51, *FTC v. Watson Pharm., Inc., et al.*, No. 10-12729 (11th Cir. July 26, 2010), *available at* http://www.ftc.gov/os/caselist/0710060/100726androgelbrief.pdf.

state laws regulating the sale of wine from out-of-state wineries.[18] Other courts have cited statistics reported in the 2002 study to provide context for their discussion of legal issues arising in the pharmaceutical industry. In *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, for example, the Court of Appeals for the Second Circuit cited the same statistic that the FTC has cited in this case, regarding the success rate for generic drug manufacturers who litigated patent challenges to a decision. 604 F.3d 98, 108 n.17 (2d. Cir. 2010). The Court of Appeals for the Seventh Circuit cited data from the 2002 study concerning the outcome of a particular subset of Hatch-Waxman patent cases. *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 900 (7th Cir. 2004).

None of the cases cited in Cephalon's motion to compel support its contention that the FTC's citation to such statistics in legal arguments makes the underlying documents and information relevant or otherwise a proper subject for discovery. *See* Ceph. Mem. at 5. Rather, the cited cases all involve requests for discovery addressing adjudicative facts bearing on the parties' claims and defenses.[19] That empirical studies may be relevant to the court's legal

---

[18] 544 U.S. 460, 466-68, 490-92 (2005) (citing Fed. Trade Comm'n, *Possible Anticompetitive Barriers to E-Commerce: Wine* (2003), *available at* http://www.ftc.gov/os/2003/07/winereport2.pdf). *See also Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 754 n.11, 765 n. 20 (1976) (referring to FTC study concerning drug price advertising restrictions).

[19] *See Segal v. Strausser Enterprises, Inc.*, Civ. A. No. 07-4647, 2010 WL 3946284, at *3 (E.D. Pa. Oct. 7, 2010) (ordering production of "financial documentation as it pertains to [the defendant] from third parties" because this financial documentation was relevant to the defendant's claim that it "lacked the financial ability to exercise the rights of first refusal"); *Muhl v. Tiber Holding Corp.*, Civ. A. No. 95-5284, 1997 WL 13680, at *3 (E.D. Pa. Jan. 9, 1997) (faulting the plaintiff for failing to "identify the documents on which it relies in support of its piercing the veil claims"); *Pettyjohn v. Goodyear Tire & Rubber Co.*, Civ. A. No. 91-2681, 1992 WL 94895, at *8 (E.D. Pa. Apr. 20, 1992) (ordering plaintiff in personal injury action to identify the specific "documents from which he has gleaned the basis for his claims").

analysis does not make them factually relevant as defined by the rules of evidence and the rules governing civil discovery. *See Daggett v. Comm'n on Governmental Ethics and Election Practices*, 172 F.3d 104, 112 (1st Cir. 1999) (explaining that "so-called 'legislative facts,' which go to the justification for a statute, usually are not proved through trial evidence but rather by material set forth in the briefs").

2. The Expert Discovery Rules Do Not Require Disclosure of Materials the FTC Has Not Provided to Its Own Experts

Cephalon's claim that it is entitled to the discovery it seeks in order to cross examine any witness relying on the studies is likewise without basis. Rule 26 requires disclosure of materials that experts consider in the formulation of their opinions. Fed. R. Civ. P. 26(a)(2)(B); *see Synthes Spine Co. v. Walden*, 232 F.R.D. 460, 463 (E.D. Pa. 2005) (explaining that the term "considered" in Rule 26(a)(2)(B) refers to "any information furnished to a testifying expert that such an expert generates, reviews, reflects upon, reads, and/or uses in connection with the formulation of his opinions"). There is no obligation to turn over materials where the experts have "never read, reviewed or considered the subject documents in forming their opinions." *Amway Corp. v. Procter & Gamble Co.*, No. 98-CV-726, 2001 WL 1877268, at *1 (W.D. Mich. Apr. 17, 2001). *See also* Fed. R. Civ. P. 26(a)(2)(B)(ii) (Dec. 2010).

