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

FEDERAL TRADE COMMISSION,	)	
Plaintiff,	)	
v.	)	Civil Action No. 2:08-cv-2141
CEPHALON, INC.,	)	
Defendant.	)	

MEMORANDUM OF LAW IN SUPPORT OF THIRD-PARTY PHARMACEUTICAL COMPANIES' MOTION FOR PROTECTIVE ORDER

Defendant Cephalon, Inc. ("Cephalon") has moved to compel the production of "all documents concerning" two studies conducted by the Federal Trade Commission (the "FTC" or "Commission") of patent litigation and settlements between branded and generic pharmaceutical manufacturers, on the grounds that the FTC may cite certain conclusions from those studies.[1] If granted, Cephalon's motion would result in the disclosure of hundreds of confidential, highly sensitive settlement agreements, contracts and related documents that have been filed with the FTC pursuant to statutory guarantees of confidentiality under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), Pub. L. No. 108-173, 117 Stat. 2006 (2003), and the Federal Trade Commission Act (the "FTCA"), 15 U.S.C. § 41 *et seq.*

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[1] Dkt No. 84 at 1. The FTC Studies are entitled *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002) ("2002 Study") and *Pay-for-Delay: How Generic Drug Company Pay-Offs Cost Consumers Billions* (January 2010) ("2010 Study").

The 37 undersigned Third-Party Pharmaceutical Companies (the "Third Parties")[2] have intervened in this litigation to seek a Protective Order prohibiting the disclosure of the confidential materials that they or their subsidiaries and affiliates have filed with the FTC under the confidentiality provisions of the MMA and the FTCA. A Protective Order barring disclosure of these materials should be entered for the following core reasons, addressed in more detail below:

- **The Materials at Issue are Highly Confidential.** Patent settlement agreements, contracts and other documents filed under the MMA and the FTCA are of the utmost commercial sensitivity. Even if these materials are designated highly confidential under the protective order, disclosure of this information to outside counsel of competitors (or to plaintiffs' class action counsel) would be highly injurious to the business and competitive interests of the Third Parties. The large number of individuals who would receive these documents significantly magnifies the risk of injury to the Third Parties from this disclosure.

- **The MMA and the FTCA Bar Disclosure of Confidential Materials.** The disclosure of these highly confidential materials is barred by the MMA and the FTCA. Neither statute allows Cephalon to seek discovery of confidential documents filed with the FTC. Further, neither statute allows disclosure of confidential materials where, as here, they are not "relevant" to the issues in the litigation.

- **The FTC Cannot Pursue a Litigation Strategy that Forces Disclosure.** The FTC is prohibited under the MMA and the FTCA from pursuing a discretionary litigation strategy that would lead to disclosure of these confidential documents, particularly when the FTC itself is not relying on them.

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[2] The Third Parties are: Abbott Laboratories; Actavis Group hf and Actavis Inc.; Almirall, S.A.; Anchen Pharmaceuticals, Inc.; Astellas Pharma Inc. and Astellas Pharma US, Inc.; AstraZeneca PLC; Bayer Healthcare Pharmaceuticals Inc.; Baxter Healthcare Corporation; Ben Venue Laboratories, Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Bristol-Myers Squibb Company; Dr, Reddy's Laboratories Inc.; Endo Pharmaceuticals Holdings Inc.; Esai Inc.; Forest Laboratories, Inc.; Fresenius Medical Care Holdings, Inc.; GlaxoSmithKline plc; Hoffmann-La Roche Inc.; Impax Laboratories, Inc.; Johnson & Johnson; King Pharmaceuticals, Inc.; Lupin Limited and Lupin Pharmaceuticals, Inc.; Merck Sharp & Dohme Corp., formerly known as Merck & Co., Inc.; Novartis Corp. and Novartis Pharmaceuticals Corp.; Paddock Laboratories; Par Pharmaceuticals, Inc.; Pfizer Inc.; Purdue Pharma L.P.; Roxane Laboratories, Inc.; Sandoz Inc.; sanofi-aventis US LLC; Shire LLC; Sunovion Pharmaceuticals, Inc., formerly known as Sepracor, Inc.; Upsher-Smith Laboratories, Inc.; URL Pharma, Inc.; Watson Pharmaceuticals, Inc.; and Wockhardt Limited and Wockhardt USA LLC.

