IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION
600 Pennsylvania Ave., N.W.,
Washington, DC 20580,

Petitioner,

v.

PAUL M. BISARO,
President and CEO,
Watson Pharmaceuticals, Inc.
360 Mt. Kemble Avenue,
Morristown, NJ 07962

Respondent.

Misc. No.

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PETITION OF FEDERAL TRADE COMMISSION FOR AN ORDER ENFORCING SUBPOENA *AD TESTIFICANDUM*

Preliminary Statement

Petitioner, the Federal Trade Commission ("FTC" or "Commission"), by its designated attorneys and pursuant to Sections 9 and 16 of the Federal Trade Commission Act (FTC Act), 15 U.S.C. §§ 49, 56, and Fed. R. Civ. P. 81(a)(5), petitions this Court for an Order requiring respondent, Paul M. Bisaro, President and Chief Executive Officer of Watson Pharmaceuticals, Inc. ("Watson"), to comply with the subpoena *ad testificandum* issued to him by the Commission on July 22, 2009. The Commission issued the subpoena in aid of an ongoing FTC investigation seeking to determine whether Watson has engaged or is engaging in unfair methods of competition in or affecting commerce, in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, by entering into an agreement regarding any modafinil product.

Mr. Bisaro has persisted in refusing to comply with the subpoena, even after the full Commission considered his petition to quash, concluded that his arguments and contentions were lacking in merit, and issued an order directing him to appear and testify. Respondent's repeated refusals to provide the requested testimony has materially impeded the Commission's investigation. The Commission, accordingly, respectfully requests that the Court enter an order directing Mr. Bisaro to appear and show cause why he should not testify in accordance with the outstanding subpoena *ad testificandum*. *See FTC v. Carter*, 636 F.2d 781, 789 (D.C. Cir. 1980); *FTC v. MacArthur*, 532 F.2d 1135, 1141-42 (7th Cir. 1976); *see also* Fed. R. Civ. P. 26(a)(1)(E); Fed. R. Civ. P. 81(a)(5).

JURISDICTION

Section 9 of the FTC Act, 15 U.S.C. § 49, authorizes the Commission to issue subpoenas to require the production of documentary evidence and the testimony of witnesses relating to any matter under investigation. If the recipient fails to comply, the Commission may petition an appropriate district court for an order requiring compliance. *Id.* Section 9 confers jurisdiction on, and establishes venue in any district court in the United States in which the investigation is being carried on. *Id.*

The Commission issued a subpoena *ad testificandum* to Mr. Bisaro on July 22, 2009 and served it by overnight delivery to Watson's Corona, California corporate headquarters and his counsel in Washington, D.C. Petition Exhibit ("Pet. Exh.") 1 (Declaration of James Rhilinger) ¶ 12; Pet. Exh. 3.[1] The instant investigation is being carried on in Washington, D.C., where attorneys in the Health Care Division of the Commission's Bureau of Competition are located

[1] Exhibits to the Commission's Petition are referred to herein as "Pet. Exh."

and are examining relevant documents and transcripts of testimony. Pet. Exh. 1 ¶ 5. Because Mr. Bisaro has failed to comply with the subpoena, this Court is empowered, pursuant to Section 9, to issue an order directing Mr. Bisaro to appear and show cause why this Court should not grant the instant petition and enter its own order enforcing the subpoena issued to respondent and requiring him to testify. *See, e.g.*, *FEC v. Comm. to Elect Lyndon LaRouche*, 613 F.2d 849, 854-58 (D.C. Cir. 1979); *FTC v. Browning*, 435 F.2d 96, 100-01 (D.C. Cir. 1970).

STATEMENT OF FACTS

1. The Parties

The Commission is an administrative agency of the United States, organized and existing pursuant to the FTC Act, 15 U.S.C. § 41 *et seq*. The Commission is authorized and directed by Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), to prevent the use of "unfair methods of competition" and "unfair or deceptive acts or practices in or affecting commerce." To carry out those responsibilities, the Commission is empowered to prosecute any inquiry necessary to its duties in any part of the United States (15 U.S.C. § 43), and "[t]o gather and compile information concerning, and to investigate from time to time the organization, business, conduct, practices, and management of any person, partnership, or corporation engaged in or whose business affects commerce." 15 U.S.C. § 46. Specifically, Section 9 of the Act empowers the Commission to require, by subpoena, the attendance and testimony of witnesses and the production of documentary evidence relating to any matter under investigation. 15 U.S.C. § 49.[2]

Respondent Paul M. Bisaro is President and Chief Executive Officer of Watson

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[2] In addition, Section 20 of the FTC Act empowers the Commission to require by Civil Investigative Demand ("CID") the production of documents or other information relating to any Commission law enforcement investigation. 15 U.S.C. § 57b-1(e).

Pharmaceuticals, Inc., a publicly held company. Pet. Exh. 1 ¶ 3. Watson develops, manufactures and markets a broad range of bioequivalent generic versions of pharmaceutical products throughout the United States. *Id.* The company is incorporated in the State of Nevada, headquartered in Corona, California, and has offices in Morristown, New Jersey, where respondent Bisaro's office is located. *Id.* Watson and Bisaro transact business throughout the United States, including Washington, D.C. *Id.* Watson and Bisaro are engaged in, and their business affects, "commerce," as that term is defined in Section 4 of the FTC Act, 15 U.S.C. § 44. *Id.*

2. Background

A. Provigil Patent Settlements and Initial Commission Investigation

The instant subpoena relates to an ongoing Commission investigation

> To determine whether Cephalon, Inc., Teva Pharmaceuticals, Inc. (and its affiliate Teva Pharmaceuticals USA, Inc.), Barr Laboratories, Inc., Ranbaxy Laboratories, Inc., Mylan Pharmaceuticals, Inc., Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding any modafinil products.[3]

Modafinil is a wakefulness-enhancing drug that Cephalon, Inc. ("Cephalon") markets under the brand name Provigil – a drug with annual sales in excess of $800 million. Pet. Exh. 1 ¶ 4. Cephalon had sued each of the generic companies identified in the process resolution, alleging that the generic manufacturers were infringing Cephalon's U.S. Reissued Patent No. 37,516 ("'516 Patent") by filing abbreviated new drug applications ("ANDAs") with the Food

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[3] Resolution Authorizing Use of Compulsory Process in a Nonpublic Investigation, File No. 06110182 (August 30, 2006). Pet. Exh. 2.

and Drug Administration ("FDA").[4] Pet. Exh. 1 ¶ 6. Cephalon settled each of these patent infringement suits between late 2005 and 2006, including a settlement reached with Watson and its development partner Carlsbad Technologies, Inc. ("Carlsbad") on August 2, 2006.[5] Pet. Exh. 1 ¶ 7. Under the settlement agreements, Watson and the other generic manufacturers agreed they would not market generic modafinil until 2012.[6] *Id.*

In 2006, the Commission opened an investigation, and authorized the use of compulsory process, to determine whether there were any agreements that would unlawfully delay the introduction of generic Provigil. Pet. Exh. 1 ¶ 5. The initial Commission investigation focused on the agreements settling the '516 patent litigation. Pet. Exh. 1 ¶¶ 5-8.

B. New Concerns about Watson's Ability to Block Generic Entry

In December 2007, Cephalon listed a new patent with the FDA relating to Provigil: U.S. Patent No. 7,297,346 ("'346 Patent"). Pet. Exh. 1 ¶ 9. On the same day, Watson/Carlsbad filed a certification with the FDA that its generic version of modafinil did not infringe the '346 patent,

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[4] ANDAs reflect a streamlined FDA approval process that enables manufacturers of generic drugs (*i.e.*, drugs that are "bioequivalent" to branded drugs) to rely on safety and efficacy studies relating to the branded drug.

[5] On February 13, 2008, the Commission filed a complaint against Cephalon, alleging that its settlement agreements, which provided compensation to the generic firms for foregoing generic entry, were anticompetitive, an abuse of monopoly power, and unlawful under Section 5 of the FTC Act. *FTC v. Cephalon, Inc.*, 08-cv-2141-MSG (E.D. Pa.). On March 29, 2010, the district court denied Cephalon's motion to dismiss the Commission's complaint.

[6] Unlike the other generics identified in the process resolution, Watson was not a "first filer" for the '516 patent. Each of the generic firms listed in the process resolution, other than Watson/Carlsbad, filed their ANDAs on the same day, before any other parties. As "first filers," these entities were eligible under applicable law for 180 days of joint marketing exclusivity at such time that the FDA approved their ANDAs. This marketing exclusivity, together with the patent settlements, functions as a bottleneck to generic competition that barred any subsequent generic filer from marketing modafinil until 2012.

or that the patent was invalid. *Id.* This event created the possibility – one that did not exist for the '516 patent – that Watson could be a "first filer" for the '346 patent, and therefore could block market entry for later-filing generics. *Id.*

In May 2009, as part of its investigation into "agreements regarding any modafinil products," the Commission issued CIDs to Watson and Carlsbad and subpoenas *ad testificandum* to executives of each company to enable it to determine, *inter alia*, whether Watson was a party to any agreement limiting its ability to relinquish any eligibility for marketing exclusivity it may have with respect to modafinil. Such an agreement, if one exists, could delay generic entry and may constitute an "unfair method of competition" in violation of the FTC Act. Pet. Exh. 1 ¶¶ 10-11.

The Commission issued a CID to Watson on May 19, 2009. Pet. Exh. 1 ¶ 10. Watson provided only partial responses to the CID. *Id.* Accordingly, Commission staff asked Watson to supplement its initial responses. *Id.* Watson's counsel denied that the initial responses were deficient and, again, failed to provide the requested information, in part, on the basis of attorney-client privilege. *Id.* On June 25, 2009, pursuant to a subpoena *ad testificandum,* David A. Buchen, Watson's Senior Vice President, General Counsel, and Secretary, appeared and testified at an investigational hearing. Pet. Exh. 1 ¶ 11. Mr. Buchen did not fully respond to the Commission's questions. However, he identified Mr. Bisaro as the only person at Watson with whom he had spoken regarding discussions he had with a third party about a possible deal for generic Provigil. *Id.*

C. Bisaro Subpoena and Proceedings Before the Commission

Accordingly on July 22, 2009, the Commission issued a subpoena *ad testificandum* to Mr. Bisaro. Pet. Exh. 3. On July 30, 2009, Mr. Bisaro petitioned the Commission to quash the

subpoena.[7] Pet. Exh. 4. In his petition, Mr. Bisaro contended that the subpoena should be quashed, asserting that it: 1) demanded information that the Commission already had; 2) improperly sought testimony from the "apex" of Watson's organization; 3) was issued for an improper purpose; and 4) imposed an undue burden by requiring travel to Washington, D.C. Additionally, he contended that the resolution authorizing the investigatory resolution had already been used in connection with an investigation that culminated in a civil action against Cephalon and, therefore, that the resolution could not be "resurrect[ed]" to burden Watson with more process. Pet. Exh. 4. On November 13, 2009, FTC Commissioner Pamela Jones Harbour, pursuant to authority delegated by the full Commission, denied the petition. Pet. Exh. 5. Mr. Bisaro then filed a petition for review by the full Commission. Pet. Exh. 6.

On April 2, 2010, the full Commission denied Mr. Bisaro's petition and directed him to appear for an investigational hearing in Washington, D.C., on April 15, 2010. Pet. Exh. 7. By letter dated April 13, 2010, Mr. Bisaro's counsel informed Commission staff attorneys that Watson would not produce Mr. Bisaro. Pet. Exh. 8. On April 19, 2010, Commission attorneys met with counsel for Mr. Bisaro, at counsel's request, to discuss Mr. Bisaro's testimony. At the meeting, counsel reiterated that Mr. Bisaro would not appear for an investigational hearing as required by the Commission's subpoena. Pet. Exh. 1 ¶ 15.

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[7] The Commission's Rules of Practice and Procedure allow subpoena recipients to petition the Commission to limit or quash any investigative subpoena, and to subsequently request review of an adverse ruling to the full Commission. *See* 16 C.F.R. § 2.7(d).

ARGUMENT

THE SUBPOENA *AD TESTIFICANDUM* IS LAWFUL, SEEKS RELEVANT TESTIMONY, AND IS NOT UNDULY BURDENSOME

A. Standards for Enforcement of Agency Process

The standards for judicial enforcement of administrative investigative process have long been settled in this Circuit. "[T]he court's role in a proceeding to enforce an administrative subpoena is a strictly limited one." *FTC v. Texaco, Inc.*, 555 F.2d 862, 871-72 (D.C. Cir. 1977) (*en banc*) (*citing Endicott Johnson Corp. v. Perkins*, 317 U.S. 501, 509 (1943); *accord, Oklahoma Press Publ'g Co. v. Walling*, 327 U.S. 186, 209 (1946); *United States v. Morton Salt Co.*, 338 U.S. 632, 643 (1950)). "[W]hile the court's function is 'neither minor nor ministerial,' the scope of issues which may be litigated in an enforcement proceeding must be narrow, because of the important governmental interest in the expeditious investigation of possible unlawful activity." *Id.* (quoting *Oklahoma Press Publ'g*, 327 U.S. at 217 n.57); *accord, FTC v. Anderson*, 631 F.2d 741, 744-45 (D.C. Cir. 1979).

Thus, a district court must enforce agency process so long as the information sought is not "unduly burdensome" to produce (*Texaco*, 555 F.2d at 881), and is "reasonably relevant" (*id.* at 872-73 n.23 (quoting *Morton Salt*, 338 U.S. at 652), or, putting it differently, "not plainly incompetent or irrelevant to any lawful purpose" of the agency. *Texaco*, 555 F.2d at 872 (quoting *Endicott Johnson,* 317 U.S. at 509). In making this determination, the agency's own appraisal of relevancy must be accepted so long as it is not "'obviously wrong.'" *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1089 (D.C. Cir. 1992) (citing *Carter*, 636 F.2d at 787-88 (quoting *Texaco*, 555 F.2d at 877 n.32)); *Appeal of FTC Line of Business Report Litigation,* 595 F.2d 685, 702-03 (D.C. Cir. 1978) (per curiam); *see also* Fed. R. Civ. P.

26(a)(1)(E). Mr. Bisaro carries a heavy burden to show that the subpoena should not be enforced.

Proceedings to enforce administrative investigative subpoenas are special statutory matters cognizable under Fed. R. Civ. P. 81(a)(5), and are entitled to summary disposition. *Carter*, 636 F.2d at 789; *FTC Line of Business Report Litig.*, 595 F.2d at 704-05. They are properly instituted by a petition and order to show cause (rather than by complaint and summons). *See* Fed. R. Civ. P. 81(a)(5); *MacArthur*, 532 F.2d at 1141-42. Furthermore, even limited discovery or evidentiary hearings are improper except upon a showing of "extraordinary circumstances." *See, e.g, Invention Submission Corp.*, 965 F.2d at 1091; *SEC v. Knopfler*, 658 F.2d 25, 26 (2d Cir. 1981); *Carter*, 636 F.2d at 789 (quoting *United States v. Exxon Corp.*, 628 F.2d 70, 77 n.7 (D.C. Cir. 1980); *MacArthur*, 532 F.2d at 1141-42; *FTC v. Browning*, 435 F.2d 96, 104 (D.C. 1970); *see also* Fed. R. Civ. P. 26(a)(1)(B)(v).

As shown below, all the standards governing enforcement of Commission compulsory process have been satisfied. The Commission plainly has the authority to issue the subpoenas, the information required by the subpoenas is reasonably relevant to the subject matter of the inquiry, and respondent has not shown that compliance would be unduly burdensome. Because respondent has not provided any valid objections to the subpoena, it must be enforced.

B. The Inquiry is Within the Commission's Authority

The Commission issued the instant subpoena *ad testificandum* in aid of an investigation into possible violations of Section 5 of the FTC Act, 15 U.S.C. § 45. The Commission initiated the investigation by issuing a Resolution Authorizing Use of Compulsory Process in a Nonpublic Investigation on August 30, 2006. Pet. Exh. 2. According to the Resolution, the Commission seeks to determine whether Watson and Carlsbad, along with Cephalon, and other generic

manufacturers, have engaged in "unfair methods of competition" in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, "by entering into agreements regarding any modafinil products." *Id.* The Commission also resolved that "all compulsory process available to it be used in connection with this investigation." *Id.*

As explained above, Sections 6 and 9 of the FTC Act give the Commission ample authority to conduct the investigation and to issue subpoenas in furtherance of such investigation. *See* 15 U.S.C. §§ 46, 49; *see also* 16 C.F.R. § 2.7(a).[8] The subpoena seeks the appearance of Mr. Bisaro, who has information that is indisputably "relating to" the subject matter of the investigation, and, as required by 15 U.S.C. § 49, was duly signed by a member of the Commission. Pet. Exh. 3. Respondent, in refusing to comply with the subpoena, has advanced the novel proposition that the Commission's investigatory resolution has already been used in connection with the Commission's investigation of, and ensuing litigation against, Cephalon. Pet. Exh. 4 at 3. As the Commission explained, however, a Commission resolution authorizing compulsory process for an investigation does not expire upon the filing of an enforcement action, or because litigation related to a similar subject may have begun. Pet. Exh. 7 at 5 (*citing Linde Thomson Langworthy Kohn & Van Dyke, P.C. v. Resolution Trust Corp.*, 5 F.3d 1508 (D.C. Cir. 1993)). As for respondent's further contention that the subpoena was issued for the purpose of pressuring Watson into relinquishing any exclusivity rights it may have in effort to "engineer[ ] generic entry into the modafinil market," (Pet. Exh. 4 at 19), the full Commission, in its April 2, 2010 denial of respondent's petition to quash reaffirmed that

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[8] Section 2.7(a) of the Commission's Rules of Practice provides, in relevant part: "The Commission or any member thereof may, pursuant to a Commission resolution, issue a subpoena * * * directing the person named therein to appear before a designated representative at a designated time and place to testify * * *."

