ORIGINAL

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In re
CEPHALON, INC. (File No. 0610182)

C4121

PETITION TO QUASH
CIVIL INVESTIGATIVE DEMAND DATED JULY 7, 2009

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Dated: July 22, 2009

PUBLIC

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I. Introduction

Pursuant to 15 U.S.C. § 57b-1(f) and 16 C.F.R. § 2.7(d), Cephalon, Inc. ("Cephalon") hereby petitions to quash the Civil Investigative Demand issued by the Federal Trade Commission (the "Commission") on July 7, 2009 ("2009 CID").[1] For the reasons described below, the Commission's authority to use compulsory process under Part II of the Commission's Rules of Practice terminated with respect to Cephalon when the Commission filed a complaint against Cephalon in federal court on February 13, 2008. The Commission cannot now attempt to circumvent the judicial process it initiated by retreating to procedural tools available to it only in its investigative role. The Commission should quash the 2009 CID as outside the scope of the agency's authority.

II. Factual and Procedural Background

The 2009 CID contains three specifications, each of which relates to purported agreements or communications between Cephalon Redacted [redacted] The 2009 CID is based on the Commission's August 30, 2006 Resolution in File No. 0610182, which authorized the use of compulsory process to determine whether Cephalon and several generic drug manufacturers, Redacted [redacted], had "engaged in any unfair methods of competition ... by entering into agreements regarding any modafinil products." *See* Commission Resolution Authorizing Use of Compulsory Process in a Nonpublic Investigation, File No. 0610182 (Aug. 30, 2006) ("Resolution").[2] On December 24, 2002, four generic pharmaceutical companies filed Abbreviated New Drug Applications ("ANDAs") for generic

[1] After consultation with the Office of the Secretary, Cephalon understands that it need not provide copies of documents that are part of the investigative record in File No. 0610182. Bates numbers are provided where applicable. Confidential courtesy copies of these documents will be provided upon request.

[2] For purposes of this Petition, the investigation leading up to the filing of the complaint is referred to as the "Modafinil Investigation."

versions of Cephalon's wakefulness drug, Provigil, with the Food and Drug Administration ("FDA"). *See* Complaint for Injunctive Relief ¶ 36, *F.T.C. v. Cephalon, Inc.*, No. 08 Civ. 2141 (E.D. Pa.), *originally filed in* 08 Civ. 244 (D.D.C. Feb. 13, 2008) ("FTC Provigil Complaint"). The four first-filers – Teva Pharmaceuticals, Inc. ("Teva"), Ranbaxy Laboratories, Inc. ("Ranbaxy"), Mylan Pharmaceuticals Inc. ("Mylan"), and Barr Laboratories, Inc. ("Barr") – each served Cephalon with "paragraph IV" notifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000), alleging that U.S. Patent Reissue No. RE37,516 (the "'516 patent") was invalid, and/or not infringed. FTC Provigil Complaint ¶ 36. On March 28, 2003, Cephalon filed patent infringement claims against each of these four first-filers. *Id.* at ¶ 41. Near the conclusion of summary judgment briefing, between December 2005 and February 2006, Cephalon separately entered into patent litigation settlements with each of the four first-filers granting them a license to market their products in 2012, several years before patent expiration, with even earlier marketing possible under certain circumstances. *Id.* at ¶¶ 42-45, 60, 64, 69, 72.

Approximately two years after the initial filings, on January 10, 2005, Carlsbad filed a paragraph IV ANDA challenging the '516 patent, and Cephalon timely sued Carlsbad for patent infringement. *See* Complaint, *Cephalon, Inc. v. Carlsbad Technologies, Inc.*, No. 05 Civ. 1089 (D.N.J.) (CFTC-S 030797 – CFTC-S 030821). On August 2, 2006, Cephalon settled with Carlsbad and its ANDA partner Watson, dismissing its infringement claims and granting Carlsbad and Watson a license to sell their generic product beginning three years before expiration of the '516 patent (subject to other conditions allowing for even earlier entry). *See*

Settlement and License Agreement between Cephalon, Inc. and Carlsbad Tech., Inc. (Aug. 2, 2006) (the "Carlsbad/Watson Settlement") (CFTC-ES_00206171 - CFTC-ES_00206200).[3]

After the Commission issued the August 30, 2006 Resolution, the staff engaged in a lengthy investigation in which – as set forth in detail in Part III.B *infra* – it sought documents, information, and testimony from Cephalon concerning the Redacted [redacted] Based on the Specifications of the 2009 CID, the Commission apparently believes or suspects that Redacted [redacted]. *See, e.g.*, 2009 CID, Specification 2 Redacted [redacted]).