- **Cephalon Has Not Sufficiently Demonstrated a Need for These Materials.** Likewise, Cephalon has failed to make any substantial showing that it needs these confidential materials to respond to the FTC Studies. Cephalon's motion should be rejected for failure to make a sufficiently detailed and concrete showing of need to support such a damaging disclosure of the Third Parties' competitively sensitive information.

* * *

In short, it would be highly unfair and injurious to the business and confidentiality interests of the Third Parties, and contrary to the statutory requirements of the MMA and the FTCA, if their confidential submissions were subjected to disclosure in this litigation. To drag practically the entire pharmaceutical industry into such a situation -- all for a litigation challenge to a single set of settlement agreements involving a single product entirely unrelated to the Third Parties' MMA and FTCA materials -- would defy common sense and basic fairness.[3]

STATUTORY BACKGROUND: THE MMA AND FTCA CONFIDENTIALITY PROVISIONS

Cephalon's request for the broad disclosure of materials related to the FTC's 2010 Study implicates a wide range of agreements and materials filed by the Third Parties with the FTC under the MMA requirements. Under the MMA, pharmaceutical companies that enter into agreements to settle patent litigation must generally file those agreements and related materials with the FTC and the Department of Justice. Pub. L. No. 108-173, § 1112, Stat. 2006 (2003). The MMA also requires the filing of other business agreements related to

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[3] The specific relief sought by this Motion is a protective order barring the disclosure of confidential materials that the Third Parties and their subsidiaries and affiliates have filed with the FTC under the MMA and FTCA. However, the policy and statutory arguments presented here are equally applicable to the confidential MMA and FTCA filings of other pharmaceutical companies that have not intervened.

patent settlements, which can include supply agreements, co-promotion contracts, or other agreements involving highly sensitive and proprietary business terms.

The MMA includes broad confidentiality protections for the filings that it requires. Section 1114 of the MMA provides that "[a]ny information or documentary material filed with the [Department of Justice] or the [FTC] pursuant to this subtitle shall be exempt from disclosure under [the Freedom of Information Act], and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding." Pub. L. No. 108-173, § 1114, 117 Stat. 2006 (2003).

The MMA confidentiality language is identical to that found in the Hart-Scott-Rodino ("HSR") Act, 15 U.S.C. § 18a(h), which requires parties to file merger and acquisition agreements and related materials with the FTC and Department of Justice. The MMA's legislative history specifically reflects Congress's intention to incorporate the confidentiality provisions of the HSR Act. *See* S. Rep. No. 107-167, 2002 WL 1350511, at *6 (June 20, 2002) (the MMA "provides for protections of the filings made by the drug manufacturers with the antitrust enforcement agencies parallel to those protections provided in the Hart-Scott-Rodino Antitrust Improvements Act") (emphasis added). By adopting confidentiality language identical to that in the HSR Act, Congress clearly intended to apply the same legal standards to the MMA confidentiality provisions as had been developed under the HSR Act. *See Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 85 (2006) ("when judicial interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute indicates, as general matter, that the intent is to incorporate its . . . judicial interpretations as well").

Under the HSR Act, the FTC has ruled that the identical confidentiality language found in the MMA -- "no such information or documentary material may be made

public, except as may be relevant to any administrative or judicial action or proceeding" -- means that the "sweeping prohibition" against disclosure "is lifted by the exception clause" only if confidential information "actually is used by the Commission in administrative or judicial proceedings." *General Motors Corp.*, 103 F.T.C. 58, 64 (1984) (emphasis added). Similarly, the Second Circuit has held that "the structure and legislative history of [the HSR confidentiality provisions] show that Congress envisioned that only the Department of Justice and the FTC would use premerger information." *Lieberman v. FTC*, 771 F.2d 32, 39 (2d Cir. 1985) (emphasis added). *See also Mattox v. FTC*, 752 F.2d 116, 121-24 (5th Cir. 1985) (precluding disclosure of HSR filings to state attorneys general and finding that the statute "favors confidentiality over disclosure in uncertain cases").