"issuing a subpoena for the testimony of the President and CEO of Watson about any company agreements and discussions with third parties with regard to relinquishment – after first issuing CIDs to the company and receiving the testimony of another of its executives – is clearly a proper purpose." Pet. Exh. 7 at 8. Respondent's speculative concerns and groundless allegations are no basis for questioning the Commission's good faith, or otherwise disturbing the presumption of regularity to which the Commission is entitled under governing law. *See FCC v. Schreiber*, 381 U.S. 279, 296 (1965); *see also Invention Submission Corp.*, 965 F.2d at 1091-92 ("validity of Commission subpoenas is to be measured against the purposes stated in the resolution, and not by reference to extraneous evidence") (quoting *Carter*, 636 F.2d at 789); *United States v. Aero Mayflower Transit Co.*, 831 F.2d 1142 (D.C. Cir. 1987) (rejecting allegations of agency misconduct where subpoenas "seek information relevant to the discharge of [agency's Inspector General's] duties"); *see also SEC v. Dresser Industries, Inc.*, 628 F.2d 1368 (D.C. Cir. 1980) (rejecting allegations of agency bad faith to justify discovery); *CFTC v. Harker*, 615 F. Supp. 420, 423-425 (D.D.C. 1985) (same).

C. The Subpoena Seeks Testimony That Is Reasonably Relevant to the Commission's Investigation

The standard for judging relevancy in an investigatory proceeding is more relaxed than in an adjudication. In an investigation, the Commission is not limited to seeking information that is necessary to prove specific charges. It merely seeks to learn whether there is reason to believe that the law is being violated and, if so, whether issuance of a complaint would be in the public interest. *See Texaco*, 555 F.2d at 872. The requested testimony, therefore, need only be relevant to the investigation – the boundary of which may be defined by the agency quite generally. *See Carter*, 636 F.2d at 787-88; *Texaco*, 555 F.2d at 874 & n.26.

In the present investigation, the Commission is seeking to determine whether Watson is a party to any agreement regarding modafinil products that may unlawfully delay consumer access to generic modafinil. Mr. Buchen identified Mr. Bisaro as having personal knowledge of events relevant to the investigation, and even testified that Mr. Bisaro was the only person at Watson with whom he spoke about certain conversations regarding relinquishment. Pet. Exh. 1 ¶ 11. The Commission, however, has been stymied in its efforts to ask Mr. Bisaro about his knowledge of the existence of such an agreement or discussions relating to such an agreement. *See e.g.*, Pet. Exh. 1 ¶¶ 10, 13, 14, 15.

While respondent argued in his petition to quash that the subpoena is unnecessary (Pet. Exh. 4 at 16), that is a judgment that the Commission, not respondent, is entitled to make. Mr. Bisaro might very well have personal knowledge of highly relevant information concerning any agreements limiting Watson's ability to relinquish any exclusivity it might possess relating to the sale of modafinil, as well as discussions with third parties concerning relinquishment, that the Commission does not already possess. As the Commission properly concluded in rejecting respondent's objection, "[w]hile Watson has provided the Commission information relating to the '346 Patent, [respondent] has not shown that his testimony will shed no additional light on matters that fall within the scope of the Commission's investigatory concerns." Pet. Exh. 7 at 7.

D. Compliance with the Subpoena is Not Unduly Burdensome

As for respondent's contention that it would be "unduly burdensome" for him to appear at Commission offices in Washington, D.C. (Pet. Exh. 4 at 19; Pet. Exh. 6 at 3), he has not offered any evidence to support that assertion. Pet. Exh. 7 at 9. It is well established that it is respondent's burden to demonstrate that compliance with investigatory process is unduly burdensome. *See, e.g., Invention Submission Corp.*, 965 F.2d at 1090; *FTC v. Rockefeller*, 591

F.2d 182, 190 (2d Cir. 1979); *Texaco*, 555 F.2d at 882.

Nor has respondent shown that the subpoena is "unreasonable" because, under the so-called "apex doctrine," the Commission must demonstrate that it cannot obtain the relevant information elsewhere. Pet. Exh. 4 at 17-19; Pet. Exh. 6 at 3. As the Commission concluded, however, respondent had provided no support for the proposition that this doctrine limits the investigatory powers of an enforcement agency. In any event, even in the very different context of civil discovery, this doctrine has limited application and high-level corporate executives have discovery obligations. As the Commission stated, respondent "is another logical, possible source of relevant information" based on his discussions with Mr. Buchen, as well as other non-privileged information he may possess. *See* Pet. Exh. 5 at 6-7; Pet. Exh. 7 at 7-8. .

The Commission has met all of the requirements necessary for enforcement of the subpoena. The Commission is investigating possible "unfair methods of competition" and marketing practices in violation of Section 5 of the FTC Act regarding agreements involving modafinil products. Mr. Bisaro's testimony is clearly relevant to the investigation. As the Commission concluded in its April 2, 2010 denial of respondent's petition to quash, Pet. Exh. 7, the Commission does not yet possess the information sought in the subpoena and, to date, has been unable to obtain the information by other means. Mr. Bisaro also has failed to articulate how attending the investigational hearing in Washington, D.C. is unduly burdensome. Finally, the Commission has made numerous attempts to gain Mr. Bisaro's cooperation in the investigation short of judicial intervention. Based on the foregoing, the subpoena should be enforced.

CONCLUSION

For all the foregoing reasons, the Commission respectfully requests that this Court issue its own order directing Mr. Bisaro to comply in full with the July 22, 2009 subpoena *ad testificandum* by providing testimony within 10 days of the date of the Court's Order, or at such later date as may be established by the Commission.

Respectfully submitted,

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Dated: April 23, 2010

Petition Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION 600 Pennsylvania Ave., N.W., Washington, DC 20580, Petitioner, v. **PAUL M. BISARO,** President and CEO, Watson Pharmaceuticals, Inc. 360 Mt. Kemble Avenue, Morristown, NJ 07962 Respondent.	)	Misc. No.

DECLARATION OF JAMES RHILINGER, ESQ.

Pursuant to 28 U.S.C. § 1746, I declare as follows:

1. I am an attorney employed by the U.S. Federal Trade Commission ("FTC" or "Commission"), in Washington, D.C. I am assigned to the FTC's investigation of Cephalon, Inc. ("Cephalon"), Watson Pharmaceuticals, Inc. ("Watson"), and Carlsbad Technologies, Inc. ("Carlsbad"), among other companies, concerning agreements regarding any modafinil products, including the branded drug Provigil and its generic equivalents.

2. I submit this declaration in support of the Petition of the Federal Trade Commission for an Order Enforcing Subpoena *Ad Testificandum* Issued in Furtherance of a Law Enforcement Investigation. I have read the petition and exhibits thereto (those exhibits are hereinafter referred to as "Pet. Exh."), and verify that Pet. Exh. 2 (this declaration is Pet. Exh. 1) through Pet. Exh. 8 are true and correct copies of the original documents contained in the Commission's files. The

facts set forth herein are based on my personal knowledge or information made known to me in the course of my official duties.

3. Watson is a publicly held company that develops, manufactures and markets bioequivalent generic pharmaceutical products. It is incorporated in the State of Nevada, with its principal place of business at 311 Bonnie Circle, Corona, California, and offices in Morristown, New Jersey. Paul M. Bisaro is the company's President and Chief Executive Officer, and works in Watson's New Jersey offices. Watson transacts business throughout the United States, including Washington, D.C. Watson is engaged in, and its businesses affect, "commerce," as that term is defined in Section 4 of the Federal Trade Act ("FTC Act"), 15 U.S.C. § 44.

4. Cephalon markets the patented drug Provigil, which contains modafinil. Provigil is a "wakefulness-enhancing" drug with annual sales of over $800 million.

5. The Commission issued an omnibus Resolution Authorizing Use of Compulsory Process in a Nonpublic Investigation, FTC File No. 0610182, dated August 30, 2006, "[t]o determine whether Cephalon, Inc., Teva Pharmaceuticals, Inc. (and its affiliate Teva Pharmaceuticals USA, Inc.), Barr Laboratories, Inc., Ranbaxy Laboratories, Inc., Mylan Pharmaceuticals, Inc., Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec 45, as amended, by entering into agreements regarding any modafinil products." Pet Exh. 2. The Commission resolved that "all compulsory processes available to it be used in connection with this investigation." *Id.* The FTC's investigation of modafinil products is nationwide in scope and is being conducted from the FTC's office in Washington, D.C., where attorneys in the Health Care Division of the Commission's Bureau of

Competition are working on this matter, and where relevant documents and information are located.

6. Carlsbad, Watson's development partner, and several other generic pharmaceutical companies, filed abbreviated new drug applications ("ANDAs") to obtain Food and Drug Administration ("FDA") approval to develop, manufacture, and sell generic versions of Provigil. Each of the generic firms listed in the process resolution, other than Watson/Carlsbad, filed their ANDAs on the same day, and before any other filers, and thus were eligible under applicable law for 180 days of joint marketing exclusivity for their modafinil product at such time the ANDA is approved.

7. Cephalon sued each of the generic companies identified in the process resolution, alleging that the generic manufacturers were infringing Cephalon's U.S. Reissued Patent No. 37,516 ("the '516 Patent") by filing their ANDAs. Cephalon subsequently settled each of these patent suits in 2005 and 2006, including a settlement on August 2, 2006 with Watson and Carlsbad. Under the terms of the settlement agreements, Watson and the other generic manufacturers agreed not to market generic Provigil until 2012.

8. On February 13, 2008, the Commission filed a complaint against Cephalon, alleging that its settlement agreements provided compensation to the generic firms for foregoing generic entry, were anticompetitive and an abuse of monopoly power, and so were unlawful under Section 5 of the FTC Act. *FTC v. Cephalon, Inc.*, 08-cv-2141-MSG (E.D. Pa.).

9. In December 2007, Cephalon listed a new patent with the FDA relating to Provigil: U.S. Patent No. 7,297,346 ("the '346 Patent"). On the same day, Watson/Carlsbad filed a certification with the FDA that its generic version of modafinil did not infringe the '346 patent, or that the patent was invalid. By doing so, Watson/Carlsbad created the possibility that Watson

was a "first filer" for the '346 patent, and thereby could block market entry for later-filing generics.

10. As part of its continuing investigation of "agreements regarding any modafinil products," the Commission issued Civil Investigative Demands ("CIDs") on May 19, 2009 to Watson and Carlsbad to determine, *inter alia*, whether Watson is a party to any agreement that limits its ability to relinquish any marketing exclusivity rights it may have with respect to modafinil. Such an agreement, if it exists, could unlawfully delay generic entry and may constitute an "unfair method of competition" in violation of the FTC Act. The Commission issued a CID to Watson on May 19, 2009, to which Watson only provided a partial response. Accordingly, Commission staff wrote to Watson's counsel, identified information Watson had failed to provide, and requested that Watson supplement its initial responses. Watson's counsel denied that the initial responses were deficient and again failed to provide the requested information, in part, on the basis of attorney-client privilege.

11. On June 25, 2009, pursuant to a subpoena *ad testificandum,* David A. Buchen, Watson's Senior Vice President, General Counsel, and Secretary, appeared and testified at an investigational hearing. Mr. Buchen did not fully respond to the Commission's questions, including those inquiring whether Watson had entered into any agreements that would prohibit or otherwise limit its ability to relinquish any marketing exclusivity rights for modafinil. Mr. Buchen identified Mr. Bisaro as the only person at Watson with whom he had spoken regarding relevant discussions with a third party about a possible deal for generic Provigil.

12. The Commission issued a subpoena *ad testificandum* dated July 22, 2009 to Mr. Bisaro, directing him to appear for an investigational hearing in Washington, D.C. on July 31, 2009. Pet. Exh. 3. This subpoena was served on Mr. Bisaro both at Watson's Corona,

California headquarters and on his counsel in Washington, D.C., and Mr. Bisaro has not contested service.

13. On July 30, 2009, Mr. Bisaro filed a petition to quash the July 22, 2009 subpoena. Pet. Exh. 4. On November 13, 2009, Commissioner Pamela Jones Harbour, acting as the Commission's delegate, denied the July 30 petition. Pet. Exh. 5. On November 27, 2009, Mr. Bisaro and Watson requested review by the full Commission of the November 13 decision. Pet. Exh. 6.

14. On April 2, 2010, the full Commission denied Watson's request for review, and ordered that Mr. Bisaro appear at an investigational hearing on April 15, 2010 or as otherwise agreed by Commission staff. Pet. Exh. 7. In a letter dated April 13, 2010, Watson's attorneys informed Commission staff that Mr. Bisaro would not appear at the April 15, 2010 investigational hearing and does not intend to comply with the July 22, 2009 subpoena issued by the Commission. Pet. Exh. 8.

15. Commission staff met with counsel for Mr. Bisaro on April 19, 2010, at counsel's request, to discuss Mr. Bisaro's testimony. At the meeting, counsel reiterated that Mr. Bisaro would not appear to testify at an investigational hearing, as required by the July 22, 2009 subpoena and the Commission's ruling of April 2, 2010.

16. The Commission requires the testimony of Mr. Bisaro to provide crucial information not yet provided by Watson. Mr. Buchen identified Mr. Bisaro as the only person at Watson with whom he spoken about certain key issues in this investigation. Mr. Bisaro's failure to comply with the subpoena materially impedes the Commission's investigation to determine whether Watson has entered into any agreements that unlawfully restrict competition for generic

Provigil potentially costing consumers hundreds of millions of dollars a year.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: April 23, 2010

James Rhilinger, Esq.

Petition Exhibit 4

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

IN RE	)
SUBPOENA *AD TESTIFICANDUM*	)
DATED JULY 22, 2009	)

PETITION TO QUASH
SUBPOENA *AD TESTIFICANDUM* DATED JULY 22, 2009

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HIGHLY CONFIDENTIAL TREATMENT REQUESTED

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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

IN RE	)
SUBPOENA *AD TESTIFICANDUM*	)
DATED JULY 22, 2009	)

COMMISSIONERS:

Jon Leibowitz, Chairman
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

File No. 0610182

PETITION TO QUASH
SUBPOENA *AD TESTIFICANDUM* DATED JULY 22, 2009

Pursuant to 16 C.F.R. § 2.7(d), petitioner Paul M. Bisaro, President and Chief Executive Officer of Watson Pharmaceuticals, Inc. ("Watson" or the "Company") petitions the Federal Trade Commission ("FTC") to quash the Subpoena *Ad Testificandum* issued on July 22, 2009 (the "Subpoena") under Sections 6, 9, 10 and 20 of the FTC Act, 15 U.S.C. §§ 46, 49, 50 and 57b-1, as amended.[1] The FTC issued the Subpoena under an August 2006 resolution authorizing the investigation of settlement agreements between Cephalon, Inc. ("Cephalon") and several generic pharmaceutical companies relating to Provigil®, Cephalon's branded modafinil drug.[2] To date, Watson, its employees and its development partner Carlsbad Technologies, Inc. ("Carlsbad") have received four civil investigative demands ("CID"), one subpoena *duces tecum*, a request for a voluntary investigational hearing, and five subpoenas *ad testificandum* relating to

[1] *See* Subpoena *Ad Testificandum* dated July 22, 2009 (Exhibit A).
[2] *See* Commission Resolution dated August 30, 2006, File No. 0610182 ("Resolution") (Exhibit B).

the modafinil investigation. Prior to the filing of this Petition, the Company has cooperated fully with each of the FTC's previous requests for information and documents.

After this long litany of investigatory burdens, FTC Staff now seek to compel the testimony of Watson's Chief Executive Officer, Mr. Bisaro. This Subpoena, however, must be quashed for three independent reasons. First, the FTC has already obtained all of the responsive information available from Watson, including through document submissions, narrative responses to interrogatories, discussions with FTC Staff, and the testimony of Watson's Senior Vice President and General Counsel, who was the primary point of contact and decision-maker responsible for the subject matter being investigated by the FTC. FTC Staff now insist on deposing Mr. Bisaro, who has *no* responsive documents, and *no* contacts with any third party, and whose knowledge about the subject matter is wholly indirect, learned only through "fewer than five" conversations with Watson's General Counsel. Subjecting Mr. Bisaro to an investigational hearing will not unearth information that the FTC does not already possess.

Even if on the margin Mr. Bisaro could provide any shred of new information, as the highest-ranking executive at Watson, he should not be compelled to undergo an investigational hearing unless he has personal knowledge of the relevant subject matter, and possesses information that is not obtainable through other means. Neither is true here, and FTC Staff cannot claim otherwise. Indeed, FTC Staff have *twice* deferred Mr. Bisaro's investigational hearing – once to determine whether such a hearing was "even necessary" in light of testimony establishing Mr. Bisaro's marginal familiarity with the subject matter, and a second time *indefinitely*, presumably after weighing the necessity of a hearing once in possession of the full evidentiary record. Nevertheless, FTC Staff now unreasonably insist that the individual at the apex of Watson's organization be burdened with a deposition.

The reason for the FTC's insistence is clear: the FTC is attempting to use its investigatory powers to pressure Watson into a business deal whereby it would relinquish legal rights associated with its Abbreviated New Drug Application (ANDA) for a generic version of modafinil. FTC Staff is apparently frustrated with the slow progress of its pending "reverse payment" litigation against Cephalon, and is using its privileged access to information from other government and private persons to engineer market entry by a third party. This is an improper use of the FTC's authority and the Subpoena should be quashed.