The FTC has not provided its experts with any of the materials underlying either the 2002 or the 2010 study, other than the Provigil agreements that are the subject of this litigation. Moreover, the FTC will disclose all materials considered by any testifying expert in accordance with the expert discovery schedule. If Cephalon believes that an expert cannot reasonably rely on an empirical study without examining its underlying data, it is free to try to challenge the expert's reliance on that study. *See, e.g., Viking Yacht Co. v. Composites One LLC*, 613

F.Supp.2d 637, 644-45 (D.N.J. 2009) (noting the "importance of experts examining relevant literature in forming a basis for their opinions" and explaining that the opposing party has an "opportunity to explore [the expert's] reliance on . . . scholarly works . . . via cross-examination").

B. Compelling Compliance With Cephalon's Request Would Contravene the Special Protections Congress Enacted for Businesses Submitting Confidential Information to the FTC

1. Most of the Material Cephalon Seeks Is Subject to Statutory Protections From Disclosure

Both the MMA and section 6 of the FTC Act provide special protections to companies submitting information to the FTC. Cephalon dismisses the significance of these protections in part by asserting they apply to "just a subset of the materials requested." Ceph. Mem. at 6. In fact, however, the vast majority of the responsive documents are either the compulsory submissions themselves or documents created by FTC staff that contain confidential business information submitted to the FTC pursuant to these provisions. *See supra* Part I.B. and I.C.

MMA Protections: Section 1114 of the MMA provides that any "information or documentary material" filed with the FTC shall be exempt from disclosure under the Freedom of Information Act, and that "no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding." 117 Stat. at 2463. Congress modeled the MMA's confidentiality provision on one contained in the Hart-Scott-Rodino Act ("HSR Act"), which requires merging companies to file certain transaction documents with the federal antitrust agencies prior to consummating a proposed merger.[20] In

[20] The relevant provision in the HSR Act provides:

> Any information or documentary material filed with the Assistant

the HSR context, courts have understood this non-disclosure provision to mean that the federal antitrust enforcement agencies are not permitted to disclose the filings even to state antitrust authorities.[21]

Cephalon suggests that the exception clause contained in both the MMA and the HSR Act – "except as may be relevant to any administrative or judicial action or proceeding" – authorizes this Court to order disclosure of all of the 425 MMA filings that underlie the 2010 study. Ceph. Mem. at 6. But, as discussed above, Cephalon has failed to show that MMA filings concerning drugs other than Provigil are relevant to this proceeding. Moreover, the

---

> Attorney General or the *Federal Trade* Commission pursuant to this section shall be exempt from disclosure under section 552 of Title 5, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this section is intended to prevent disclosure to either body of Congress or to any duly authorized committee or subcommittee of the Congress.

15 U.S.C. §18a(h) (emphasis added to highlight unique language).

Section 1114 of the MMA provides:

> Any information or documentary material filed with the Assistant Attorney General or the Commission pursuant to this subtitle shall be exempt from disclosure under section 552 of title 5, *United States Code*, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this section is intended to prevent disclosure to either body of the Congress or to any duly authorized committee or subcommittee of the Congress.

117 Stat. at 2463 (emphasis added to highlight unique language).

[21] *See Lieberman v. FTC*, 771 F.2d 32, 39-40 (2d Cir. 1985) ("[T]he structure and legislative history . . . show that Congress envisioned that only the Department of Justice and the FTC would use premerger information."); *Mattox v. FTC*, 752 F.2d 116, 122 (5th Cir. 1985) ("[T]he premerger provisions of HSR were not intended to make either the FTC or the Justice Department a 'clearing house for the facts' concerning mergers . . . .").

Commission's longstanding interpretation of this language in the HSR context has been that this "sweeping prohibition" against disclosure "is lifted by the exception clause *to the extent that such data actually is used* by the Commission in administrative or judicial proceedings." *In re General Motors Corp.*, 103 F.T.C. 58, 64 (1984) (emphasis added). Thus, the prohibition is lifted as to information concerning Cephalon's agreements regarding generic versions of Provigil. But the FTC has not and will not introduce any non-Provigil MMA filings (or information disclosed in such filings) in this proceeding.