Cephalon's request for materials related to the 2002 Study would involve information submitted to the FTC pursuant to Section 6(b) of the FTCA, which provides the FTC with authority to require pharmaceutical companies to file annual or special reports answering the FTC's specified questions. *See* 15 U.S.C. § 46(b). Under Section 21(c) of the FTCA, materials submitted to the FTC under Section 6(b) "shall be considered confidential when so marked by the person supplying the information and shall not be disclosed." 15 U.S.C. § 57b-2(c). Materials marked confidential under Section 21(c) may be disclosed only when "relevant and material to" to judicial proceedings "to which the Commission is a party." 15 U.S.C. § 57b-2(d)(1)(C).

This confidentiality language under the FTCA is similar to the confidentiality provisions of the HSR Act, but adopts an even stricter standard of confidentiality because it adds a requirement of materiality. It should thus be read to bar at least the same disclosures also barred by the HSR provisions. Like the HSR provisions, the confidentiality provisions in the FTCA facilitate the FTC's reporting and investigatory authority by ensuring the

confidentiality of information submitted under the statute. As a corollary, private litigants cannot have access to confidential information obtained by the Commission pursuant to the powers granted by the FTCA. *See Texas Industries, Inc.*, 67 F.T.C. 1378, 1380 (1965) ("the Section 6(b) procedure for obtaining information and data is an extraordinary power vested in the Federal Trade Commission" and a private party "may not compel the Commission to turn over to him the fruits of such a survey where it has not been conducted by the Commission for the purpose of aiding in the prosecution of the case against" that party); *Union Bag-Camp Paper Corp. v. FTC*, 233 F. Supp. 660, 666 (S.D.N.Y. 1964) ("[T]he exercise of the procedure outlined in 6(b) was reserved exclusively to the F.T.C. in its function as a protector of the public interest. There is no indication that this extraordinary power was ever meant to be utilized by a private party to an enforcement proceeding.").

In short, the confidentiality provisions of both statutes are clearly meant to allow the FTC to introduce an MMA or FTCA filing in litigation that challenges a particular filed agreement. Neither statute provides a basis for the Commission to disclose confidential information in an unrelated litigation where the filed material is not "relevant." We are aware of no authority or example of such disclosure having occurred. In this litigation, the FTC is permitted to use the MMA or FTCA materials related to the modafinil agreements, but not MMA or FTCA filings involving other drugs, other companies and other settlement agreements that are not at issue and thus are not "relevant" or "material." Further, neither statute includes any provision that allows private litigants such as Cephalon to seek discovery of confidential materials filed under the MMA or FTCA.

ARGUMENT

I. THE COURT SHOULD ENTER A PROTECTIVE ORDER BARRING THE FTC FROM DISCLOSING CONFIDENTIAL MMA AND FTCA MATERIALS IN THIS LITIGATION.

Under Fed. R. Civ. P. 26(c)(1)(G), the Court may issue an order "requiring that a trade secret or other confidential, research, development, or commercial information not be revealed or be revealed only in a specified way." *See also* FTC Rule of Practice 4.10(g), 16 C.F.R. § 4.10(g) ("Prior to disclosure of such [confidential] material in a proceeding, the submitter will be afforded an opportunity to seek an appropriate protective or *in camera* order.").

For the reasons addressed below, the Court should deny Cephalon's motion to compel and enter a protective order barring the FTC from disclosing confidential MMA or FTCA materials filed by the Third Parties or their subsidiaries or affiliates.

A. The MMA and FTCA Materials Contain Highly Sensitive Information, and Disclosure Would Cause Substantial Harm to the Third Parties.

As required by the MMA, the Third Parties have filed numerous patent settlement agreements and many other related agreements with the FTC and Department of Justice. More than 250 such agreements have been filed since the MMA was enacted in 2003, and the FTC has indicated that more than 70 different pharmaceutical companies filed settlement agreements in FY 2010 alone.[4] Likewise, for purposes of the 2002 Study, the FTC required the submission of all agreements since 1994 between branded and generic drug companies, including but not limited to patent settlement agreements and related information on costs and sales of generic drugs.[5]

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[4] Letter from Bradley S. Albert to Mark A. Ford (Dec. 7, 2010) (Ex. 1 at 2, 5).

[5] *See* 2002 Study, at A-20-23.