BACKGROUND

History of the '516 Patent Litigation and Settlements

This Petition relates to the FTC's investigation of modafinil, a wakefulness-enhancing drug developed and marketed by Cephalon under the brand name Provigil®. At the time the Federal Food and Drug Administration (FDA) approved Provigil® on December 24, 1998, the FDA Orange Book listed two patents covering the product: US Patent No. 4,927,855 (the "'855 Patent") and U.S. Reissued Patent No. 37,516 (the "'516 Patent"). On December 22, 2002, four generic pharmaceutical companies – Barr Laboratories, Inc., Mylan Pharmaceuticals Inc., Ranbaxy Laboratories Ltd. and Teva Pharmaceutical Industries Ltd. (together, the "First Filers") – filed ANDAs seeking approval to market generic modafinil. Each of the ANDAs included a Paragraph IV certification relating to the listed patents. Thus, according to prevailing FDA rules at the time, each of the four First Filers shared the 180-day period of marketing exclusivity provided by the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman") to the first generic challengers to file ANDAs with Paragraph IV certifications. On March 28, 2003, Cephalon filed a complaint in the United States District Court for the District of New Jersey charging each of the First Filers with infringement of the '516 Patent. Between December 9, 2005 and February 1, 2006, all four generic companies with first-filer status settled

their litigation with Cephalon and entered into licensing agreements providing for generic entry prior to the expiration of the patents covering Provigil®.

Watson and its development partner, Carlsbad, filed their ANDA for Provigil® in December 2004, approximately two years after the First Filers.[3] Watson and Carlsbad's ANDA also contained a Paragraph IV certification as to the then-listed patents.[4] Cephalon responded to the ANDA notification by suing Carlsbad for infringement of the '516 Patent in the United States District Court for the District of New Jersey on February 24, 2005.[5] On August 2, 2006, after all of the First Filers had reached settlements, Watson, Carlsbad and Cephalon settled their dispute and entered into a Settlement and License Agreement (the "Settlement Agreement") pursuant to which Watson obtained a license to market generic modafinil prior to the expiration of the listed patents.[6]

The Pre-Complaint Investigation

Shortly thereafter, by resolution dated August 30, 2006, the FTC initiated a non-public inquiry "to determine whether Cephalon, Inc. [and others] engaged in any unfair methods of competition . . . by entering into agreements regarding any modafinil products."[7] The investigation focused on Cephalon's alleged use of patent settlements as a means of preventing generic competition, most immediately from the four First Filers – Teva, Barr, Mylan and Ranbaxy. In connection with its investigation, on November 9, 2006, the FTC issued a subpoena *duces tecum* to Watson, demanding voluminous documents relating to Provigil®, generic

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3 Declaration of Steven C. Sunshine ("Sunshine Decl.") ¶ 4. Pursuant to Watson and Carlsbad's development agreement, Carlsbad and its majority shareholder Yung Shin Pharmaceutical Ind. Co., Ltd. are responsible for the development of generic modafinil, and the preparation of the ANDA and any other regulatory documents required to be submitted in connection with obtaining FDA approval of the product.

4 *Id.* ¶ 5.

5 *See* Complaint, *Cephalon, Inc. v. Carlsbad Techs., Inc.*, Doc. No. 1, C.A. No. 05-01089 (D.N.J. Feb. 24, 2005).

6 Sunshine Decl. ¶ 7. Watson obtained a license to market generic modafinil beginning on April 6, 2012.

7 *See* Resolution (Exhibit B).

modafinil, and the Settlement Agreement.[8] On May 18, 2007, the FTC issued a further request for information and documents – a CID consisting of 17 different specifications regarding generic modafinil, the Settlement Agreement and the '516 patent litigation.[9] Carlsbad received a similar request dated June 5, 2007 – a CID containing 7 different specifications on these same subjects.[10]

Watson and Carlsbad cooperated fully with each of the FTC's inquiries, providing thousands of documents and extensive information relevant to the investigation.[11] The FTC cited no deficiencies with Watson's response to either the November 9, 2006 subpoena or the May 18, 2007 CID. In addition, on August 7, 2007, Watson's Senior Vice President, General Counsel and Secretary, Mr. David A. Buchen, voluntarily appeared and provided sworn testimony in an investigational hearing requested by FTC Staff in connection with its inquiry.[12] Counsel for Watson also met with FTC Staff on May 8, 2007 and September 25, 2007, and provided detailed presentations regarding the Settlement Agreement in an effort to address the FTC Staff's questions and concerns.[13] In short, the FTC has had every opportunity to explore all aspects of the Settlement Agreement, which it has now had in its possession for nearly three years.

On February 13, 2008, the FTC brought an action against Cephalon, alleging that its settlements with the First Filers prevented generic competition to Provigil® in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.[14] None of the First Filers – at least some of whom had maintained their Hatch-Waxman exclusivity – were named in the FTC's

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8 *See* Subpoena *Duces Tecum* dated November 9, 2006 (Exhibit C).

9 *See* Civil Investigative Demand dated May 18, 2007 (Exhibit D). Pursuant to Watson and Carlsbad's development agreement, Watson is responsible for any legal costs arising out of the modafinil ANDA.

10 *See* Civil Investigative Demand dated June 5, 2007 (Exhibit E).

11 Sunshine Decl. ¶¶ 10 – 11.

12 *Id.* ¶ 12.

13 *Id.*

14 *F.T.C. v. Cephalon, Inc.*, C.A. No. 08-2141 (E.D. Pa. filed May 8, 2008) (originally filed in 08-00244 (D.D.C. Feb. 13, 2008)).

complaint.[15] Watson and Carlsbad were also not named in the FTC's complaint. The FTC instituted the action against Cephalon in the District of Columbia, resisting transfer on the basis that consolidation with related class actions in Pennsylvania would contravene the public interest in expediting the FTC's case.[16] The case was nonetheless transferred to United States District Court for the Eastern District of Pennsylvania over the FTC's objection, where it has remained relatively dormant for over a year.

The Current Phase of the Investigation

More recently, using the same August 30, 2006 resolution that culminated in a suit against Cephalon only, the FTC has taken steps to continue its investigation by issuing new demands for information and testimony to Watson and Carlsbad, and their respective senior executives. These requests arise out of Cephalon's listing of a new patent relating to modafinil – U.S. Patent No. 7,297,346 (the "'346 Patent") – in the FDA Orange Book on December 19, 2007.[17] Because Provigil® is now covered by a new patent, under prevailing rules the FDA requires every ANDA applicant to file a Paragraph IV certification as to the '346 Patent before approving any ANDA for generic modafinil. This requirement applies even to an applicant whose ANDA was already pending when the '346 Patent was listed. Watson and Carlsbad, whose ANDA was on file with the FDA when the new patent was listed, therefore filed a supplemental Paragraph IV certification, identifying their Settlement Agreement and the resulting license as the basis for non-infringement of the '346 Patent.[18]

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[15] Commissioner Leibowitz dissented in part from the Commission's decision to bring suit, stating that he would have named as additional defendants any generic that "now refuses to relinquish their 180-day exclusivity." Statement of Commissioner Jon Leibowitz Concurring in Part and Dissenting in Part in the Matter of Cephalon, Inc., Matter Number 061-0182.

[16] *See* Opposition to Transfer, *F.T.C. v. Cephalon, Inc.*, Doc. No. 8, C.A. No. 1:08-cv-00244 (D.D.C. Mar. 6, 2008).

[17] Sunshine Decl. ¶ 13. The '346 Patent was issued by the United States Patent and Trademark Office (USPTO) on November 20, 2007.

[18] Sunshine Decl. ¶ 14.

Watson and Carlsbad filed their supplement on December 19, 2007, the same day that the '346 Patent was listed in the Orange Book.[19] Because the supplement was filed on the first possible day of filing, Watson knew it was not late to file on the '346 Patent. However, Watson did not know whether and/or which other generic companies had also filed on the first possible day, making the exclusivity status for Watson highly uncertain.[20] Moreover, because Watson and Carlsbad were late to file the original application challenging the '516 Patent, unless Watson was the lone first filer on December 19, 2007, and all of the four First Filers had relinquished their exclusivity as to the '516 Patent, according to FDA rules Watson would not be able to take advantage of its potential first filer status or even gain final approval of its ANDA. All of the facts required to make these determinations, however, are confidential information held by the FDA. Only in the event that Watson's ANDA received final approval would Watson learn whether it had marketing exclusivity relating to the '346 Patent.

Nevertheless, on March 4, 2009, Markus H. Meier, Assistant Director in the Health Care Division at the FTC, telephoned Steven C. Sunshine of Skadden, Arps, Slate, Meagher & Flom LLP, counsel for Watson, and indicated that he had been in contact with the FDA.[21] In the course of that conversation, Mr. Meier suggested that it might be in Watson's financial interest to relinquish or "waive" the exclusivity associated with its supplemental ANDA to clear the way for generic competition to Provigil®.[22] Messrs. Meier and Sunshine spoke again by telephone on March 10, 2009 and March 13, 2009, and Mr. Meier again pursued the question of whether Watson had determined to relinquish its marketing exclusivity.[23]

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19 *Id.* ¶¶ 13 – 14.
20 *See* Transcript, *In the Matter of Cephalon, Inc.*, FTC File No. 0610182, dated June 25, 2009 ("Buchen Dep."), at 28 – 29.
21 Sunshine Decl. ¶ 15.
22 *Id.*
23 *Id.* ¶ 16.

Within a week, Watson also received a telephone from a third party generic pharmaceutical company seeking to negotiate a transaction with Watson involving the Company's purported first-to-file rights.[24] At the time, Watson had no information regarding whether it possessed first filer status in connection with the '346 Patent.[25] Indeed, the FDA has still not made this information available to Watson.[26] Watson understood that FTC Staff had been in contact with this third-party generic company regarding modafinil.[27] In response to these contacts, Watson considered its alternatives. Responsibility for the business decisions lay with Mr. Buchen, Watson's Senior Vice President and General Counsel, and a member of the Executive Committee.[28] Mr. Buchen had not reached a conclusion by the time that the FTC issued compulsory process.[29]

Apparently frustrated by Watson's failure to relinquish quickly, Mr. Meier also indicated to Mr. Sunshine that Watson's failure to waive its rights in the near term would likely cause the FTC "Front Office" to initiate an investigation.[30] Shortly thereafter, on May 19, 2009, the FTC issued a new CID and a subpoena *ad testificandum* to Mr. Buchen.[31] On May 22, 2009, the FTC issued another subpoena *ad testificandum* to Mr. Bisaro.[32] The FTC also issued a CID and two subpoenas *ad testificandum* to Watson's development partner, Carlsbad, even though Carlsbad had no real participation in any of the relevant events.[33] The CIDs and subpoenas seek

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24 *Id.* ¶ 17.
25 *Id.* ¶ 15.
26 Buchen Dep. at 28.
27 Sunshine Decl. ¶ 17.
28 Buchen Dep. at 67.
29 *Id.* at 40, 67.
30 Sunshine Decl. ¶ 16.
31 *See* Civil Investigative Demand dated May 19, 2009 (Exhibit F) and Subpoena *Ad Testificandum* dated May 19, 2009 issued to David Buchen (Exhibit G). While the CID and subpoena were issued on May 19, 2009, they were actually served on May 28, 2009. Declaration of Maria A. Raptis ("Raptis Decl.") ¶ 8.
32 *See* Subpoena *Ad Testificandum* dated May 22, 2009 issued to Paul Bisaro (Exhibit H). While the subpoena was issued on May 22, 2009, it was actually served on May 28, 2009.
33 *See* Civil Investigative Demand dated May 19, 2009 (Exhibit I); Subpoena *Ad Testificandum* dated May 19, 2009 issued to Robert Wan (Exhibit J); and Subpoena *Ad Testificandum* dated May 19, 2009 issued to Lanie

information and documents relating to the '346 Patent and any associated marketing exclusivity, including any contacts Watson may have had with any company regarding these issues. Through discussions with FTC Staff, counsel for Watson learned that the FTC was primarily interested in understanding whether Watson has reached any agreements with Cephalon regarding relinquishment of any marketing exclusivity associated with the '346 Patent.[34]

Beginning on May 21, 2009, counsel for Watson contacted Saralisa C. Brau, Deputy Assistant Director in the Health Care Division at the FTC, to discuss the May 19, 2009 CID and subpoenas.[35] Watson's counsel informed Ms. Brau that Watson had not reached any agreements or decisions regarding relinquishment.[36] Watson's counsel further sought to limit Watson's response to the CID and subpoenas to narrative responses which would confirm that Watson had not reached any agreements whatsoever on relinquishment.[37] However, the FTC Staff declined to narrow the scope of its investigation.[38] Watson then agreed to respond to the CID fully, but sought a one-week extension of the return date; the CID as issued listed a return date of June 3, 2009 – less than one week after Watson was served.[39] Watson's counsel also sought a temporary deferral of the subpoenas until such time as the FTC could have the opportunity to review Watson's response to the CID and thereby confirm that Watson had not

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Wang (Exhibit K). The subpoena issued to Lanie Wang, Supervisor of Regulatory Affairs at Carlsbad, was withdrawn because Ms. Wang has not been employed by Carlsbad since September 2007. *See* June 2, 2009 Letter from Saralisa Brau, Deputy Assistant Director, Health Care Division, FTC ("June 2, 2009 Letter") (Exhibit L).

34 Raptis Decl. ¶ 6.

35 *Id.*

36 *Id.*

37 *Id.* ¶ 7.

38 *Id.*

39 *Id.* ¶ 8.

reached any agreements or decisions regarding relinquishment.[40] The FTC declined to reach an agreement on a reasonable extension of time.[41]

Watson then informed FTC Staff that it would respond to the CID in its entirety by June 10, 2009, but absent an agreement on a short extension of the original return dates of June 10, 2009 for Mr. Buchen, and June 22, 2009 for Mr. Bisaro, the Company would in all likelihood seek to quash the subpoenas for testimony on the basis that the FTC should defer questioning Watson's senior executives until Staff had an opportunity to review the Company's CID response.[42] On June 1, 2009, the FTC and Watson agreed on new dates for the investigational hearings (June 25 and June 30, respectively), and one-week extensions on Watson's deadline to file a petition to quash the subpoenas.[43]

On June 10, 2009, Watson submitted its response to the May 19, 2009 CID.[44] In its response, Watson once again informed FTC Staff that it had not reached any agreements or decisions regarding relinquishment.[45] Watson also identified its limited contacts with one third-party generic company on the subject of relinquishment.[46] Moreover, Watson submitted all documents relevant to these topics together with its written response to the CID.[47] Notably, Mr. Bisaro had *no responsive documents*, and *did not have any contacts with any company on the subject of relinquishment.*

Counsel for Watson then met with FTC Staff on June 12, 2009 to discuss Watson's response to the CID, and to confirm once more that Watson had not reached any

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40 *Id.*
41 *Id.*
42 *Id.* ¶ 9.
43 *Id.* ¶ 10; *see also* June 2, 2009 Letter (Exhibit L).
44 Raptis Decl. ¶ 11.
45 *Id.*
46 *Id.*
47 *Id.*

agreements or decisions with respect to relinquishment.[48] Watson's counsel suggested that the subpoena for Mr. Bisaro's testimony should be withdrawn and informed Staff that Watson would in all likelihood resist Mr. Bisaro's investigational hearing on the basis that he had no responsive documents and had not participated in any third party discussions regarding relinquishment.[49] While deposing Mr. Buchen was also unlikely to yield significant additional information, in the interest of avoiding a dispute, Watson's counsel informed Staff that it would nonetheless proceed with Mr. Buchen's hearing.[50]

On June 25, 2009, Mr. Buchen provided sworn testimony in this matter in an investigational hearing conducted by Mr. Meier. Mr. Buchen testified that Watson had not reached any agreement or decision with any party relating to relinquishment.[51] In fact, Mr. Buchen testified that the FTC's CID and subpoenas caused Watson to suspend consideration of relinquishment.[52] Mr. Buchen also testified that he was the only individual at Watson involved in any discussions with third parties relating to this topic, that he had no discussions with Cephalon, and that he was the primary decision-maker with respect to relinquishment.[53] Moreover, Mr. Buchen testified that he spoke with Mr. Bisaro about relinquishment "fewer than five" times, and only for the purposes of keeping Mr. Bisaro informed.[54] Due to Mr. Buchen's role as General Counsel of the Company, however, these conversations would implicate legal advice.[55]

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48 *Id.* ¶ 12.
49 *Id.*
50 *Id.*
51 Buchen Dep. at 40, 67.
52 *Id.* at 39 – 40.
53 *Id.* at 29, 40, 51, 66 – 67.
54 *Id.* at 37, 67.
55 *Id.* at 37 – 38.

The Pending Subpoena

At the time of Mr. Buchen's investigational hearing, the first subpoena *ad testificandum* issued to Mr. Bisaro was still pending. Therefore, in light of Mr. Buchen's testimony regarding Mr. Bisaro's marginal familiarity with the relevant topics, Mr. Meier and Mr. Sunshine reached an agreement on the record extending the return date for Mr. Bisaro's subpoena to July 2, 2009.[56] Mr. Meier further stated that, in the interim, he would "talk with people at the FTC about whether it's *even necessary* to do an investigational hearing of Mr. Bisaro."[57] Mr. Sunshine reiterated that Watson would petition to quash the subpoena issued to Mr. Bisaro if the FTC determined to enforce the subpoena.

Shortly thereafter, Mr. Meier telephoned Mr. Sunshine and indicated that the FTC had no present intention of conducting an investigational hearing of Mr. Bisaro.[58] Mr. Meier agreed to indefinitely postpone the hearing, but preserved the right to seek to enforce the subpoena at a later date. Watson also preserved its right to petition to quash Mr. Bisaro's subpoena. A letter memorializing this agreement was provided to Mr. Meier for his countersignature on June 30, 2009.[59]

Weeks later, on the afternoon of Friday, July 17, 2009, Mr. Meier telephoned Mr. Sunshine to inform him that the FTC had determined to proceed with Mr. Bisaro's investigational hearing.[60] Mr. Meier acknowledged the testimony on the record that Mr. Bisaro had had "fewer than five" conversations with his General Counsel regarding the possibility of

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56 *Id.* at 71.