Although Cephalon asserts that the pre-merger enforcement context presents unique concerns, Congress's choice to incorporate the HSR language into the MMA – after this language had been interpreted narrowly – indicates that Congress intended the exception clause in the MMA to have the same meaning. Indeed, the legislative history of the filing requirement confirms that Congress intended to provide drug companies submitting agreements to the FTC with protections "parallel" to those established under the HSR Act.[22] Moreover, the policy interests protected by the disclosure provision in the HSR Act – a balance of private confidentiality concerns with the needs of the federal antitrust agencies – apply with equal force to the MMA notification provision. Not surprisingly, Cephalon has failed to identify a single case under either statute authorizing the type of disclosure that it asks the Court to compel here.

FTC Act Section 6 Protections: Section 6 of the FTC Act likewise contains protections for companies who submit information to the FTC. Section 6(b) grants the FTC authority to

[22] The Senate Judiciary Committee Report regarding the standalone bill that was later incorporated into the MMA, S. 754, 107th Cong. (2001), explains that the disclosure provision "provides for protections of the filings made by the drug manufacturers with the antitrust agencies parallel to those protections provided in the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. 18a(h)." S. Rep. No. 107-167, at 6 (2002).

require companies to submit confidential information, while section 6(f) limits disclosure of that information where it involves "trade secret[s]" and "commercial or financial information . . . which is privileged or confidential." 15 U.S.C. § 46(f). *See TK-7 Corp. v. FTC*, 729 F.Supp. 1313, 1315 (W.D. Okla. 1990) ("15 U.S.C. § 46(f) prohibits FTC from disclosing a corporation's trade secrets except to appropriate federal or state law enforcement agencies.").

Thus, in both statutes, Congress has balanced the need to protect confidential business information submitted under compulsion of law with the FTC's need to use such information to fulfill its statutory mission. Cephalon offers no basis for the Court to override this congressional balance.

2. The Protective Order Does Not Justify Disclosure Here

A "protective order is not a substitute for establishing relevance or need." *Micro Motion, Inc. v. Kane Steel Co., Inc.*, 894 F.2d 1318, 1325 (Fed. Cir. 1990).[23] Cephalon's attempt to use the protective order as a justification for seeking confidential documents that it concedes are irrelevant to the subject matter of this case lends no support to its motion. *See King v. Hasbro*, No. 07-4001, 2009 WL 3157319, at *1 (E.D. Pa. Sept. 28, 2009) (denying discovery of certain accident reports to the Consumer Products Safety Commission where the plaintiff failed to adequately explain the relevance of the reports, particularly in light of statutory provisions for confidentiality of such reports).

[23] Even in routine civil discovery matters raising no potential threat to congressionally-protected interests, courts have acknowledged the need to consider the interests of non-parties. *See, e.g., Micro* Motion, 894 F2d at 1318; *Musarra v. Digital Dish, Inc.*, No. 2:05-CV-545, 2008 WL 4758699, at *3 (S.D. Ohio Oct. 30, 2008) (denying motion to compel because it would "impose an unreasonable burden on [a] non-party"); *Solarex Corp. v. Arco Solar, Inc.*, 121 F.R.D. 163, 179 (E.D.N.Y. 1988) (non-party status a "significant" factor in denying motion to compel identity of independent reviewer who evaluated academic manuscript for publication).

CONCLUSION

Cephalon has not demonstrated that the material it seeks is relevant within the meaning of Rule 26(b)(1). Nor has it shown any compelling basis for discovery of that information given the statutory protections that Congress has afforded to non-parties to this case. Accordingly, the FTC respectfully requests that the Court deny Cephalon's motion to compel.

Dated: January 18, 2011

/s/ *Markus H. Meier*

MARKUS H. MEIER
BRADLEY S. ALBERT
ELIZABETH R. HILDER
MICHAEL J. PERRY
Federal Trade Commission
601 New Jersey Avenue, N.W.
Washington, D.C. 20580
Tel: (202) 326-3759
Fax: (202) 326-3384

Counsel for Plaintiff Federal Trade Commission

CERTIFICATE OF SERVICE

I certify that on January 18, 2011, the foregoing Plaintiff Federal Trade Comission's Memorandum in Opposition to Cephalon's Motion to Compel was electronically filed pursuant to the court's CM/ECF system. Notice of this filing will be sent to all counsel of record by operation of the CM/ECF system.

Dated: January 18, 2011 /s/ *Michael J. Perry*