According to the FTC, the total number of settlement agreements sought by Cephalon's motion is "significantly higher" than 250 for the two-decade period covered by the motion to compel.[6] While the legality of these settlement agreements or related agreements is not at issue in this litigation, all are within the scope of Cephalon's motion to compel because (according to the FTC) they were source materials for the FTC Studies.[7]

The settlement agreements and related materials filed under the MMA and FTCA contain highly sensitive and proprietary business information. They include supply agreements, co-promotion contracts, licensing terms, royalty rates, and conditions on entry by competitors. Almost any patent settlement agreement includes confidential business provisions that are secret and, if disclosed, would be highly injurious to the parties to that agreement. For example, the terms by which one pharmaceutical company is licensed by another to make and sell a drug product -- including the royalties it must pay, the scope of its license rights, and whether and when those license rights go into effect or expire -- are highly sensitive commercial secrets that are held in strict confidence. Settlement and license agreements may also reveal the terms of authorized generic agreements, including dates of entry or exit. Supply agreements filed under the MMA may include highly sensitive information on the price by which one company will supply finished products or active ingredients to another. Co-promotion agreements filed under the MMA may reflect royalty rates and other consideration being paid by one company to other. This is highly sensitive

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6 Letter from Bradley S. Albert to Mark A. Ford (Dec. 7, 2010) (Ex. 1 at 5).

7 Letter from Bradley S. Albert to Outside Counsel (Dec. 20, 2010) (Ex. 2 at 1).

commercial information. Disclosure of these and other terms would harm not only the parties to those agreements, but also the public interest in competition.[8]

Cephalon argues that the terms of the protective order governing this litigation are sufficient to protect any such commercial information. However, under the protective order, disclosure would be made to outside counsel (and their experts) who represent the competitors of the Third Parties. This includes counsel for Cephalon as well outside counsel in the related civil litigation (where the defendants include Barr, Teva, Ranbaxy and Mylan, and Apotex is a plaintiff).

All of these parties to the litigation are significant competitors of the Third Parties. Their outside counsel have been, are now or in the future likely will be involved in representing these parties in matters adverse to the Third Parties. In particular, the Third Parties are regularly involved in patent litigation with one or more of these competitors, which includes pending litigation between some of the Third Parties and some of these competitors.

Further, outside counsel for these competitors (including Cephalon, Apotex, Barr, Teva, Ranbaxy and Mylan) have been, are now or in the future likely will be involved on behalf of their clients in negotiating the terms of patent settlements in different matters with various Third Parties, advising on the terms of licenses, and providing other advice where their knowledge of the Third Parties' confidential MMA and FTCA materials would provide an unwarranted and unfair competitive advantage. Experts retained by outside counsel would also obtain access to the Third Parties' confidential information; and such experts are reasonably likely to be retained in future litigation adverse to the Third Parties.

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[8] For example, depending on the circumstances, competition could be harmed by disclosure of proprietary information on costs, royalty rates, supply prices, or the terms of entry and exit.

The concern about disclosure to competitors' outside counsel is particularly significant in this context, which involves litigation settlements and settlement negotiating strategy, areas in which these outside counsel are or likely will be heavily involved in matters adverse to the Third Parties. Disclosure to these outside counsel of royalty terms, the structure of profit-sharing agreements, most-favored-nations clauses, the financial terms of settlements, agreed-upon entry dates and other proprietary terms will place the Third Parties at a significant competitive disadvantage when dealing with these outside counsel now or in the future. The FTC itself has acknowledged these concerns. *See* Letter from Bradley S. Albert to Mark A. Ford (Dec. 7, 2010) (Ex. 1 at 3) ("[E]ven if designated as 'highly confidential' under the terms of the protective order, the private patent settlement documents and related business transactions of dozens of pharmaceutical companies would be turned over to their competitors' lawyers (some of whom might be found on the other side of future settlement and business negotiations) as well as to numerous class action lawyers who routinely sue pharmaceutical companies for anticompetitive behavior.").