57 *Id.* (emphasis added).

58 Sunshine Decl. ¶ 21.

59 *See* Letter dated June 30, 2009 from Steven C. Sunshine to Markus H. Meier ("June 30, 2009 Letter") (Exhibit M). Mr. Meier was traveling when the letter was transmitted on June 30, 2009. While he was therefore unable to sign the letter, during subsequent telephone calls he twice reiterated that the parties had an agreement and that his workload was the only factor preventing him from providing a countersigned copy of the letter. (Sunshine Decl. ¶ 21.)

60 Sunshine Decl. ¶ 22.

relinquishment.[61] Notwithstanding Watson's claim that these discussions would certainly implicate privileged communications, Mr. Meier indicated that there might be portions of the conversations which could be disclosed.[62] Mr. Sunshine informed Mr. Meier that Watson would in all probability petition to quash the subpoena. Mr. Meier asked Mr. Sunshine to telephone Ms. Brau on the following Monday, July 20, 2009, to agree on a schedule.[63]

On Monday, July 20, 2009, counsel for Watson contacted Ms. Brau and proposed a return date of August 21, 2009.[64] Ms. Brau indicated that the FTC's preferred return date was Friday, July 24, 2009 (*i.e.*, four days later), and that a return period of roughly a month was a non-starter.[65] At best, Ms. Brau suggested a return date of August 3, 2009.[66] Counsel for Watson explained that due to vacation schedules during the month of August, and Mr. Sunshine's absence during this period, Watson would not be able to agree to these dates.[67]

On Tuesday, July 21, 2009, counsel for Watson telephoned Ms. Brau to propose August 17, 2009 as an alternative date.[68] However, Ms. Brau indicated that despite the existence of an indefinite extension on the return date for Mr. Bisaro's subpoena, the FTC did not need to negotiate this matter and could issue a new subpoena to unilaterally set its schedule.[69] Counsel for Watson then proposed August 14, 2009.[70] Ms. Brau declined to consider this new proposal, and notwithstanding the present agreement between the FTC and Watson, reiterated that Staff

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61 *Id.*
62 *Id.*
63 *Id.*
64 Raptis Decl. ¶ 15; *see also* Letter dated July 21, 2009 from Maria A. Raptis to Saralisa C. Brau ("July 21, 2009 Letter") (Exhibit N) and Letter dated July 22, 2009 from Saralisa C. Brau to Maria A. Raptis ("July 22, 2009 Letter") (Exhibit O).
65 Raptis Decl. ¶ 15.
66 *Id.*
67 *Id.*
68 *Id.* ¶ 16.
69 *Id.*
70 *Id.*

felt no need to reach an agreement with Watson.[71] On July 22, 2009, the FTC issued a second subpoena *ad testificandum* to Mr. Bisaro. The subpoena was received on July 23, 2009 and carries a return date of July 31, 2009.[72]

APPLICABLE STANDARDS

Congress has conferred upon the FTC investigative powers to fulfill its mandate under Section 5 of the Federal Trade Commission Act to prevent "unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a)(2). The FTC's investigative authority includes the power to issue compulsory process, including civil investigative demands or subpoenas. 15 U.S.C. § 49. However, none of the FTC's compulsory process is self-executing; rather, the FTC must seek enforcement of the subpoena in an appropriate district court. *Id.* In general, the mandate of the courts is to protect recipients of agency process from "unreasonable" inquiries. *See United States v. Morton Salt Co.*, 338 U.S. 632, 652-53 (1950) (citing *Okla. Press Publ'g Co. v. Walling*, 327 U.S. 186, 208 (1946)).

The Supreme Court has articulated four criteria which must be met for the FTC to obtain enforcement of a subpoena or other compulsory process: (i) the investigation must be conducted pursuant to a legitimate purpose; (ii) the inquiry must be relevant to the purpose of the investigation; (iii) the information sought must not already be within the agency's possession; and (iv) the agency must have followed the administrative steps required by the applicable law. *See United States v. Powell*, 379 U.S. 48, 57-8 (1964). Moreover, the Supreme Court has held that even where these criteria are met, agency process may not be enforceable if it has been issued for an improper purpose, such as "to harass the [recipient] or to put pressure on him to

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[71] *Id.*

[72] *Id.* ¶ 17. The subpoena was mailed to Watson's Corona location rather than to the New Jersey location, where Mr. Bisaro resides. *Id.*

settle a collateral dispute, or for any other purpose reflecting on the good faith of the particular investigation." *Id.* at 58 (stating that "[i]t is the court's process which is invoked to enforce the administrative summons and a court may not permit its process to be abused").

LEGAL OBJECTIONS

1. The Subpoena Unreasonably Demands Information That the FTC Already Possesses.

Where, as here, the FTC already possesses the information being sought by subpoena, enforcement of the subpoena is improper. *Id.*[73] The FTC is seeking oral testimony from Mr. Bisaro regarding marketing exclusivity related to the '346 Patent, and the basis for any decision by Watson regarding relinquishment. These topics have been covered at length – repeatedly – including under the CID issued contemporaneously with the original subpoena to Mr. Bisaro. Specifically, the FTC's CID sought the following categories of information:

- Whether Watson believes it is eligible to claim marketing exclusivity for its modafinil product;
- Which company – Watson or Carlsbad – has authority to relinquish any claim of exclusivity;
- Whether there is any agreement that prevents Watson or Carlsbad from relinquishing exclusivity;
- Information regarding contacts between Watson and any company regarding the '346 Patent, Watson's first filer status, eligibility to claim exclusivity or the relinquishment of exclusivity;
- Information regarding whether Watson has reached any agreement regarding relinquishment with any third party, and the basis for its decision; and
- Any documents constituting or relating to communications regarding the '346 Patent, Watson's first filer status, eligibility to claim exclusivity or the relinquishment of exclusivity.[74]

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[73] Watson also objects to the Subpoena on the grounds that the Resolution authorizing compulsory process resulted in a lawsuit against Cephalon, and a public decision not to challenge any generic company. The Commission may not now resurrect this Resolution to burden Watson with more process.

[74] *See* Civil Investigative Demand dated May 19, 2009 (Exhibit F).

Watson has responded to each and every inquiry fully. To the extent it possessed documents that were responsive to the CID, Watson produced them. Notably, Mr. Bisaro had *no responsive documents*. Moreover, through written responses to interrogatories, Watson informed the FTC that:

- Watson does not have definitive information regarding whether it is eligible for exclusivity, and in fact believes that the FTC possesses better information regarding this issue through its contacts with the FDA;
- As between Watson and Carlsbad, Watson has the right to make all decisions regarding commercialization of generic modafinil;
- There is no agreement between Watson and any other party preventing Watson from relinquishing any first-to-file rights it may have;[75]
- Watson had only limited contacts with one third-party generic company regarding the '346 Patent and any associated exclusivity, which it described in its responses; and
- Watson has not reached any decision about whether or not to relinquish exclusivity.[76]

Mr. Buchen confirmed this information during his investigational hearing. In particular, he testified that Watson still does not definitively know whether it is eligible for marketing exclusivity.[77] He also reiterated that there is no agreement preventing Watson from relinquishing any exclusivity associated with the '346 Patent.[78] Finally, Mr. Buchen described Watson's limited contacts with a third-party generic manufacturer on these topics, and explained in detail

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[75] Out of an abundance of caution, Watson cited the Settlement Agreement as 'possibly relating' to the issue of relinquishment. During his investigational hearing, Mr. Buchen explained that one possible example of the relationship between the Settlement Agreement and relinquishment was the very existence of the FTC's investigation, and the fact that it implicated the indemnification provision of the Settlement Agreement. (*See* Buchen Dep. at 43 – 44.) At no point did Watson say that the Settlement Agreement prevented relinquishment.

[76] *See* Watson Pharmaceuticals, Inc., Responses to Civil Investigative Demand, FTC File No. 061-0182 (June 10, 2009).

[77] Buchen Dep. at 28.

[78] *Id.* at 52.

that Watson had not reached any agreement or decision with any party relating to relinquishment.[79]

It is clear, moreover, that there is nothing more on these subjects for the FTC to unearth. Mr. Buchen testified that he was the *only* individual at Watson involved in any discussions with third parties relating to this topic.[80] He also testified that he was the primary decision-maker with respect to relinquishment, and that he only spoke with Mr. Bisaro about relinquishment "fewer than five" times for the purposes of keeping Mr. Bisaro informed.[81] Due to Mr. Buchen's role as General Counsel of the Company, Mr. Buchen also explained that these conversations likely were privileged.[82] In short, enforcing Mr. Bisaro's subpoena can only yield information that the FTC already possesses.[83]

2. The Subpoena Unreasonably Seeks Testimony from the Apex of Watson's Organization.

FTC Staff's insistence on questioning Mr. Bisaro under these circumstances is particularly unreasonable in light of the fact that he is the President and Chief Executive Officer of Watson. Courts routinely hold that it is improper to depose a high-ranking or "apex" employee unless the requesting party has reason to believe that he has personal knowledge of

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79 *Id.* at 35 – 37, 40, 67.

80 *Id.* at 29, 40, 51, 66 – 67. Nor can the FTC claim that persons outside Watson may have had relevant discussions that Mr. Bisaro is uniquely aware of; the FTC also deposed Carlsbad's Chief Executive Officer, Robert Wan, regarding these issues. Mr. Wan testified that he had not discussed relinquishment with any party, and he did not even know who Mr. Bisaro was. *See* Transcript, *In the Matter of Cephalon, Inc.*, FTC File No. 061-0182, dated July 15, 2009, at 10.

81 Buchen Dep. at 37.

82 *Id.* at 37 – 38.

83 This is not a situation in which there is merely "some redundancy" between the information the agency already has and the information expected to be provided under the challenged subpoena. *See Adamowicz v. United States*, 531 F.3d 151, 159 (2d Cir. 2008) (finding that "if the bulk of the materials" requested are not in the possession of the agency, then some overlap between what is requested and what the agency already possesses does not render the subpoena unenforceable). Nor is this a situation in which the FTC issued the subpoena to help it isolate relevant facts among huge volumes of information it already possesses. *See United States v. Berkowitz*, 355 F. Supp. 897, 901 (E.D. Pa. 1973) (finding that although the information was already in the agency's possession, it was "impossible or unjustifiably difficult and expensive to identify"); *see also United States v. Monumental Life Ins. Co.*, 440 F.3d 729, 734-35 (6th Cir. 2006) (where information was already in government's possession, agency must prove that its interests in requesting such information outweighed hardship on defendant in producing it).

relevant information that cannot be obtained through other means. *See, e.g., Thomas v. IBM*, 48 F.3d 478, 483 (10th Cir. 1995) (upholding protective order to prevent apex deposition where potential deponent lacked personal knowledge of relevant facts and the requesting party had made no attempt to demonstrate it could not obtain the requested information elsewhere); *Salter v. Upjohn Co.*, 593 F.2d 649, 651 (5th Cir. 1979) (upholding a lower court's interim prohibition of the deposition of a company president until depositions of lower-level employees revealed whether the president had personal knowledge of facts that could not be obtained elsewhere); *Baine v. Gen. Motors Corp.*, 141 F.R.D. 332, 335 (M.D. Ala. 1991) (finding apex deposition inappropriate because the requesting party failed to establish that the information sought could not be obtained from lower-level employees without imposing burden and inconvenience on the company's top executive).[84]

The FTC cannot claim that Mr. Bisaro has personal knowledge of facts that could not be obtained elsewhere. FTC Staff has already deposed Mr. Buchen – the only individual at Watson who participated in the limited communications between Watson and one third-party generic company regarding relinquishment. Mr. Buchen testified that while he kept Mr. Bisaro informed, Mr. Bisaro did not participate in any discussions first-hand.[85] Any non-privileged information told to Mr. Bisaro by Mr. Buchen was discoverable during Mr. Buchen's investigational hearing. Finally, as General Counsel of Watson, much of the substance of Mr. Buchen's conversations with Mr. Bisaro are attorney-client communications and constituted

[84] Federal Rule of Civil Procedure 26 provides the underlying justification for the "apex" doctrine. Rule 26 proscribes discovery that is obtainable "from some other source that is more convenient, less burdensome, or less expensive," Fed. R. Civ. P. 26(b)(2)(C)(i), or that will result in "annoyance, embarrassment, oppression, or undue burden or expense," Fed. R. Civ. P. 26(c)(1). The *Powell* criteria address many of the same concerns underlying restrictions on private party discovery requests in Rule 26, see *generally United States v. Powell*, 379 U.S. 48, 57-58 (1964), and apply with equal force to assess the reasonability of an apex deposition in this context.

[85] Buchen Dep. at 67.

attorney work product, and as such are protected from disclosure by privilege.[86] Under these circumstances, there is no reasonable basis to expend valuable time and resources on the deposition of Watson's Chief Executive Officer. Watson further objects that FTC Staff is seeking to compel Mr. Bisaro to travel to the District of Columbia to sit for an investigational hearing. If the Staff insists on burdening Mr. Bisaro, it should travel to his place of residence.

3. The Subpoena Was Likely Issued for an Improper Purpose.

According to long-standing Supreme Court precedent, a subpoena is unenforceable if it has been issued for an improper purpose, such as "to harass the [recipient] or to put pressure on him to settle a collateral dispute, or for any other purpose reflecting on the good faith of the particular investigation." *Powell*, 379 U.S. at 58. FTC Staff is aware that subjecting Mr. Bisaro to an investigational hearing will not yield any new or different information than it already possesses. Indeed, Mr. Meier indefinitely deferred Mr. Bisaro's hearing, *after* deposing Mr. Buchen, ostensibly because the hearing no longer appeared to be necessary or reasonably calculated to lead to new information.[87]

The only conceivable reason for the FTC to insist on an apex deposition at this stage is to pressure Watson to relinquish any exclusivity rights it may have, and thereby attempt to engineer generic entry into the modafinil market. The FTC Staff has been unable to achieve this result through its pending litigation against Cephalon, and now appears to be using its investigatory power and access to confidential information to accomplish its goals.[88] The FTC's intentions have been evident since FTC Staff first contacted Watson's counsel. In particular,

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[86] Even if the FTC could articulate a good-faith basis for believing Mr. Bisaro has personal information that is discoverable, a simple interrogatory would have been more appropriate than subjecting the CEO of the company to provide testimony. *See, e.g., Baine v. Gen. Motors Corp.*, 141 F.R.D. 332, 334-35 (M.D. Ala. 1991).

[87] *See* June 30, 2009 Letter (Exhibit M).

[88] Document and testimonial discovery of relevant persons may yield clarity as to the extent of such disclosures and the propriety of its use.

FTC Staff suggested hypothetical regulatory scenarios to encourage Watson to relinquish its legitimate intellectual property rights.[89] It further acted as a go-between with a third party generic company seeking to enter the market.[90] More disturbingly, notwithstanding the FTC's decision ultimately not to sue any of the First Filers, FTC Staff *told* Watson's counsel that the FTC would renew its investigation of Watson if the Company did not make the business decision the FTC Staff desired.[91] When Watson did not comply, the CID and subpoenas to Messrs. Buchen and Bisaro followed, and despite repeated attempts by Watson to provide what limited information exists on this subject matter in an efficient manner, FTC Staff continue to issue new process. Most recently, Staff jettisoned an agreement between the FTC and Watson to indefinitely postpone Mr. Bisaro's hearing and preserve both parties' rights in connection with the May 19, 2009 subpoena.[92] Rather than engage in a good faith negotiation on a revised return date, the FTC simply issued a new subpoena.

Under these circumstances, the FTC's insistence on deposing Mr. Bisaro can only be characterized as harassment. It is amply clear that the FTC has learned all it can regarding this subject matter and is seeking merely to achieve the arguably desirable – but nonetheless improperly conceived and *ultra vires* goal – of generic entry into the modafinil market.

CONCLUSION

For all of the foregoing reasons, the subpoena *ad testificandum* issued on July 22, 2009 for the investigational hearing of Mr. Paul Bisaro should be quashed.

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89 Sunshine Decl. ¶ 15.
90 *Id.* ¶ 17.
91 *Id.* ¶ 16.
92 Raptis Decl. ¶ 16; *see also* June 30, 2009 Letter (Exhibit M); July 21, 2009 Letter (Exhibit N); and July 22, 2009 Letter (Exhibit O).

REQUEST FOR CONFIDENTIAL TREATMENT

Watson requests that this entire Petition, as well as all supporting Exhibits, be maintained by the FTC as highly confidential. The information contained herein includes sensitive and proprietary business information of Watson. Accordingly, Watson requests that the Petition and all of its Exhibits receive the highest level of protection for confidentiality available under the Federal Trade Commission Act, including 15 U.S.C. § 57b-2, the Commissions' Rules of Practice (including 16 C.F.R. §§ 2.7(g) and 4.10(a)), the Freedom of Information Act (including 5 U.S.C. § 552(b)), and all other applicable statutes, rules and regulations.