[3] Cephalon's patent settlements with Teva, Ranbaxy, Mylan, Barr, and Carlsbad/Watson are collectively referred to as the "Provigil Settlements."

[4] Redacted [redacted]

On February 13, 2008, the Commission filed a complaint against Cephalon in the United States District Court for the District Columbia, alleging that the settlement agreements with the four first-filers restrained competition in violation of section 5 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45. FTC Provigil Complaint ¶ 85. Redacted

On April 28, 2008, Judge Bates issued an order transferring the Commission's case against Cephalon to the United States District Court for the Eastern District of Pennsylvania pursuant to 28 U.S.C. § 1404(a). *See* Order, Docket No. 14, No. 08 Civ. 244 (D.D.C.) On May 2, 2008, Cephalon moved to dismiss the Commission's complaint. Motion to Dismiss by Cephalon, Inc., No. 08 Civ. 2141 (E.D. Pa.), *originally filed in* 08 Civ. 244 (D.D.C.). The motion is fully briefed and pending before the court. A status conference before Judge Goldberg (to whom the case was recently transferred) is scheduled for July 28, 2009. Order, Docket No. 20, No. 08 Civ. 2141 (E.D. Pa.).

On July 7, 2009, the staff issued the 2009 CID, demanding further information about the Redacted. *See* Letter from Markus H. Meier, Assistant Director, F.T.C., to James C. Burling, Wilmer Cutler Pickering Hale and Dorr LLP (July 7, 2009) (stating that the CID seeks information about whether Redacted

[redacted]

III. Argument

A. The Commission's Investigation Effectively Ended When the Agency Filed a Complaint Against Cephalon in Federal Court.

The Commission cannot resurrect its investigation of Cephalon after instituting federal court litigation based on its prior investigation of the same subject — [redacted]. If the Commission wants to question Cephalon on this point, or seeks related documents, it must pursue discovery in the federal court action.

The FTC Act permits the staff to use investigative compulsory processes (such as CIDs) only until the Commission institutes an adjudicative proceeding. In particular, section 20 of the FTC Act provides that investigative compulsory process may be used "*before* the institution of any proceedings[,]" 15 U.S.C. § 57b-1(c) (2009) (emphasis added), and expressly excludes the use of such tools from any *adjudication* under the FTC Act or any other provision of law, 15 U.S.C. § 57b-1(j) (2009) (emphasis added). In addition, courts have recognized that there is a "shift" from investigative rules to adjudicative rules once a complaint issues. *Genuine Parts Co.*

v. F.T.C., 445 F.2d 1382, 1388 (5th Cir. 1971). *See also United States v. Associated Merchandising Corp.*, 261 F. Supp. 553, 558 (D.C.N.Y. 1966) ("[I]t is the adjudicative rules, not the investigative ones, which are to govern once a complaint has issued."); *Hannah v. Larche*, 363 U.S. 420, 446 (1960) (stating that the Commission's "rules draw a clear distinction between adjudicative proceedings and investigative proceedings"); *Standard Oil Co v. F.T.C.*, 475 F. Supp. 1261, 1268 (N.D. Ind. 1979) (same); *General Motors Corp. v. F.T.C.*, No. C77-706, 1977 WL 1552 (N.D. Ohio Nov. 4, 1977) (same).[5]

This limitation on the agency's investigative powers, embodied in the FTC Act, serves a basic fairness purpose and is driven by due process principles. See *Hannah*, 363 U.S. at 446; *F.T.C. v. Atlantic Richfield Co.*, 567 F.2d 96, 102 (D.C. Cir. 1977) ("[R]egulatory agencies have an obligation to keep [investigative and adjudicative] roles separate insofar as is possible, in order to insure the judicial fairness of adjudicative proceedings and also the unrestricted vigor of investigative proceedings.").

Accordingly, because the Commission ended its investigation of Cephalon by filing an action in federal court, its authority to issue a CID—an investigative tool that may not be used in "any adjudicative proceeding under any . . . provision of law[,]" 15 U.S.C. § 57b-1(j)—terminated with respect to Cephalon. Rather, the Commission must seek discovery pursuant to the Federal Rules of Civil Procedure. *See Turner*, 609 F.2d at 745 n.3.

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[5] *F.T.C. v. Waltham Watch Co.*, 169 F. Supp. 614, 620 (S.D.N.Y. 1959), is not to the contrary because the Complaint is not limited to allegations of "specific and limited violations[.]" Rather, the Complaint encompasses Cephalon's relationship with any generic drug company that might have [redacted], which the Commission [redacted]. *See* FTC Provigil Complaint ¶ 88; 2009 CID Specifications 1-3.