It is not plausible to expect that these outside counsel for the Third Parties' competitors or their experts could separate the information gained in this discovery from the general body of knowledge on which they rely in representing their clients in matters adverse to the Third Parties. *See, e.g., Mikohn Gaming Co. v. Acres Gaming Inc.*, No. CV-S-97-1383, 1998 WL 1059557, 50 U.S.P.Q. 2d 1783, 1784 (D. Nev. Apr. 15, 1998) (where counsel acted as both a company's outside litigation counsel and patent prosecution counsel, a protective order could not prevent inadvertent disclosure of confidential information); *Motorola, Inc. v. Interdigital Tech. Co.*, No. 93-488, 1994 WL 16189689, at *4 (D. Del. Dec. 19, 1994) (counsel acting as both a company's outside litigation counsel and patent prosecution counsel

could not be expected to "distill and compartmentalize" confidential information in order to prevent its use).

Further, this disclosure of highly confidential patent settlements and other related materials would also be made to outside counsel for the plaintiffs the class actions pending before the Court as part of this litigation. Those outside counsel, whose business model is based on finding companies to sue, are regularly involved in antitrust litigation against pharmaceutical companies on subjects that are interrelated with the subjects of the MMA and FTCA materials. Again, it is not plausible that these plaintiffs' counsel or their experts could segregate the information gleaned from the MMA and FTCA materials from other matters they handle now or that they might commence in the future against the Third Parties.

The risk of significant harm to the Third Parties' commercial interests is, furthermore, greatly magnified by the large number of outside counsel and experts to whom disclosure would be made. With so many counsel and experts receiving this information, this significantly intensifies the risk of improper (even if inadvertent) use of the Third Parties' proprietary information, and the risk that such disclosure thus translates into concrete harm to the Third Parties.

Under these circumstances, disclosure of these highly sensitive MMA and FTCA materials would cause unfair and unwarranted injury to the business interests of the Third Parties. A protective order precluding this disclosure should be entered to protect the Third Parties' confidential materials and to prevent this competitive harm. *See, e.g., Bimbo Bakeries USA, Inc. v. Botticella*, 613 F.3d 102, 118 (3d Cir. 2010) (precluding discovery where disclosure of trade secrets to competitor would create a "competitive disadvantage"); *OSHA Data/CIH, Inc. v. U.S. Dept. of Labor*, 220 F.3d 153, 166 (3d Cir. 2000) (Department

of Labor appropriately refused disclosure of information to competitors that "could cause . . . substantial competitive harm"); *Miles v. Boeing Co.*, 154 F.R.D. 112, 114 (E.D. Pa. 1994) ("it is clear that a court may issue a protective order restricting the disclosure of discovery materials to protect a party from being put at a competitive disadvantage").

B. The Statutory Confidentiality Provisions Bar Cephalon's Demand for MMA and FTCA Materials.

The MMA and FTCA do not permit this injury to the legitimate confidentiality interests of the Third Parties. One simple point is fully dispositive: The statutes bar a private litigant such as Cephalon from seeking confidential MMA and FTCA materials in discovery.

The only exception to the MMA's "sweeping prohibition" against the disclosure of confidential materials, the FTC has ruled, is where such information "actually is used by the Commission in administrative or judicial proceedings." *General Motors*, 103 F.T.C. at 64 (emphasis added).[9] Similarly, under the FTCA, the FTC has ruled that a private litigant "may not compel the Commission to turn over" materials filed under Section 6(b) if not compiled "for the purpose of aiding in the prosecution of the case against" that party. *Texas Industries*, 67 F.T.C. at 1380.[10]

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[9] As discussed above (pages 4-5), the *General Motors* case and other authorities cited in this section are addressed specifically to the confidentiality language found in the HSR Act. However, because the confidentiality language of the HSR Act is identical to that found in the MMA, the case law construing the HSR confidentiality requirements controls the construction of the MMA confidentiality provisions. *See, e.g., Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 85 (2006). Cephalon's contention that the HSR case law can be distinguished because those cases involved potential disclosure to different types of parties ignores that the confidentiality provisions are designed to protect the submitting parties, and thus should not turn on the party seeking disclosure.

[10] Under standard principles of *Chevron* deference, this Court is bound to defer to these reasonable constructions by the FTC of the statutory limits on its own authority. *National Railroad Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407, 417 (1992) ("Judicial deference to reasonable interpretations by an agency of a statute that it administers is a dominant, well-settled principle of federal law.").