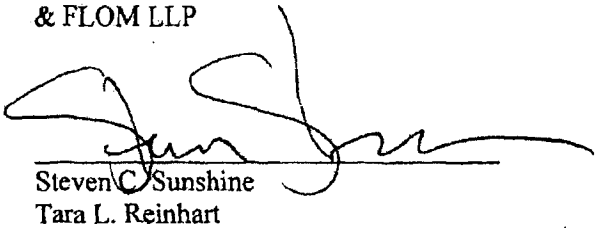
Given that the May 19, 2009 and July 22, 2009 compulsory processes relate to commercially sensitive information regarding Watson's ANDA and the terms of its agreements with Carlsbad and Cephalon, any disclosure by the Commission regarding this Petition has the potential to cause competitive harm to Watson. In particular, Watson's filing of a Paragraph IV certification relating to the '346 Patent is competitively sensitive information. Watson has not made the filing of the Paragraph IV public. Moreover the filing of the Paragraph IV, and the identify of the potential first filer is highly sensitive information given the 180-day exclusivity period available under Hatch-Waxman. Disclosure by the Commission of any part of this Petition would reveal the subject matter of the May 19, 2009 and July 22, 2009 compulsory process, including the ANDA supplement and related potential first-filer rights, thereby causing severe harm to Watson.

At a minimum, however, the Commission should limit disclosure of the Petition and its Exhibits to the redacted non-confidential version submitted with this Petition. The redacted information is exempt from disclosure under 16 C.F.R. § 4.10(a), 5 U.S.C. § 552(b) and other applicable statutes, rules and regulations.

Dated: July 30, 2009

Respectfully submitted,

SKADDEN, ARPS, SLATE, MEAGHER
& FLOM LLP



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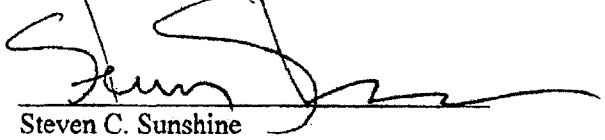
CERTIFICATION REQUIRED BY 16 C.F.R. § 2.7(d)(2)

Pursuant to 16 C.F.R. § 2.7(d)(2), counsel for Watson Pharmaceuticals, Inc. ("Watson") and petitioner Paul M. Bisaro, President and Chief Executive Officer of Watson, hereby certifies that they have conferred repeatedly with Federal Trade Commission ("FTC") counsel and staff on numerous occasions in a good faith effort to resolve by agreement the issues raised by this petition. Counsel have been unable to reach such an agreement.

In particular, counsel to Watson and Mr. Bisaro, including Steven C. Sunshine, Esq. and Maria A. Raptis, Esq., had oral and written communications with FTC Staff, including Markus H. Meier, Assistant Director in the Health Care Division at the FTC, Bradley S. Albert, Deputy Assistant Director in the Health Care Division at the FTC, and Saralisa C. Brau, Deputy Assistant Director in the Health Care Division at the FTC, regarding the FTC's requests for information, and agreed to respond to the Civil Investigative Demand and Subpoena *Ad Testificandum* issued on May 19, 2009 in connection with this matter. These agreements and discussions are reflected in correspondence between Watson's counsel and FTC counsel, dated June 2, 2009, June 30, 2009, July 21, 2009 and July 22, 2009.[91]



Steven C. Sunshine

[91] *See* Exhibits L – O.

CERTIFICATE OF SERVICE

I hereby certify that on the 30th day of July, 2009, I caused the original and twelve (12) copies of the Petition to Quash the Subpoena *Ad Testificandum* with attached Exhibits and documentation to be filed by hand delivery with the Secretary of the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C., 20580; and a copy of Petition to be filed by hand delivery with Markus H. Meier, Bradley S. Albert, Saralisa C. Brau, Mark Woodward, Ellen Connelly and Alpa Gandhi, Federal Trade Commission, 601 New Jersey Avenue, N.W., Washington, D.C., 20580.

Maria A. Raptis

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

IN RE	)
SUBPOENA *AD TESTIFICANDUM*	)
DATED JULY 22, 2009	)

DECLARATION OF STEVEN C. SUNSHINE

Pursuant to 28 U.S.C. § 1746, Steven C. Sunshine, Esq. declares as follows:

1. I am an attorney and a member of the bars of New York and the District of Columbia. I am a partner in the firm of Skadden, Arps, Slate, Meagher & Flom LLP. I am counsel to Watson Pharmaceuticals, Inc. ("Watson") in connection with the FTC's modafinil investigation. I am also counsel to Paul M. Bisaro in connection with the Petition to Quash the Subpoena *Ad Testificandum* dated July 22, 2009.

2. I submit this declaration in support of the Petition to Quash the Subpoena *Ad Testificandum* dated July 22, 2009. The facts set forth herein are based on my personal knowledge or information made known to me in the course of my duties.

3. Watson is a leading generic pharmaceutical company engaged in the research, development, manufacture, sale, marketing and distribution of generic versions of branded pharmaceutical drugs.

4. Watson and its development partner, Carlsbad Technology, Inc. ("Carlsbad"), filed an ANDA for generic Provigil®, Cephalon Inc.'s ("Cephalon") branded modafinil drug, in December 2004.

5. Watson and Carlsbad's ANDA contained a Paragraph IV certification as to certain patents then listed in the Federal Food and Drug Administration (FDA) Orange Book, including U.S. Reissued Patent No. 37,516 (the "'516 Patent").

6. Cephalon responded to the ANDA notification by suing Carlsbad for infringement of the '516 Patent in the United States District Court for the District of New Jersey on February 24, 2005.

7. On August 2, 2006, Watson, Carlsbad and Cephalon settled their dispute and entered into a Settlement and License Agreement (the "Settlement Agreement") pursuant to which Watson obtained a license to market generic modafinil prior to the expiration of the listed patents.

8. Shortly thereafter, by resolution dated August 30, 2006, the Federal Trade Commission (FTC) initiated a non-public inquiry to investigate whether Cephalon engaged in any unfair methods of competition by entering into a series of settlements agreements regarding its modafinil products. The investigation culminated in the FTC bringing a complaint against Cephalon. None of the four generic companies with first-to-file rights as to the '516 Patent were sued.

9. Watson was investigated but not sued in connection with the FTC's investigation.

10. Watson complied with an FTC subpoena *duces tecum* issued on November 9, 2006 by producing volumes of responsive documents to the FTC.

11. Watson and Carlsbad likewise complied with Civil Investigative Demands ("CID") for additional categories of information issued on May 18, 2007 and June 5, 2007.

12. Other cooperation provided by Watson included voluntary participation on August 7, 2007 in an investigational hearing by Watson's Senior Vice President, General Counsel and Secretary, Mr. David A. Buchen; and counsel presentations to FTC Staff on May 8 and September 25, 2007.

13. On December 19, 2007, Cephalon listed a new patent relating to modafinil – U.S. Patent No. 7,297,346 (the "'346 Patent") – in the FDA Orange Book.

14. Also on December 19, 2007, Watson and Carlsbad filed a supplemental ANDA containing a Paragraph IV certification as to the '346 Patent. Watson and Carlsbad's ANDA supplement identified a license from Cephalon as the basis for non-infringement of the '346 Patent.

15. On March 4, 2009, Markus H. Meier, Assistant Director in the Health Care Division at the FTC, telephoned me to discuss the modafinil matter. Mr. Meier suggested that Watson should consider relinquishment or "waiver" of the exclusivity associated with its supplemental ANDA and that this might clear the way for generic competition to Provigil®. At the time, Watson had no information regarding whether it possessed first filer status in connection with the '346 Patent. Mr. Meier indicated that he discussed the regulatory status with the FDA. During the call, he posited certain hypothetical regulatory scenarios under which Watson could profit from relinquishment.

16. Mr. Meier telephoned me again on March 10, 2009 and March 13, 2009, and both times reiterated that Watson should consider relinquishing its marketing exclusivity. During one conversation, Mr. Meier stated that Watson's failure to waive its rights would likely cause the FTC "Front Office" to reopen the modafinil investigation.

17. Mr. Meier also acknowledged that he was in communication with a third-party generic company regarding these issues, and later that company contacted Watson seeking an agreement relating to Watson's relinquishment.

18. On May 19, 2009, the FTC issued a CID and a subpoena *ad testificandum* to Mr. Buchen, and on May 22, 2009 the FTC issued a subpoena *ad testificandum* to Mr. Bisaro.

19. Watson complied with the May 19, 2009 CID by producing all responsive documents and relevant information.

20. Mr. Buchen complied with the May 19, 2009 subpoena issued to him by participating in an investigational hearing conducted by Mr. Meier on June 25, 2009.

21. On June 29, 2009, Mr. Meier informed me by telephone that the FTC had no present intention of conducting an investigational hearing with respect to Mr. Bisaro. During that conversation, Mr. Meier and I reached an agreement to indefinitely postpone Mr. Bisaro's hearing. On June 30, 2009, a letter memorializing this agreement was provided to Mr. Meier for his countersignature. On subsequent telephone calls, Mr. Meier twice reiterated that the parties had an agreement and that his workload was the only factor preventing him from providing a countersigned copy of the letter.

22. On July 17, 2009, Mr. Meier telephoned to inform me that the FTC had determined to proceed with Mr. Bisaro's investigational hearing. Mr. Meier acknowledged the testimony on the record that Mr. Bisaro had had "fewer than five" conversations with his General Counsel regarding the possibility of relinquishment. Notwithstanding Watson's claim that these discussions would certainly implicate privileged communications, Mr. Meier indicated that there might be portions of the conversations which could be disclosed.

I declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct.

Signed on this 30th day of July, 2009 at Washington, D.C.

Steven C. Sunshine
Counsel for Watson Pharmaceuticals, Inc.,
Paul M. Bisaro

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

IN RE	)
SUBPOENA *AD TESTIFICANDUM*	)
DATED JULY 22, 2009	)

DECLARATION OF MARIA A. RAPTIS

Pursuant to 28 U.S.C. § 1746, Maria A. Raptis, Esq. declares as follows:

1. I am an attorney and a member of the bar of New York. I am an associate in the firm of Skadden, Arps, Slate, Meagher & Flom LLP. I am counsel to Watson Pharmaceuticals, Inc. ("Watson") in connection with the FTC's modafinil investigation. I am also counsel to Paul M. Bisaro in connection with the Petition to Quash the Subpoena *Ad Testificandum* dated July 22, 2009.

2. I submit this declaration in support of the Petition to Quash the Subpoena *Ad Testificandum* dated July 22, 2009. The facts set forth herein are based on my personal knowledge or information made known to me in the course of my duties.

3. I have read the Petition to Quash the Subpoena *Ad Testificandum* dated July 22, 2009 and the exhibits attached thereto, and verify that Exhibits A through O are true and correct copies of original documents.

4. On May 19, 2009, the FTC issued a Civil Investigative Demand and a subpoena *ad testificandum* to David A. Buchen, Senior Vice President, General Counsel and Secretary of Watson.

5. On May 22, 2009, the FTC issued a subpoena *ad testificandum* to Mr. Bisaro, President and Chief Executive Officer of Watson.

6. On May 21, 2009, together with Mr. Steven C. Sunshine, a partner at Skadden, Arps, Slate, Meagher & Flom LLP, I spoke with Ms. Saralisa C. Brau, Deputy Assistant Director in the Health Care Division at the FTC, by telephone to discuss the May 19, 2009 CID issued to Watson and the May 19, 2009 and May 22, 2009 subpoenas *ad testificandum* issued to Mr. Buchen and Mr. Bisaro. The CID and subpoenas seek information and documents relating to the '346 Patent and any associated marketing exclusivity, including any contacts Watson may have had with any company regarding these issues. Through discussions with Ms. Brau, we learned that the FTC was primarily interested in understanding whether Watson has reached any agreements regarding relinquishment of any marketing exclusivity associated with the '346 Patent, and the basis for any decision by Watson not to waive exclusivity. We informed Ms. Brau that Watson had not reached any agreements or decisions regarding relinquishment.

7. On May 26, 2009, Mr. Sunshine and I contacted Ms. Brau by telephone and sought to limit Watson's response to the CID and subpoenas to narrative responses which would confirm that Watson had not reached any agreements on relinquishment. Ms. Brau initially indicated that she would consider this proposal, but later declined to narrow the scope of the FTC's investigation.

8. On May 28, 2009, Mr. Sunshine and I contacted Ms. Brau by telephone to confirm that Watson would respond to the CID fully, but also to seek a one-week extension of the return date; the CID as issued listed a return date of June 3, 2009 – less than one week after Watson and its senior executives were served on May 28, 2009. We also sought a temporary deferral of the subpoenas until such time as the FTC could have the opportunity to review Watson's response to the CID and thereby confirm that Watson had not reached any agreements

or decisions regarding relinquishment. Later that day, Ms. Brau telephoned me and declined to reach an agreement on an extension of time for either the CID or the subpoenas.

9. On May 29, 2009, I informed Ms. Brau that we would respond fully to the CID by June 10, 2009. In addition, I again suggested deferring the subpoenas until such time as FTC Staff would have the opportunity to review Watson's responses to the CID. Absent an agreement on a short extension of the original return dates of June 10, 2009 for Mr. Buchen, and June 22, 2009 for Mr. Bisaro, I informed Ms. Brau that the Company would in all likelihood seek to quash the subpoenas for testimony. Later that day, Ms. Brau proposed allowing a one-week extension on the return dates if Watson provided certain firm dates for investigational hearings for Mr. Buchen and Mr. Bisaro.

10. On June 1, 2009, Ms. Brau and I spoke by telephone and agreed on new dates for the investigational hearings of Mr. Buchen (June 25, 2009) and Mr. Bisaro (June 30, 2009), and a one-week extension (to June 17 and June 29, respectively) on Watson's deadline to file a petition to quash the subpoenas. A letter memorializing this agreement is dated June 2, 2009.

11. On June 10, 2009, Watson submitted its response to the May 19, 2009 CID. In its response, Watson confirmed that it had not reached any agreements or decisions regarding relinquishment. Watson also identified its limited contacts with third parties on the subject of relinquishment. Moreover, Watson submitted all documents relevant to these topics together with its written response to the CID.

12. On June 12, 2009, Mr. Sunshine and I met with FTC Staff, including Mr. Bradley S. Albert, Deputy Assistant Director in the Health Care Division at the FTC, and Ms. Brau, to discuss Watson's response to the CID. We informed Mr. Albert and Ms. Brau that

Watson would proceed with Mr. Buchen's hearing, but suggested that the subpoena for Mr. Bisaro's testimony should be withdrawn.

13. On June 29, 2009, Mr. Meier and Mr. Sunshine agreed to indefinitely postpone the hearing of Mr. Bisaro. A letter memorializing this agreement was provided to Mr. Meier for his countersignature on June 30, 2009.

14. On the afternoon of Friday, July 17, 2009, Mr. Meier telephoned Mr. Sunshine to inform him that the FTC had determined to proceed with Mr. Bisaro's investigational hearing.

15. On Monday, July 20, 2009, I contacted Ms. Brau to agree on a schedule and proposed a return date of August 21, 2009. Ms. Brau indicated that the FTC's preferred return date was Friday, July 24, 2009 (*i.e.*, four days later), and that a return period of roughly a month was a non-starter. At best, Ms. Brau suggested a return date of August 3, 2009. I explained that due to vacation schedules during the month of August, and Mr. Sunshine's absence during this period, Watson would not be able to agree to these dates.

16. On Tuesday, July 21, 2009, I telephoned Ms. Brau to propose August 17, 2009 as an alternative date. However, Ms. Brau stated that the FTC did not need to negotiate the matter and could issue a new subpoena to unilaterally set its schedule. I then proposed August 14, 2009. Ms. Brau declined to consider this new proposal and reiterated that Staff felt no need to reach an agreement with Watson.

17. On July 22, 2009, the FTC issued a second subpoena *ad testificandum* to Mr. Bisaro. The subpoena was received at Watson's Corona location on July 23, 2009 rather than in New Jersey, where Mr. Bisaro resides, and carries a return date of July 31, 2009.

I declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct.

Signed on this 29th day of July, 2009 at Washington, D.C.

Maria A. Raptis
Counsel to Watson Pharmaceuticals, Inc.,
Paul M. Bisaro

Exhibit A

Exhibit A is the Commission's July 22, 2009, Subpoena *Ad Testificandum* to Respondent, which is Petition Exhibit 3

Exhibit B

Exhibit B is the Commission Resolution Authorizing Use of Compulsory Process – FTC File No. 0610182, which is Petition Exhibit 2

Exhibit C

SUBPOENA DUCES TECUM

1. TO	2. FROM
Legal Department Watson Pharmaceuticals, Inc. 311 Bonnie Circle Corona, CA 92880 Attn: General Counsel	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoena requires you to appear and testify at the request of the Federal Trade Commission at a hearing [or deposition] in the proceeding described in Item 6.

3. LOCATION OF HEARING	4. YOUR APPEARANCE WILL BE BEFORE
Federal Trade Commission 601 New Jersey Ave., NW Room NJ-7207 Washington, DC 20001	No appearance required.
	5. DATE AND TIME OF HEARING OR DEPOSITION
	Documents to be produced in accordance with subpoena.

6. SUBJECT OF INVESTIGATION

Cephalon, Inc.; File No. 0610182

7. RECORDS YOU MUST BRING WITH YOU

See attached Definitions, Instructions, and Specifications.

8. RECORDS CUSTODIAN/DEPUTY RECORDS CUSTODIAN	9. COMMISSION COUNSEL
Markus H. Meier, Records Custodian Philip M. Eisenstat, Deputy Records Custodian	Philip M. Eisenstat, John P. DeGeeter, Saralisa C. Brau

DATE ISSUED	COMMISSIONER'S SIGNATURE
November 9, 2006	William E. Kovacic

GENERAL INSTRUCTIONS

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

PETITION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any petition to limit or quash this subpoena be filed within 20 days after service or, if the return date is less than 20 days after service, prior to the return date. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission. Send one copy to the Commission Counsel named in Item 9.

TRAVEL EXPENSES

Use the enclosed travel voucher to claim compensation to which you are entitled as a witness for the Commission. The completed travel voucher and this subpoena should be presented to Commission Counsel for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from Commission Counsel.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

RETURN OF SERVICE

I hereby certify that a duplicate original of the within subpoena was duly served: (check the method used)

○ *in person.*

○ *by registered mail.*

○ *by leaving copy at principal office or place of business, to wit:*

.....