While these cases arise in the context of Part III adjudicative proceedings, the principle is the same where the Commission has brought a civil rather than an administrative complaint. *See F.T.C. v. Turner*, 609 F.2d 743, 745 n.3 (5th Cir. 1980) ("Although the Federal Rules of Civil Procedure do not bind administrative agencies in conducting purely administrative investigations, administrative agencies are unquestionably bound by the rules when they are parties in civil actions." (internal citation omitted)).

B. Contrary to the Staff's Assertions, the CID Seeks Information Relating to the Subject Matter of the Earlier Investigation and the Pending Lawsuit Against Cephalon.

Recognizing that it cannot both investigate and litigate with Cephalon on the same subject matter, the staff attempts to justify the 2009 CID by claiming it is unrelated to the Complaint. Specifically, the staff contends that the Complaint does not expressly mention the Redacted [redacted]. *See* Letter from Markus H. Meier to James C. Burling (July 7, 2009). This position is fundamentally flawed.

First, the Complaint Redacted [redacted]

Second, the investigation culminating in the Complaint covered the Redacted [redacted] in depth. The Resolution expressly includes Redacted [redacted]

On March 15, 2007, the Commission issued a Subpoena *Duces Tecum* to Cephalon (the "2007 Subpoena"). Its 40 specifications directed Cephalon to produce a wide array of

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[6] The Resolution uses each company's full legal name.

documents related to the Provigil Settlements and also requested documents related to [redacted].[7] In response to the 2007 Subpoena, Cephalon produced the [redacted], several earlier drafts [redacted], and thousands of documents and emails referencing [redacted] [redacted] Declaration of Wendy A. Terry ("Terry Decl.") ¶ 2.

On April 26, 2007, the Commission issued a Civil Investigative Demand to Cephalon ("2007 CID"). No fewer than 49 specifications directed Cephalon to identify and produce documents and other information on, among other things, the negotiations and scope of the agreements with the generic ANDA filers, including [redacted].[8] Cephalon's response to the 2007 CID includes significant information about [redacted]. *See* Cephalon's responses to 2007 CID specifications 1-3, 5, and 11; Terry Decl. ¶¶ 4, 6-7. Indeed, the staff recognizes that documents responsive to the 2009 CID may have been produced in response to the 2007 Subpoena or 2007 CID.[9]

Finally, the staff examined five Cephalon witnesses about [redacted]. Witnesses who testified [redacted]. *See* Transcript of John E. Osborn at 378:18-400:20, *In re Cephalon, Inc.*, Matter No. 0610182, (Vol. 2, June 6, 2007); Transcript of Randall J. Zakreski at 190:2-15, *In re Cephalon, Inc.*, Matter No. 0610182, (Vol. 1, June 28,

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[7] The 2007 Subpoena defined the settlements and business transactions jointly as "Generic Agreements"—a [redacted]

[redacted]

[redacted]

[9] Instruction 3 of the 2009 CID states: "[w]here Cephalon has previously produced documents responsive to this CID, Cephalon need not produce another copy of the document but may instead identify responsive documents by Bates number."

2007); Transcript of Randall J. Zakreski at 344:1-373:24, *In re Cephalon, Inc.*, Matter No. 0610182, (Vol. 2, June 29, 2007). Cephalon also believes that the staff issued compulsory process to Redacted produced documents in response to staff requests.[10]

The Commission cannot justify the 2009 CID by claiming there has been a change in circumstance since the Complaint was filed that requires a new factual investigation. First, the 2009 CID expressly seeks documents dating back to March 15, 2007 – nearly a year before the Commission filed the Complaint. 2009 CID Instruction 1. Moreover, the 2009 CID appears to focus on Redacted , was plainly within the scope of the Commission's investigatory Resolution, Redacted . Moreover, the Commission knew or should have known Redacted well before it filed the Complaint in February 2008. Redacted both during the investigatory phase. *See supra* Part II.

In fact, the Commission specifically focused on the Redacted prior to filing the Complaint, as evidenced by Redacted The staff also Redacted

[10] During the Modafinil Investigation, Commission staff introduced documents bearing bates numbers with Redacted *See* Osborn Tr., 390:1-5; Zakreski Tr., 367:24 and 370:19. While staff represented that one of the documents came from Cephalon's production, Cephalon did not produce any documents Redacted . Terry Decl. ¶ 3.

[redacted] during the investigation. [redacted] . Letter from James C. Burling, Wilmer Cutler Pickering Hale and Dorr LLP, to Philip M. Eisenstat and Saralisa C. Brau, F.T.C. (Oct. 23, 2007). [redacted] , the staff had ample opportunity to use its investigative powers to probe Cephalon on that issue before it brought suit in 2008. Now that the Commission has filed a civil complaint, however, it must obtain discovery pursuant to the Federal Rules of Civil Procedure.