Here, the FTC has itself stated that the "requested MMA underlying settlement materials do not relate to the conduct which gave rise to this action, are not part of the Commission's modafinil investigative file, and will not be used by the Commission in this action."[11] Thus, the FTC will not use or introduce the Third Parties' confidential settlement agreements or other MMA and FTCA materials in seeking to prove that Cephalon violated the antitrust laws. Accordingly, given the FTC's position, the statutory exception where MMA materials are "actually . . . used by the Commission" has not been triggered. Likewise, the FTCA exception for disclosure of "a survey . . . conducted by the Commission for the purpose of aiding in the prosecution of the case against" that party has not been triggered.

Instead, Cephalon is seeking to use the discovery mechanisms of the Federal Rules of Civil Procedure to obtain material that is shielded from disclosure under the MMA and FTCA. Neither statute, however, contains an exception permitting use by other parties (i.e., other than the FTC or DOJ) in a civil action. Rather, under the MMA and FTCA, the only confidentiality exception is if the FTC uses the material itself. *See Lieberman*, 771 F.2d at 39 ("Congress envisioned that only the Department of Justice and the FTC would use" information filed under the MMA confidentiality provisions) (emphasis added); *Union Bag-Camp Paper Corp.*, 233 F. Supp. at 666 ("[T]he exercise of the procedure outlined in 6(b) was reserved exclusively to the F.T.C. in its function as a protector of the public interest. There is no indication that this extraordinary power was ever meant to be utilized by a private party to an enforcement proceeding.") (emphasis added).

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[11] Letter from Bradley S. Albert to Mark A. Ford (Dec. 7, 2010) (Ex. 1 at 5).

Thus, Cephalon's motion should be denied on this basis alone. The FTC is barred by statute from producing MMA or FTCA materials in response to a private litigant's discovery request.

C. The MMA and FTCA Bar Disclosure of these Materials Because They Are Not "Relevant" to this Litigation.

There is also a second statutory bar to disclosure of these MMA and FTCA materials.

Under the MMA, "no such information or documentary material may be made public" unless it is "relevant to any administrative or judicial action or proceeding." 117 Stat. 2066, § 1114 (emphasis added). Similarly, materials designated as confidential under Section 21(c) of the FTCA may only be disclosed if they are "relevant and material" to a judicial proceeding. 15 U.S.C. § 57b-2(d)(1)(C) (emphasis). Thus, without the requisite demonstration that this information is "relevant" to the litigation, the statutes bar disclosure of MMA or FTCA materials.

The MMA and FTCA materials at issue here, as noted, consist of substantially more than 250 settlements agreements (and related agreements and materials) filed by companies throughout the pharmaceutical industry. These filings have nothing to do with the Provigil/Modafinil agreements, or the patents or product markets at issue here. The only reason these materials are requested by Cephalon is that the FTC and private plaintiffs apparently intend to refer to certain conclusions from the FTC Studies, which in turn were based (at least in part) on the Third Parties' confidential materials.

The FTC's general views about patent settlements and patent litigation in the pharmaceutical industry, as expressed in the studies, have no relevance to any issue in this litigation. The FTC's studies do not tend to show that the specific modafinil agreements at issue here are unlawful. Nor do they help prove the likely outcome of Cephalon's patent

claims or that generic modafinil would have entered the market sooner absent the agreements. Nor do they address the specific agreements at issue in this litigation or the specific competitive issues raised by these agreements. Even Cephalon recognizes that the FTC's studies are irrelevant.[12]

In any event, the relevance of the FTC studies is one step removed from the relevance of the Third Parties' MMA and FTCA materials. Whether or not the Court finds the FTC studies admissible, the statutory confidentiality provisions do not permit disclosure of MMA and FTCA filings unless those are "relevant" (or "relevant" and "material") to this litigation. And this point is definitively resolved by the FTC's own statement that these MMA and FTCA materials "do not relate to the conduct which gave rise to this action" and "are not part of the Commission's modafinil investigative file."[13] In short, the FTC has acknowledged that these MMA and FTCA materials are not "relevant" to this litigation. These filings involving other products, other markets and other settlement agreements are simply not related to the issues presented in this litigation.

Accordingly, the Third Parties' confidential materials do not satisfy the "relevance" requirements found in the MMA and FTCA. *See* 117 Stat. 2066, § 1114.; 15 U.S.C. § 57b-2(d)(1)(C). Disclosure is therefore barred as a matter of law under both statutes.