.....

.....

.....

on the person named herein on:

.....
(Month, day, and year)

.....
(Name of person making service)

.....
(Official title)

SUBPOENA DUCES TECUM TO WATSON PHARMACEUTICALS, INC.

DEFINITIONS

1. "Watson, "You," "Your," or "the Company" refers to Watson Pharmaceuticals, Inc., its domestic and foreign parents, predecessors, divisions, and wholly or partially owned subsidiaries, affiliates, partnerships, and joint ventures; and all directors, officers, employees, consultants, agents and representatives of the foregoing. The terms "subsidiary," "affiliate," and "joint venture" refer to any person in which there is partial (25 percent or more) or total ownership or control by Watson.

2. "Barr Agreements" means any agreement or side-agreement between Barr Laboratories, Inc. or any of its affiliates (collectively, "Barr") and Cephalon, Inc. and any of its affiliates (collectively, "Cephalon") related to patent litigation settlement for Provigil, including, but not limited to, the following agreements between Barr and Cephalon, all dated February 1, 2006, which were filed with the Federal Trade Commission pursuant to Section 1112(a) of Subtitle B of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Modernization Act"), and any subsequent additions, amendments or modifications thereto: the Provigil Settlement Agreement, the Modafinil License and Supply Agreement, the Actiq Settlement Agreement, the Actiq Supplemental License and Supply Agreement, and the letter from Paul M. Bisaro (President and COO of Barr) to Boaz Laor (President of Chemagis Ltd.) concerning modafinil sales to Cephalon.

3. "Carlsbad/Watson Agreements" means any agreements or side agreements between Watson or Carlsbad Technology, Inc. ("Carlsbad"), and any of their affiliates, and Cephalon related to patent litigation settlement for Provigil, including, but not limited to, the following agreements dated August 2, 2006, which were filed with the Federal Trade Commission pursuant to the Medicare Modernization Act, and any subsequent additions, amendments or modifications thereto: the Provigil Settlement and License Agreement by and among Carlsbad, Watson and Cephalon, and the Oral Transmucosal Fentanyl Citrate Sales Agent Agreement by and between Watson and Cephalon. For the purpose of this definition, "side agreements" include any agreement entered into between (1) Cephalon and Carlsbad; (2) Cephalon and Watson; or (3) Cephalon and any affiliate of Carlsbad or Watson, either (1) within 30 days of the signing of the Provigil Settlement and License Agreement or (2) that is in any way related to the negotiation of the Provigil Settlement and License Agreement.

4. "Communication" is used in the broadest possible sense and means every conceivable manner or means of disclosure, transfer, or exchange of oral, written, or electronic information between one or more persons or entities.

5. "Document" means all written, recorded, or graphic materials of every kind, prepared by any person, that are in the possession, custody, or control of Watson. The term "document" includes the complete original document (or a copy thereof if the original is not available), all drafts, whether or not they resulted in a final document, and all copies that differ in any respect from the original, including any notation, underlining, marking, or information not on

the original. Documents covered by this subpoena include, but are not limited to, the following: Electronically Stored Information; letters; memoranda; all papers filed with a court in litigation and relating to litigation settlement; reports; contracts, including patent license agreements; studies; plans; notes; entries in calendars; publications; facsimiles; tabulations; ledgers and other records of financial matters or commercial transactions; audio and video tapes; and computer printouts.

6. "Electronically Stored Information" refers to any portion of data found only on a computer or other device capable of storing electronic data, where such data is capable of being manipulated as an entry. "Electronically Stored Information" includes, but is not limited to, e-mail, spreadsheets, databases, word processing documents, images, presentations, application files, executable files, log files, and all other files present on any type of device capable of storing electronic data. Devices capable of storing Electronically Stored Information include, but are not limited to: servers, desktop computers, portable computers, handheld computers, flash memory devices, wireless communication devices, pagers, workstations, minicomputers, mainframes, and any other forms of online or offline storage, whether on or off company premises.

7. "Generic Agreements" means the Barr Agreements, Carlsbad/Watson Agreements, Mylan Agreements, Ranbaxy Agreements and/or Teva Agreement.

8. "Mylan Agreements" means any agreement or side-agreement between Mylan Pharmaceuticals, Inc. or any of its affiliates (collectively, "Mylan") and Cephalon related to patent litigation settlement for Provigil, including, but not limited to, the following agreements between Mylan and Cephalon, which were filed with the Federal Trade Commission pursuant to the Medicare Modernization Act, and any subsequent additions, amendments or modifications thereto: the Provigil Settlement Agreement dated January 9, 2006, the Modafinil License Agreement dated March 23, 2006, the Transdermal Fentanyl Patch Option and Exclusivity Agreement, and the Transdermal Fentanyl Patch Collaboration Agreement, both dated January 9, 2006

9. "Product" refers to both the commercialized version of a drug, as well as any pre-commercialized, proposed, or anticipated versions of a drug.

10. "Ranbaxy Agreements" means any agreement or side-agreement between Ranbaxy Laboratories, Inc. or any of its affiliates (collectively, "Ranbaxy") and Cephalon related to patent litigation settlement for Provigil, including, but not limited to, the following agreements between Ranbaxy and Cephalon, which were filed with the Federal Trade Commission pursuant to the Medicare Modernization Act, and any subsequent additions, amendments or modifications thereto: the Provigil Settlement Agreement dated December 12, 2005, and the Modafinil License Agreement dated May 23, 2006.

11. "Relating to" is used in the broadest possible sense and means, in whole or in part, addressing, analyzing, concerning, constituting, containing, commenting, in connection with, dealing with, discussing, describing, embodying, evidencing, identifying, pertaining to, referring to, reflecting, reporting, stating, or summarizing.

12. "Teva Agreement" means any agreement or side-agreement between Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., or any of their affiliates (collectively, "Teva") and Cephalon related to patent litigation settlement for Provigil, including, but not limited to, the Settlement Agreement between Teva and Cephalon dated December 8, 2005 which was filed with the Federal Trade Commission pursuant to the Medicare Modernization Act, and any subsequent additions, amendments or modifications thereto.

INSTRUCTIONS

1. Unless otherwise indicated, each specification in this subpoena covers any and all Documents prepared, created, sent, or received during, and all Documents relating to, the period from January 1, 2002, to present. This subpoena is continuing in nature and requires the production of all documents written or obtained by You up to fourteen (14) days prior to the time of the final response to this request.

2. Documents requested are those in actual or constructive possession, custody, or control of Watson, and its representatives, attorneys, and other agents, including but not limited to, consultants, accountants, lawyers, or any other persons retained, consulted by, or working on behalf or under the direction of Watson, wherever they may be located.

3. Documents shall be accompanied by an index that identifies: (i) the name of each person from whom responsive Documents are submitted (e.g., files of "X", Vice President of Watson); and (ii) the corresponding consecutive document control number(s) used to identify that person's Documents.

4. Produce all Documents in complete, unredacted form, unless privileged. Submit Documents as stored by the Company or individual. Mark in a color other than black each page of each Document with a corporate identification and consecutive Bates numbers, except that bound pamphlets or books with numbered pages may be marked with corporate identification and a single Bates number. Provide a translation of non-English Documents into English; submit the foreign language Document, with the English translation attached.

5. The Company shall discuss the form and method of production of responsive documents with the Commission representative identified in paragraph 10, or with the representative's designee. The Company shall be permitted to use any form and method of production of responsive documents that the Commission representative specifically approves.

A. You may, with the prior approval from the FTC, submit copies of original hard copy Documents as either hard copies or electronic copies in lieu of original Documents, provided that such copies are accompanied by an affidavit of an officer of the Company stating that the copies are true, correct, and complete copies of the original Documents.

(1). Hard copies. Provide color photocopies where the original Document is in color. Submit copies in sturdy cartons not larger than 1.5 cubic feet. Number and mark each box with corporate identification. Produce all Documents as they are kept in the ordinary course of business (e.g., produce Documents that in their original condition were stapled, clipped, or otherwise fastened in the same form).

(2). Electronic copies. You may submit original hard copy Documents as fully text-searchable electronic copies in single-page, 300 DPI (dots per inch) - Group IV TIFF (tagged image file format) files, named for the Bates number of the Document, and accompanied by a Summation image load file (*.dii), which denotes the appropriate information to allow the loading of the images into Summation with all Document breaks (Document delimitation) preserved, and a corresponding text file containing the optical character recognition (OCR) for either each page or each Document.

B. Electronically Stored Information. You may, with the prior approval of the FTC, produce Electronically Stored Information in the following forms and formats, provided that such copies are true, correct, and complete copies of the original Documents:

(1). Microsoft Excel and Access files must be submitted in native format. Documents provided in native format shall be accompanied by a Summation Class III DII file containing document control numbers for each file submitted.

(2). TIFF files. Submit files as single-page, 300 DPI - Group IV TIFF files, with a corresponding file containing the extracted text from the Document. Name each file, comprised of both images and text, for the Bates number of the Document. Include a Summation DII file that denotes the appropriate information and allows the loading of the images into Summation, while preserving all Document breaks (Document delimitation). Include metadata and other

information about the Documents in delimited ASCII format. Produce Microsoft PowerPoint presentations in "Notes Pages" format. "Notes Pages" includes a small version of the slide that appears at the top of the page with any notes appearing directly below.

(i). Include the following metadata fields for electronic files other than email: creation date/time; modified date/time; last accessed date/time; size; location or "path"; file name; and custodian.

(ii). Include the following metadata fields for emails: to; from; CC; BCC; subject; date and time sent; attachment (range or begin attach, end attach); file name of attachments; and custodian.

(3). Native format. Submit files, accompanied by a Summation Class III DII file containing Document control numbers for each Document. Provide any Documents that are originally stored in .ZIP format, or any other compressed format, as extracted, uncompressed files. Microsoft Outlook files may be produced as Outlook .PST files. Each .PST file should contain e-mails from only one custodian, and should be accompanied by a Summation Class III DII file containing a Bates number and Message ID for each e-mail. Please note that any .MSG files located on a file system should be treated as an electronic Document and not as an e-mail. All other e-mail formats must be produced in TIFF or PDF formats. Any PDF files produced must be searchable and include all metadata and attachments.

C. Data productions as ASCII text files. You may submit database files, with prior approval, as delimited ASCII text files, with field names as the first record, or as fixed-length flat files with appropriate record layout. For ASCII text files, provide field-level Documentation and ensure that delimiters and quote characters do not appear in the data. All database files should include or be accompanied with the definitions of the field names, codes, and abbreviations used in the database and, upon request from the FTC, the instructions for using the database. The FTC may require that a sample of the data be sent for testing. File and record structures must conform to the following requirements:

(1). File structures. The FTC will accept sequential files only. Convert all other file structures into sequential format.

(2). Record structures. The FTC will accept fixed-length records only. Include all data in the record as it would appear in printed format: viz, numbers unpacked, and decimal points and signs printed.

D. Submit electronic iles and images in any combination of the following forms:

(1). For any production over 10 gigabytes, use IDE and EIDE hard disk drives, formatted in Microsoft Windows-compatible, uncompressed data.

(2). For productions under 10 gigabytes, CD-R CD-ROMs formatted to ISO 9660 specifications, DVD-ROM for Windows-compatible personal computers, and USB 2.0 Flash Drives are also acceptable storage formats.

E. All documents produced in electronic format shall be scanned for and free of viruses. The FTC will return any infected media for replacement.

6. You are to produce entire Documents including all attachments, cover letters, memoranda, and appendices, as well as the file, folder tabs, and labels appended to or containing any Documents. Copies which differ in any respect from an original (because, by way of example only, handwritten or printed notations have been added) should be produced separately. Each Document requested herein must be produced in its entirety and without deletion, abbreviation, redaction, expurgation, or excisions, regardless of whether You consider the entire Document to be relevant or responsive to these Requests. If You have redacted any portion of a Document, stamp the word "redacted" where the redacted material originally appeared, on each page of the Document which You have redacted. Privileged redactions must be included in a privilege log prepared pursuant to Paragraph 7; any non-privileged redactions must also be included in a log describing the basis for redaction, prepared pursuant to Paragraph 8.

7. If any privilege is claimed as a ground for not producing a Document or tangible thing, provide a privilege log describing the basis for the claim of privilege and all information necessary for the FTC to assess the claim of privilege. Separately, for each Document and attachment withheld or redacted, the log shall include the following: (i) specific grounds for the claim of privilege; (ii) the title of the Document or attachment; (iii) the date of the Document or attachment; (iv) the author of the Document or attachment; (v) the addressees and recipients of the Document or attachment or any copy thereof (including persons "cc'd," or "bcc'd," or "blind

cc'd"); (vi) a description of the subject matter of the Document or attachment in sufficient detail to assess the claim of privilege; (vii) the Bates range or page length of the Document or attachment; and (viii) the Requests to which the Document or attachment are responsive. Additionally, for each Document withheld under a claim of attorney work product immunity, state whether the Document was produced in anticipation of litigation or for trial, and, if so, identify the anticipated litigation or trial upon which the assertion is based. Any attachment to a Document withheld under a claim of privilege or immunity shall be produced unless the attachment is also subject to a claim of privilege or immunity, and the basis for such claim is described in a privilege log.

8. If any Documents are redacted on a basis other than privilege, provide the information and reason for redacting that Document per instruction 7.

9. Whenever necessary to bring within the scope of a Request a response that might otherwise be construed to be outside its scope, the following constructions should be applied:

A. Construing the terms "and" and "or" in the disjunctive or conjunctive, as necessary, to make the Request more inclusive;

B. Construing the singular form of any word to include the plural and the plural form to include the singular;

C. Construing the past tense of the verb to include the present tense and the present tense to include the past tense;

D. Construing the masculine form to include the feminine form; and

E. Construing the term "Date" to mean the exact day, month, and year if ascertainable; if not, the closest approximation that can be made by means of relationship to other events, locations, or matters.

10. You are required to submit all documents specified in the subpoena on or before the formal return date together with the attached executed affidavit stating that the attached submission constitutes full compliance with the subpoena. You should comply with this subpoena by submitting all responsive documents on or before the return date to Kelly Vaughan, Federal Trade Commission, Bureau of Competition, 601 New Jersey Avenue, N.W., Room 6148, Washington, D.C. 20001. Please contact Saralisa Brau at (202) 326-2774 with any questions.

SPECIFICATIONS

In accordance with the above Definitions and Instructions, submit the following documents:

1. All Documents relating to the Generic Agreements and the terms contained therein, including but not limited to Documents relating to the negotiations of such agreement(s); discussions, communications, analyses, evaluations, and notes regarding such agreements; and drafts of the agreements (whether or not incorporated in the executed agreement).

2. All Documents discussing competition for the sale of any modafinil product.

3. All Documents (including forecasts) discussing the marketing or sale of Provigil or any generic Provigil product, including but not limited to: business plans, marketing plans, strategic plans, short term and long range strategies and objectives, collaboration plans, budgets and financial projections, and presentations to management committees, executive committees, and boards of directors.

4. All Documents constituting or relating to any communication relating to the sale of any modafinil product between or among any parties to the Generic Agreements or any other company that has filed an Abbreviated New Drug Application (ANDA) referencing Provigil.

5. Submit one copy of each organization chart and personnel directory in effect since January 1, 2004 for the Company as a whole and for each of the Company's facilities or divisions involved in any activity relating to any modafinil product.

6. One unredacted copy of each of the following Documents relating to any patent infringement litigation concerning Provigil or a generic version of Provigil:

   A. All complaints and counterclaims and answers, replies or responses thereto, and any amendments or supplements to the foregoing filed by your Company;

   B. All motions and briefs and oppositions, replies and other responsive pleadings thereto filed by your Company, including any memoranda, exhibits, or other Documents filed in support of such pleadings; and

   C. All expert reports prepared by or for your Company and all supporting Documents and exhibits.

7. All Documents constituting or relating to any communication involving any intellectual property that does, could, or is claimed to apply to the manufacture, sale, and composition of a modafinil product.

SUBPOENA DUCES TECUM TO WATSON PHARMACEUTICALS, INC.

CERTIFICATION

This response to the Subpoena Duces Tecum issued by the Federal Trade Commission, together with any and all appendices and attachments thereto, was prepared and assembled under my supervision in accordance with instructions issued by the Federal Trade Commission. Subject to the recognition that, where so indicated, reasonable estimates have been made because books and records do not provide the required data, the information is, to the best of my knowledge, true, correct, and complete in accordance with the statute and rules.

Where copies rather than original documents have been submitted, the copies are true, correct, and complete. If the Commission uses such copies in any court or administrative proceeding, the Company will not object based on the Commission not offering the original document.

I declare under penalty of perjury that the foregoing is true and correct.

_____

TYPE OR PRINT NAME AND TITLE

_____

(Signature)

Subscribed and sworn to before me at the City of _____,

State of _____, this _____ day of _____, 2006.

_____

(Notary Public)

My Commission expires: _____

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Deborah Platt Majoras, Chairman
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

RESOLUTION AUTHORIZING USE OF COMPULSORY PROCESS IN A NONPUBLIC INVESTIGATION

File No. 0610182

Nature and Scope of Investigation:

To determine whether Cephalon, Inc., Teva Pharmaceutical Industries, Inc. (and its affiliate Teva Pharmaceuticals USA, Inc.), Barr Laboratories, Inc., Ranbaxy Laboratories, Inc., Mylan Pharmaceuticals, Inc., Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding any modafinil products.

The Federal Trade Commission hereby resolves and directs that any and all compulsory processes available to it be used in connection with this investigation.

Authority to Conduct Investigation:

Sections 6, 9, 10, and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; FTC Procedures and Rules of Practice, 16 C.F.R. *et. seq.*, and supplements thereto.