In short, the staff is not legitimately pursuing a new inquiry or one differentiated by new circumstances, but is attempting to circumvent the judicial process by investigating matters already concluded at the administrative level.

IV. Conclusion

For all the foregoing reasons, the Commission should quash the 2009 CID.[11]

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Attorneys for Cephalon, Inc.

Dated: July 22, 2009

[11] To the extent this CID seeks the production of documents or the disclosure of information subject to attorney-client privilege, work product doctrine, or joint defense/common interest doctrine, Cephalon also objects, and reserves its right to assert these privileges if and when required to respond to this CID.

APPENDIX – PUBLIC VERSION

UNITES STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In re **CEPHALON, INC. (File No. 0610182)**

CERTIFICATE OF SERVICE AND OF ACCURACY OF ELECTRONIC COPY

I, Hartmut Schneider, hereby certify that I have caused the following documents to be filed, by hand, with the Office of the Secretary of the Federal Trade Commission on this 22nd day of July, 2009: (i) one original and twelve (12) copies of the confidential version of Cephalon, Inc.'s Petition to Quash Civil Investigative Demand Dated July 7, 2009 and supporting Appendix (jointly, the "Petition"); (ii) one original and twelve (12) copies of a redacted version of the Petition; and (iii) a Compact Disc with an electronic version of the confidential Petition, which contains a true and correct copy of the paper original. At the request of the Secretary, an electronic version of the redacted Petition was e-mailed to DClark@ftc.gov today.

WILMER CUTLER PICKERING HALE AND DORR LLP

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Dated: July 22, 2009

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In re
CEPHALON, INC. (File No. 0610182)

REQUEST FOR CONFIDENTIAL TREATMENT

REDACTED – NON-PUBLIC

UNITES STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In re **CEPHALON, INC. (File No. 0610182)**

STATEMENT REQUIRED BY 16 C.F.R. § 2.7 (d)(2)

On July 20, 2009, James C. Burling of Wilmer Cutler Pickering Hale and Dorr LLP ("WilmerHale"), counsel to Cephalon, Inc. ("Cephalon"), spoke by telephone from the Boston, MA office of WilmerHale with Saralisa Brau, Deputy Assistant Director in the Commission's Health Care Division, and Alpa Gandhi, also of the Health Care Division. Mr. Burling explained why Cephalon believes the July 7, 2009 CID cannot be sustained because the Commission has moved from an investigative to an adjudicative position upon its filing of a civil action against Cephalon. After discussion, Ms. Brau and Mr. Burling agreed that the only way to resolve the parties' disagreement regarding the basis for the June 7, 2009 CID was through a Petition to Quash. This discussion represents a good faith attempt by counsel to resolve by agreement the issues raised by this Petition.

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Dated: July 22, 2009

UNITES STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In re **CEPHALON, INC. (File No. 0610182)**

DECLARATION OF WENDY A. TERRY IN SUPPORT OF CEPHALON, INC.'S PETITION TO QUASH CIVIL INVESTIGATIVE DEMAND DATED JULY 7, 2009

I, Wendy A. Terry, Esq., declare under penalty of perjury, pursuant to 28 U.S.C. § 1746:

1. I am a counsel at the law firm of Wilmer Cutler Pickering Hale and Dorr LLP, attorneys for Cephalon, Inc. ("Cephalon"). I am a member in good standing of the Bars of the District of Columbia and the Commonwealth of Virginia. I make this declaration in support of Cephalon's Petition to Quash Civil Investigative Demand Dated July 7, 2009.

2. In response to the Subpoena dated March 15, 2007, Cephalon produced the final Redacted multiple drafts Redacted and thousands of pages of documents relating to Redacted.

3. Cephalon produced documents using bates number prefixes starting with the letter C. In addition, there were a small number of documents that used SHEK and VE.

4. On May 30, 2007, in response to Specifications 1-3 of the Civil Investigative Demand ("CID") dated April 26, 2007, Cephalon provided information about the Redacted including on Schedule 1, CFTC-C 000001 and Schedule 2, CFTC-C 000002.

5. On June 12, 2007, in response to Specification 20 of the CID, Redacted Redacted

6. On June 25, 2007, in response to Specification 11 of the CID, Cephalon provided information about Redacted

7. On July 3, 2007, in response to Specification 5 of the CID, Cephalon provided information about the Redacted.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge. Executed on this 22nd day of July, 2009.

Wendy A. Terry

July 22, 2009

REDACTED – NON-PUBLIC

REDACTED – NON-PUBLIC