D. The FTC Is Precluded Under the MMA and the FTCA from Pursuing a Discretionary Strategy that Would Trigger the Disclosure of MMA and FTCA Materials.

The foregoing two arguments establish why, as a matter of law, the MMA and the FTCA bar disclosure of these settlement agreements and related materials: (a) Cephalon

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[12] Dkt. No. 84, n.4.

[13] Letter from Bradley S. Albert to Mark A. Ford (Dec. 7, 2010) (Ex. 1 at 5) (emphasis added).

as a private litigant cannot obtain these materials in discovery; and (b) the statutes bar disclosure of these materials because they are not "relevant" to this litigation (and in fact the FTC has specifically stated they are not relevant).

There is, in addition, yet a further reason why these statutes bar disclosure of these MMA and FTCA materials: The statutes do not allow the FTC to use a voluntary litigation tactic to sidestep its obligation to preserve the confidentiality of MMA and FTCA materials -- especially in litigation having nothing to do with the filings that would be disclosed.

Thus, if the Court concludes that the FTC's insistence on using conclusions from the FTC Studies opens the door to disclosure of confidential MMA and FTCA materials, the FTC should be barred from continuing to rely on the FTC Studies in this case. The FTC's discretionary decision to cite its studies is barred by statute if the consequence is a compelled disclosure of confidential MMA and FTCA materials that the FTC itself does not rely upon in litigation.

This conclusion follows, again, from the "sweeping prohibition" against disclosure of MMA and FTCA materials embodied in the confidentiality provisions of both statutes. *See General Motors*, 103 F.T.C. at 64 (construing identical HSR Act language). In particular, the FTC itself has recognized that the confidentiality language in the MMA is intended to prohibit the "discretionary" disclosure of confidential information. *Id.* at 64. The same principle is embedded in the FTCA confidentiality provisions.

The motion to compel is precipitated by the prospect that the FTC will seek to introduce or rely on its studies in this litigation, while disclaiming reliance on the Third Parties' confidential MMA and FTCA materials. In these circumstances, a compelled disclosure of those MMA or FTCA materials would be by definition "discretionary" if the

FTC persists in this litigation tactic. The FTC would be making a choice to continue to rely on its studies, and if the Court rules that that choice necessitates disclosure of confidential MMA and FTCA materials, then the disclosure would necessarily be the result of the FTC's exercise of its discretion. Put another way, under its own precedent, the FTC cannot take a "discretionary" action, *General Motors*, 103 F.T.C. at 64, that would force disclosure of MMA and FTCA materials.[14]

The conclusion that the FTC cannot rely on these studies at the price of forced disclosure of confidential materials is only amplified by the fact that these studies (as discussed above) have no relevance to proving an antitrust violation in this case. The FTC studies are so far removed from proving an antitrust violation against Cephalon that the Court should refuse to permit this discretionary litigation tactic to proceed. The costs of the FTC's strategy to the Third Parties, and the competitive damage that will be inflicted across the entire industry, are simply not justified by the limited benefit that the Studies would provide in this case.

E. Cephalon Has Not Made a Sufficient Showing To Support Overriding the Confidentiality of These MMA and FTCA Materials.

Even putting aside the fact that disclosure is barred under the terms of the MMA and the FTCA, Cephalon has failed to establish that its need for the MMA and FTCA

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[14] The fact that the private plaintiffs also rely on the FTC studies does not justify disclosure, since the studies are no more relevant to the private cases than the FTC's, and since material submitted to government agencies under confidentiality protections is intended for the use of the government and not private litigants. *See, e.g.*, 15 U.S.C. § 57b-2(d)(1)(C) (prohibiting disclosure of confidential material unless it is "relevant and material" to judicial proceedings "to which the Commission is a party") (emphasis added); *Lieberman*, 771 F.2d at 39 ("the structure and legislative history of [the HSR confidentiality provisions] show that Congress envisioned that only the Department of Justice and the FTC would use premerger information") (emphasis added); *Union Bag-Camp Paper Corp.*, 233 F.Supp. at 666 ("this extraordinary power [of FTCA Section 6(b)] was [not] meant to be utilized by a private party").