By direction of the Commission.

Donald S. Clark
Secretary

ISSUED: August 30, 2006

Exhibit D

United States of America
Federal Trade Commission

CIVIL INVESTIGATIVE DEMAND

1. TO

Watson Pharmaceuticals, Inc.
c/o Steven C. Sunshine
Skadden, Arps, Slate, Meagher & Flom, LLP
1440 New York Ave. NW
Washington, D.C. 20005

This demand is issued pursuant to Section 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1, in the course of an investigation to determine whether there is, has been, or may be a violation of any laws administered by the Federal Trade Commission by conduct, activities or proposed action as described in Item 3.

2. ACTION REQUIRED

☐ You are required to appear and testify.

LOCATION OF HEARING	YOUR APPEARANCE WILL BE BEFORE
	No appearance required.
	DATE AND TIME OF HEARING OR DEPOSITION

☒ You are required to produce all documents described in the attached schedule that are in your possession, custody, or control, and to make them available at your address indicated above for inspection and copying or reproduction at the date and time specified below.

☒ You are required to answer the interrogatories or provide the written report described on the attached schedule. Answer each interrogatory or report separately and fully in writing. Submit your answers or report to the Records Custodian named in Item 4 on or before the date specified below.

DATE AND TIME THE DOCUMENTS MUST BE AVAILABLE

Return date is 30 days from date of CID.

3. SUBJECT OF INVESTIGATION

See attached resolution, File No. 0610182.

4. RECORDS CUSTODIAN/DEPUTY RECORDS CUSTODIAN	5. COMMISSION COUNSEL
Markus H. Meier, Records Custodian Philip M. Eisenstat, Deputy Records Custodian	Philip M. Eisenstat, Saralisa C. Brau, Mark Woodward, Jeffrey Bank

DATE ISSUED	COMMISSIONER'S SIGNATURE
18 May 2007	William E. Kovacic

INSTRUCTIONS AND NOTICES

The delivery of this demand to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply. The production of documents or the submission of answers and report in response to this demand must be made under a sworn certificate, in the form printed on the second page of this demand, by the person to whom this demand is directed or, if not a natural person, by a person or persons having knowledge of the facts and circumstances of such production or responsible for answering each interrogatory or report question. This demand does not require approval by OMB under the Paperwork Reduction Act of 1980.

PETITION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any petition to limit or quash this demand be filed within 20 days after service, or, if the return date is less than 20 days after service, prior to the return date. The original and twelve copies of the petition must be filed with the Secretary of the Federal Trade Commission, and one copy should be sent to the Commission Counsel named in Item 5.

YOUR RIGHTS TO REGULATORY ENFORCEMENT FAIRNESS

The FTC has a longstanding commitment to a fair regulatory enforcement environment. If you are a small business (under Small Business Administration standards), you have a right to contact the Small Business Administration's National Ombudsman at 1-888-REGFAIR (1-888-734-3247) or www.sba.gov/ombudsman regarding the fairness of the compliance and enforcement activities of the agency. You should understand, however, that the National Ombudsman cannot change, stop, or delay a federal agency enforcement action.

The FTC strictly forbids retaliatory acts by its employees, and you will not be penalized for expressing a concern about these activities.

TRAVEL EXPENSES

Use the enclosed travel voucher to claim compensation to which you are entitled as a witness for the Commission. The completed travel voucher and this demand should be presented to Commission Counsel for payment. If you are permanently or temporarily living somewhere other than the address on this demand and it would require excessive travel for you to appear, you must get prior approval from Commission Counsel.

Form of Certificate of Compliance*

I/We do certify that all of the documents required by the attached Civil Investigative Demand which are in the possession, custody, control, or knowledge of the person to whom the demand is directed have been submitted to a custodian named herein.

If a document responsive to this has not been submitted, the objection to its submission and the reasons for the objection have been stated.

Signature _____

Title _____

Sworn to before me this day

_____ _____

_____
Notary Public

_____

*In the event that more than one person is responsible for complying with this demand, the certificate shall identify the documents for which each certifying individual was responsible. In place of a sworn statement, the above certificate of compliance may be supported by an unsworn declaration as provided for by 28 U.S.C. § 1746.

CIVIL INVESTIGATIVE DEMAND TO WATSON PHARMACEUTICALS, INC.

DEFINITIONS

A. The term "'516 Patent" means U.S. Reissue Patent No. RE37,516.

B. The term "'516 Patent Litigation" means the actions captioned *Cephalon, Inc. v. Carlsbad Technology, Inc.*, Civil Action No. 05-CV-1089 (JCL) and *Cephalon, Inc. v. Mylan Pharmaceuticals Inc., et al.*, Civil Action No. 03-CV-1394 (JCL), each filed in the United States District Court for the District of New Jersey.

C. The term "Actiq Authorized Generic Agreement" means the August 2, 2006 Oral Transmucosal Fentanyl Citrate Sales Agent Agreement between Cephalon and Watson, and any additions, amendments or modifications to the foregoing.

D. The term "August 2, 2006 Agreements" means (1) the Provigil Settlement Agreement; and (2) the Actiq Authorized Generic Agreement; (3) any Side Agreement; and (4) any additions, amendments or modifications to any of the foregoing.

E. The term "Carlsbad" means Carlsbad Technology, Inc., its successors, predecessors, divisions, wholly or partially owned subsidiaries, domestic or foreign parents (including, but not limited to Yung Shin Pharmaceutical Ind. Co., Ltd.), affiliates, partnerships, and joint ventures; and all the directors, officers, employees, consultants, agents, and representatives of the foregoing.

F. The term "Cephalon" means Cephalon, Inc., its successors, predecessors, divisions, wholly or partially owned subsidiaries, domestic or foreign parents, affiliates, partnerships, and joint ventures; and all the directors, officers, employees, consultants, agents, and representatives of the foregoing.

G. The term "Claim Chart" means any type of document where a patent is analyzed or compared to another thing on a claim-by-claim basis, regardless of whether all or less than all of the claims in the patent are analyzed, for purposes relating to invalidity, infringement or non-infringement.

H. The term "Generic Provigil" means a product sold or projected to be sold pursuant to an ANDA which references NDA 20-717.

I. The term "identify," when used in reference to a natural person, shall mean to state the person's (1) full name; (2) present or last known business address and telephone number; (3) present or last known employer and job title; and (4) the nature (including job title) and dates of any affiliation, by employment or otherwise, with Watson. For any person

identified, if any of the above information was different during the time period relevant to the CID, supply both the current information and such different information as applies to the time period relevant to the CID. Once a natural person has been identified properly, it shall be sufficient thereafter when identifying that same person to state the name only.

The term "identify," when used in reference to a corporation or other non-natural person, shall mean (1) to state that entity's name; (2) to describe its nature (*e.g.*, corporation, partnership, etc.); (3) to state the location of its principal place of business; and (4) to identify the natural person or persons employed by such entity whose actions on behalf of the entity are responsive to the CID. Once such a person has been identified properly, it shall be sufficient thereafter when identifying that same person to state the name only.

The term "identify," when used in reference to facts, acts, events, occurrences, meetings, or communications, shall mean to describe with particularity the fact, act, event, occurrence, meeting, or communication in question, including but not limited to (1) identifying the participants and witnesses of the fact, act, event, occurrence, meeting, or communication; (2) stating the date or dates on which the fact, act, event, occurrence, meeting, or communication took place; (3) stating the location or locations at which the fact, act, event occurrence, meeting, or communication took place; and (4) providing a description of the substance of the fact, act, event, occurrence, meeting, or communication.

J. The term "Modafinil Development Agreement" means the May 3, 2002 Development Agreement between Watson and Yung Shin Pharmaceutical Ind. Co., Ltd. ("YSP"), and any additions, amendments, or modifications to the foregoing, including but not limited to the March 31, 2003 Amended and Restated Development Agreement (Modafinil) between Watson and YSP.

K. The term "Provigil Settlement Agreement" means the August 2, 2006 Settlement and License Agreement among Cephalon, Watson, and Carlsbad, and any additions, amendments or modifications to the foregoing.

L. The term "relating to" is used in the broadest possible sense and means, in whole or in part, addressing, analyzing, concerning, constituting, containing, commenting, in connection with, dealing with, discussing, describing, embodying, evidencing, identifying, pertaining to, referring to, reflecting, reporting, stating, or summarizing.

M. The term "Side Agreement" means any agreement, whether oral or written, entered into among Cephalon, Watson, or Carlsbad, either (i) within 30 days of August 2, 2006 or (ii) that is in any way related to the August 2, 2006 Agreements.

INSTRUCTIONS

1. Unless otherwise indicated, each specification in this CID covers information and documents dated, generated, received or in effect from January 1, 2002 to the present.

2. For procedures applicable to the search for and production of documents responsive to this CID, the Instructions contained in the Federal Trade Commission Subpoena dated November 9, 2006 are incorporated herein by reference.

3. Where Watson has previously produced documents responsive to this CID, Watson need not produce another copy of the document but may instead identify responsive documents by Bates number.

4. Watson is required to submit all information and documents demanded by this CID on or before the return date, which is 30 days from the date of the CID. Watson should comply with this CID by submitting all responsive information and documents to Kelly Vaughan, Federal Trade Commission, Bureau of Competition, 601 New Jersey Avenue, N.W., Room 6148, Washington, D.C. 20001. Please contact Jeffrey Bank at (202) 326-3102 or Philip Eisenstat at (202) 326-2769 with any questions.

SPECIFICATIONS

SPECIFICATION 1: Identify the date and amount of each payment made by Cephalon to Watson relating to the August 2, 2006 Agreements. For each payment, identify the services, product, or right associated with the payment.

SPECIFICATION 2: Identify the date and amount of each payment made by Watson to Carlsbad relating to the August 2, 2006 Agreements. For each payment, identify the services, product, or right associated with the payment.

SPECIFICATION 3: Identify each employee, officer, or director of Watson involved in the decision to enter the August 2, 2006 Agreements. For each employee, officer, or director, identify (i) his or her current title, (ii) title as of the dates of the August 2, 2006 Agreements (if different), (iii) the name and address of the current employer if no longer employed by Watson, and (iv) the agreement(s) and/or subject matter with respect to which the individual was involved in decision making.

SPECIFICATION 4: Identify each and every reason why Watson entered into the Provigil Settlement Agreement, including each and every reason why Watson agreed to a Date Certain of April 6, 2012, as that term is defined in the Provigil Settlement Agreement.

SPECIFICATION 5: Identify each and every reason why each of (1) the Provigil Settlement Agreement; and (2) the Actiq Authorized Generic Agreement were entered on the same day (August 2, 2006).

SPECIFICATION 6: Identify each and every reason why Watson proposed amending the Modafinil Development Agreement on August 3, 2006 so as to pay Carlsbad $150,000, as indicated in the document bearing the Bates number WAT-E-0300546.

SPECIFICATION 7: Identify and provide one copy of each and every forecast or analysis of Watson's projected revenues or profits under the August 2, 2006 Agreements.

SPECIFICATION 8: Identify and estimate the value of each and every benefit to Watson of entering into the Actiq Authorized Generic Agreement.

SPECIFICATION 9: Identify and provide one copy of each and every forecast or analysis of projected revenues or profits from Watson's sales of Generic Provigil, including but not limited to forecasts or analyses prepared on or after December 8, 2005.

SPECIFICATION 10: Identify and provide one copy of each agreement Watson has entered to market, distribute or sell any authorized generic product. In response to this Specification, provide one copy of each such agreement regardless of date.

SPECIFICATION 11: Identify and provide one copy of each report prepared under Section 4.2.3 of the Actiq Authorized Generic Agreement.

SPECIFICATION 12: Identify and provide one copy of each Indemnification Notice, Indemnification Acknowledgment and statement of expenses prepared or exchanged under Section 5 of the Provigil Settlement Agreement.

SPECIFICATION 13: Identify and provide one copy of documents sufficient to show Watson's actual or forecasted cost per kilogram for the acquisition of modafinil API to be incorporated into Carlsbad/Watson's Generic Provigil, separately for both (1) acquisition of API in commercial

quantities; and (2) acquisition of API in pre-commercial launch quantities.

SPECIFICATION 14: Provide one copy of each document produced by Watson or Carlsbad in the '516 Patent Litigation and one copy of each privilege log prepared by Watson or Carlsbad.

SPECIFICATION 15: Provide one copy of each communication between Carlsbad or Watson and the Food and Drug Administration concerning (i) any drug or proposed drug containing modafinil or r-modafinil; or (ii) modafinil API.

SPECIFICATION 16: Provide one copy of each document that expresses an opinion as to the validity, invalidity, enforceability, unenforceability, infringement, or non-infringement of the '516 Patent or U.S. Patent No. 5,618,845, including but not limited to freedom to practice opinions and Claim Charts.

SPECIFICATION 17: Identify the steps Watson took to preserve documents related to the Federal Trade Commission's review of the January 9, 2006 Agreements.

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Deborah Platt Majoras, Chairman
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

RESOLUTION AUTHORIZING USE OF COMPULSORY PROCESS IN A NONPUBLIC INVESTIGATION

File No. 0610182

Nature and Scope of Investigation:

To determine whether Cephalon, Inc., Teva Pharmaceutical Industries, Inc. (and its affiliate Teva Pharmaceuticals USA, Inc.), Barr Laboratories, Inc., Ranbaxy Laboratories, Inc., Mylan Pharmaceuticals, Inc., Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding any modafinil products.

The Federal Trade Commission hereby resolves and directs that any and all compulsory processes available to it be used in connection with this investigation.

Authority to Conduct Investigation:

Sections 6, 9, 10, and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; FTC Procedures and Rules of Practice, 16 C.F.R. *et. seq.*, and supplements thereto.

By direction of the Commission.

Donald S. Clark
Secretary

ISSUED: August 30, 2006

Exhibit E

United States of America
Federal Trade Commission

CIVIL INVESTIGATIVE DEMAND

1. TO

Carlsbad Technology, Inc.
c/o Steven C. Sunshine
Skadden, Arps, Slate, Meagher, & Flom, LLP
1440 New York Avenue NW
Washington, DC 20005

This demand is issued pursuant to Section 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1, in the course of an investigation to determine whether there is, has been, or may be a violation of any laws administered by the Federal Trade Commission by conduct, activities or proposed action as described in Item 3.

2. ACTION REQUIRED

☐ You are required to appear and testify.

LOCATION OF HEARING	YOUR APPEARANCE WILL BE BEFORE
	No appearance required.
	DATE AND TIME OF HEARING OR DEPOSITION

☒ You are required to produce all documents described in the attached schedule that are in your possession, custody, or control, and to make them available at your address indicated above for inspection and copying or reproduction at the date and time specified below.

☒ You are required to answer the interrogatories or provide the written report described on the attached schedule. Answer each interrogatory or report separately and fully in writing. Submit your answers or report to the Records Custodian named in Item 4 on or before the date specified below.

DATE AND TIME THE DOCUMENTS MUST BE AVAILABLE

Return date is 30 days from date of CID.

3. SUBJECT OF INVESTIGATION

See attached resolution, File No. 0610182.

4. RECORDS CUSTODIAN/DEPUTY RECORDS CUSTODIAN	5. COMMISSION COUNSEL
Markus H. Meier, Records Custodian Philip M. Eisenstat, Deputy Records Custodian	Philip M. Eisenstat, Saralisa C. Brau, Mark Woodward, Ellen Connelly, Jeffrey Bank

DATE ISSUED	COMMISSIONER'S SIGNATURE
5 June 2007	William E. Kovacic

INSTRUCTIONS AND NOTICES

The delivery of this demand to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply. The production of documents or the submission of answers and report in response to this demand must be made under a sworn certificate, in the form printed on the second page of this demand, by the person to whom this demand is directed or, if not a natural person, by a person or persons having knowledge of the facts and circumstances of such production or responsible for answering each interrogatory or report question. This demand does not require approval by OMB under the Paperwork Reduction Act of 1980.

PETITION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any petition to limit or quash this demand be filed within 20 days after service, or, if the return date is less than 20 days after service, prior to the return date. The original and twelve copies of the petition must be filed with the Secretary of the Federal Trade Commission, and one copy should be sent to the Commission Counsel named in Item 5.

YOUR RIGHTS TO REGULATORY ENFORCEMENT FAIRNESS

The FTC has a longstanding commitment to a fair regulatory enforcement environment. If you are a small business (under Small Business Administration standards), you have a right to contact the Small Business Administration's National Ombudsman at 1-888-REGFAIR (1-888-734-3247) or www.sba.gov/ombudsman regarding the fairness of the compliance and enforcement activities of the agency. You should understand, however, that the National Ombudsman cannot change, stop, or delay a federal agency enforcement action.

The FTC strictly forbids retaliatory acts by its employees, and you will not be penalized for expressing a concern about these activities.

TRAVEL EXPENSES

Use the enclosed travel voucher to claim compensation to which you are entitled as a witness for the Commission. The completed travel voucher and this demand should be presented to Commission Counsel for payment. If you are permanently or temporarily living somewhere other than the address on this demand and it would require excessive travel for you to appear, you must get prior approval from Commission Counsel.

Form of Certificate of Compliance*

I/We do certify that all of the documents required by the attached Civil Investigative Demand which are in the possession, custody, control, or knowledge of the person to whom the demand is directed have been submitted to a custodian named herein.

If a document responsive to this has not been submitted, the objection to its submission and the reasons for the objection have been stated.

Signature _____

Title _____

Sworn to before me this day

_____ _____

_____

Notary Public

_____

*In the event that more than one person is responsible for complying with this demand, the certificate shall identify the documents for which each certifying individual was responsible. In place of a sworn statement, the above certificate of compliance may be supported by an unsworn declaration as provided for by 28 U.S.C. § 1746.

CIVIL INVESTIGATIVE DEMAND TO CARLSBAD TECHNOLOGY, INC.

DEFINITIONS

A. The term "Carlsbad" means Carlsbad Technology, Inc., its successors, predecessors, divisions, wholly or partially owned subsidiaries, domestic or foreign parents (including, but not limited to Yung Shin Pharmaceutical Ind. Co., Ltd. ("YSP")), affiliates, partnerships, and joint ventures; and all the directors, officers, employees, consultants, agents, and representatives of the foregoing.

B. The term "August 2, 2006 Agreements" means (1) the Provigil Settlement Agreement; (2) any Side Agreement; and (3) any additions, amendments or modifications to any of the foregoing.

C. The term "Cephalon" means Cephalon, Inc., its successors, predecessors, divisions, wholly or partially owned subsidiaries, domestic or foreign parents, affiliates, partnerships, and joint ventures; and all the directors, officers, employees, consultants, agents, and representatives of the foregoing.

D. The term "Communication" is used in the broadest possible sense and means every conceivable manner or means of disclosure, transfer, or exchange of oral, written, or electronic information between one or more persons or entities.

E. The term "identify," when used in reference to a natural person, shall mean to state the person's (1) full name; (2) present or last known business address and telephone number; (3) present or last known employer and job title; and (4) the nature (including job title) and dates of any affiliation, by employment or otherwise, with Carlsbad. For any person identified, if any of the above information was different during the time period relevant to the CID, supply both the current information and such different information as applies to the time period relevant to the CID. Once a natural person has been identified properly, it shall be sufficient thereafter when identifying that same person to state the name only.

The term "identify," when used in reference to a corporation or other non-natural person, shall mean (1) to state that entity's name; (2) to describe its nature (*e.g.*, corporation, partnership, etc.); (3) to state the location of its principal place of business; and (4) to identify the natural person or persons employed by such entity whose actions on behalf of the entity are responsive to the CID. Once such a person has been identified properly, it shall be sufficient thereafter when identifying that same person to state the name only.

The term "identify," when used in reference to facts, acts, events, occurrences, meetings, or Communications, shall mean to describe with particularity the fact, act, event,

occurrence, meeting, or communication in question, including but not limited to (1) identifying the participants and witnesses of the fact, act, event, occurrence, meeting, or Communication; (2) stating the date or dates on which the fact, act, event, occurrence, meeting, or Communication took place; (3) stating the location or locations at which the fact, act, event occurrence, meeting, or Communication took place; and (4) providing a description of the substance of the fact, act, event, occurrence, meeting, or Communication.

F. The term "Modafinil Development Agreement" means the May 3, 2002 Development Agreement between Watson and YSP, and any additions, amendments, or modifications to the foregoing, including but not limited to the March 31, 2003 Amended and Restated Development Agreement (Modafinil) between Watson and YSP.

G. The term "Provigil Settlement Agreement" means the August 2, 2006 Settlement and License Agreement among Cephalon, Watson, and Carlsbad, and any additions, amendments or modifications to the foregoing.

H. The term "relating to" is used in the broadest possible sense and means, in whole or in part, addressing, analyzing, concerning, constituting, containing, commenting, in connection with, dealing with, discussing, describing, embodying, evidencing, identifying, pertaining to, referring to, reflecting, reporting, stating, or summarizing.

I. The term "Side Agreement" means any agreement, whether oral or written, entered into between or among Cephalon, Watson, or Carlsbad, either (i) within 30 days of August 2, 2006 or (ii) that is in any way related to the August 2, 2006 Agreements.

INSTRUCTIONS

1. Unless otherwise indicated, each specification in this CID covers information and documents dated, generated, received or in effect from January 1, 2002 to the present.

2. For procedures applicable to the search for and production of documents responsive to this CID, the Instructions contained in the Federal Trade Commission Subpoena dated November 9, 2006 are incorporated herein by reference.

3. Where Carlsbad has previously produced documents responsive to this CID, Carlsbad need not produce another copy of the document but may instead identify responsive documents by Bates number.

4. Carlsbad is required to submit all information and documents demanded by this CID on or before the return date, which is 30 days from the date of the CID. Carlsbad should

comply with this CID by submitting all responsive information and documents to Kelly Vaughan, Federal Trade Commission, Bureau of Competition, 601 New Jersey Avenue, N.W., Room 6148, Washington, D.C. 20001. Please contact Jeffrey Bank at (202) 326-3102 or Philip Eisenstat at (202) 326-2769 with any questions.

SPECIFICATIONS

SPECIFICATION 1: Identify the date and amount of each payment made by Watson to Carlsbad, or to YSP, relating to (i) the August 2, 2006 Agreements or (ii) the Modafinil Development Agreement. For each payment, identify the services, product, or right associated with the payment.

SPECIFICATION 2: Identify each employee, officer, or director of Carlsbad involved in the decision to enter the August 2, 2006 Agreements. For each employee, officer, or director, identify (i) his or her current title, (ii) title as of the dates of the August 2, 2006 Agreements (if different), (iii) the name and address of the current employer if no longer employed by Carlsbad, and (iv) the agreement(s) and/or subject matter with respect to which the individual was involved in decision making.

SPECIFICATION 3: Identify each and every reason why Carlsbad entered into the Provigil Settlement Agreement, including each and every reason why Carlsbad agreed to a Date Certain of April 6, 2012, as that term is defined in the Provigil Settlement Agreement.

SPECIFICATION 4: Identify each and every reason why YSP believed that it was entitled to compensation related to the August 2, 2006 Agreements, as indicated in the document bearing the Bates number CTI-E-0100048.

SPECIFICATION 5: Identify and provide one copy of each Communication between or among YSP, Carlsbad, and Watson relating to YSP's request for compensation related to the document bearing the Bates number CTI-E-0100048.

SPECIFICATION 6: Provide one copy of each Communication between Carlsbad or Watson and the Food and Drug Administration concerning (i) any drug or proposed drug containing modafinil or r-modafinil; or (ii) modafinil API.

SPECIFICATION 7: Identify the steps Carlsbad took to preserve documents related to the Federal Trade Commission's review of the August 2, 2006 Agreements.

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Deborah Platt Majoras, Chairman
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

RESOLUTION AUTHORIZING USE OF COMPULSORY PROCESS IN A NONPUBLIC INVESTIGATION

File No. 0610182

Nature and Scope of Investigation:

To determine whether Cephalon, Inc., Teva Pharmaceutical Industries, Inc. (and its affiliate Teva Pharmaceuticals USA, Inc.), Barr Laboratories, Inc., Ranbaxy Laboratories, Inc., Mylan Pharmaceuticals, Inc., Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding any modafinil products.

The Federal Trade Commission hereby resolves and directs that any and all compulsory processes available to it be used in connection with this investigation.

Authority to Conduct Investigation:

Sections 6, 9, 10, and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; FTC Procedures and Rules of Practice, 16 C.F.R. *et. seq.*, and supplements thereto.

By direction of the Commission.

Donald S. Clark
Secretary

ISSUED: August 30, 2006

Exhibit F

United States of America
Federal Trade Commission

CIVIL INVESTIGATIVE DEMAND

1. TO

Watson Pharmaceuticals, Inc.
c/o Steven C. Sunshine
Skadden, Arps, Slate, Meagher, & Flom, LLP
1440 New York Avenue NW
Washington, DC 20005

This demand is issued pursuant to Section 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1, in the course of an investigation to determine whether there is, has been, or may be a violation of any laws administered by the Federal Trade Commission by conduct, activities or proposed action as described in Item 3.

2. ACTION REQUIRED

☐ You are required to appear and testify.

LOCATION OF HEARING	YOUR APPEARANCE WILL BE BEFORE
	No appearance required.
	DATE AND TIME OF HEARING OR DEPOSITION

☒ You are required to produce all documents described in the attached schedule that are in your possession, custody, or control, and to make them available at your address indicated above for inspection and copying or reproduction at the date and time specified below.

☒ You are required to answer the interrogatories or provide the written report described on the attached schedule. Answer each interrogatory or report separately and fully in writing. Submit your answers or report to the Records Custodian named in Item 4 on or before the date specified below.

DATE AND TIME THE DOCUMENTS MUST BE AVAILABLE

Return date is 15 (fifteen) days from date of CID.

3. SUBJECT OF INVESTIGATION

See attached resolution, File No. 0610182.

4. RECORDS CUSTODIAN/DEPUTY RECORDS CUSTODIAN	5. COMMISSION COUNSEL
Markus H. Meier, Records Custodian Saralisa C. Brau, Deputy Records Custodian	Saralisa Brau, Mark Woodward, Ellen Connelly, Alpa Gandhi

DATE ISSUED	COMMISSIONER'S SIGNATURE
MAY 19 2009	William E. Kovacic

INSTRUCTIONS AND NOTICES

The delivery of this demand to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply. The production of documents or the submission of answers and report in response to this demand must be made under a sworn certificate, in the form printed on the second page of this demand, by the person to whom this demand is directed or, if not a natural person, by a person or persons having knowledge of the facts and circumstances of such production or responsible for answering each interrogatory or report question. This demand does not require approval by OMB under the Paperwork Reduction Act of 1980.

PETITION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any petition to limit or quash this demand be filed within 20 days after service, or, if the return date is less than 20 days after service, prior to the return date. The original and twelve copies of the petition must be filed with the Secretary of the Federal Trade Commission, and one copy should be sent to the Commission Counsel named in Item 5.

YOUR RIGHTS TO REGULATORY ENFORCEMENT FAIRNESS

The FTC has a longstanding commitment to a fair regulatory enforcement environment. If you are a small business (under Small Business Administration standards), you have a right to contact the Small Business Administration's National Ombudsman at 1-888-REGFAIR (1-888-734-3247) or www.sba.gov/ombudsman regarding the fairness of the compliance and enforcement activities of the agency. You should understand, however, that the National Ombudsman cannot change, stop, or delay a federal agency enforcement action.

The FTC strictly forbids retaliatory acts by its employees, and you will not be penalized for expressing a concern about these activities.

TRAVEL EXPENSES

Use the enclosed travel voucher to claim compensation to which you are entitled as a witness for the Commission. The completed travel voucher and this demand should be presented to Commission Counsel for payment. If you are permanently or temporarily living somewhere other than the address on this demand and it would require excessive travel for you to appear, you must get prior approval from Commission Counsel.

Form of Certificate of Compliance*

I/We do certify that all of the documents and information required by the attached Civil Investigative Demand which are in the possession, custody, control, or knowledge of the person to whom the demand is directed have been submitted to a custodian named herein.

If a document responsive to this Civil Investigative Demand has not been submitted, the objections to its submission and the reasons for the objection have been stated.

If an interrogatory or a portion of the request has not been fully answered or a portion of the report has not been completed, the objections to such interrogatory or uncompleted portion and the reasons for the objections have been stated.

Signature _____

Title _____

Sworn to before me this day

_____ _____

_____
Notary Public

_____

*In the event that more than one person is responsible for complying with this demand, the certificate shall identify the documents for which each certifying individual was responsible. In place of a sworn statement, the above certificate of compliance may be supported by an unsworn declaration as provided for by 28 U.S.C. § 1746.

CIVIL INVESTIGATIVE DEMAND TO WATSON PHARMACEUTICALS, INC.

DEFINITIONS

A. The term "'346 patent" means U.S. Patent No. 7,297,346.

B. The term "180-day Marketing Exclusivity" means the period of time established by the Hatch-Waxman Act which awards the initial generic challenger(s) 180 days of marketing exclusivity during which the Food and Drug Administration (FDA) may not approve a potential competitor's ANDA, as defined in 21 U.S.C. § 355(j)(5)(B)(iv).

C. The term "ANDA" means Abbreviated New Drug Application, as defined in 21 U.S.C. § 355(j).

D. The term "communication" is used in the broadest possible sense and means every conceivable manner or means of disclosure, transfer, or exchange of oral, written, or electronic information between one or more persons or entities.

E. The term "Carlsbad" means Carlsbad Technology, Inc., its successors, predecessors, divisions, wholly or partially owned subsidiaries, domestic or foreign parents, affiliates, partnerships, and joint ventures; and all the directors, officers, employees, consultants, agents, and representatives of the foregoing.

F. The term "Cephalon" means Cephalon, Inc., its successors, predecessors, divisions, wholly or partially owned subsidiaries, domestic or foreign parents, affiliates, partnerships, and joint ventures; and all the directors, officers, employees, consultants, agents, and representatives of the foregoing.

G. The term "document" means all written, recorded, or graphic materials of every kind, prepared by any person, that are in the Company's possession, custody, or control. The term "document" includes the complete original document (or a copy thereof if the original is not available), all drafts, whether or not they resulted in a final document, and all copies that differ in any respect from the original, including any notation, underlining, marking, or information not on the original. Documents covered by this CID include, but are not limited to, the following: Electronically Stored Information; letters; memoranda; all papers filed with a court in litigation and relating to litigation settlement; reports; contracts, including patent license agreements; studies; plans; notes; entries in calendars; publications, including the publication entitled "Datamonitor"; facsimiles; tabulations; ledgers and other records of financial matters or commercial transactions; audio and video tapes; recorded voice mail messages and computer printouts.

H. The term "Electronically Stored Information" refers to any portion of data found only on a computer or other device capable of storing electronic data, where such data is capable of being manipulated as an entry. "Electronically Stored Information" includes, but is

not limited to, e-mail, spreadsheets, databases, word processing documents, images, presentations, application files, executable files, log files, and all other files present on any type of device capable of storing electronic data. Devices capable of storing Electronically Stored Information include, but are not limited to: servers, desktop computers, portable computers, handheld computers, flash memory devices, wireless communication devices, pagers, workstations, minicomputers, mainframes, and any other forms of online or offline storage, whether on or off company premises.

I. The term "First Filer" means the initial generic challenger(s) to certify to the FDA that a brand drug company's patent is invalid or not infringed, as defined in 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

J. The term "Generic Provigil" means a product sold or projected to be sold pursuant to an ANDA which references New Drug Application 20-717.

K. The term "identify," when used in reference to a natural person, shall mean to state the person's (1) full name; (2) present or last known business address and telephone number; (3) present or last known employer and job title; and (4) the nature (including job title) and dates of any affiliation, by employment or otherwise, with Watson. For any person identified, if any of the above information was different during the time period relevant to the CID, supply both the current information and such different information as applies to the time period relevant to the CID. Once a natural person has been identified properly, it shall be sufficient thereafter when identifying that same person to state the name only.

The term "identify," when used in reference to a corporation or other non-natural person, shall mean (1) to state that entity's name; (2) to describe its nature (*e.g.*, corporation, partnership, etc.); (3) to state the location of its principal place of business; and (4) to identify the natural person or persons employed by such entity whose actions on behalf of the entity are responsive to the CID. Once such a person has been identified properly, it shall be sufficient thereafter when identifying that same person to state the name only.

The term "identify," when used in reference to facts, acts, events, occurrences, meetings, or communications, shall mean to describe with particularity the fact, act, event, occurrence, meeting, or communication in question, including but not limited to (1) identifying the participants and witnesses of the fact, act, event, occurrence, meeting, or communication; (2) stating the date or dates on which the fact, act, event, occurrence, meeting, or communication took place; (3) stating the location or locations at which the fact, act, event, occurrence, meeting, or communication took place; and (4) providing a description of the substance of the fact, act, event, occurrence, meeting, or communication.

L. The term "relating to" is used in the broadest possible sense and means, in whole or in part, addressing, analyzing, concerning, constituting, containing, commenting, in

connection with, dealing with, discussing, describing, embodying, evidencing, identifying, pertaining to, referring to, reflecting, reporting, stating, or summarizing.

M. The term "relinquish" or "relinquishment" is used in the broadest possible sense and means a First Filer's agreement or unilateral action to inform the FDA that it relinquishes any claim to eligibility for 180-day Marketing Exclusivity for a particular drug product.

N. The term "Watson" means Watson Pharmaceuticals, Inc., its successors, predecessors, divisions, wholly or partially owned subsidiaries, domestic or foreign parents, affiliates, partnerships, and joint ventures; and all the directors, officers, employees, consultants, agents, and representatives of the foregoing.

INSTRUCTIONS

1. Unless otherwise indicated, each specification in this CID covers information and documents dated, generated, received or in effect from November 9, 2006 to the present.

2. For procedures applicable to the search for and production of documents responsive to this CID, the Instructions contained in the Federal Trade Commission Subpoena dated November 9, 2006 are incorporated herein by reference.

3. Where Watson has previously produced documents responsive to this CID, Watson need not produce another copy of the document but may instead identify responsive documents by Bates number.

4. Watson is required to submit all information and documents demanded by this CID on or before the return date, which is 15 days from the date of the CID. Watson should comply with this CID by submitting all responsive information and documents to Saralisa Brau, Federal Trade Commission, Bureau of Competition, 601 New Jersey Avenue, N.W., Room 7225, Washington, D.C. 20001. Please contact Saralisa Brau at (202) 326-2774 with any questions.

[remainder of page intentionally left blank]

SPECIFICATIONS

SPECIFICATION 1: Identify whether Watson believes it is eligible to claim 180-day Marketing Exclusivity for Generic Provigil. Identify each and every reason for Watson's view.

SPECIFICATION 2: Identify which company, Watson or Carlsbad, has the authority to relinquish any eligibility to claim 180-day Marketing Exclusivity for Generic Provigil. Identify each and every reason for Watson's view.

SPECIFICATION 3: Identify and provide one copy of each agreement, written or oral, that prohibits, blocks, prevents, compromises, or limits in any way Watson or Carsbad's ability to relinquish eligibility to claim 180-day Marketing Exclusivity for Generic Provigil. For each agreement, identify:

(a) The name and address of the parties to the agreement;

(b) The date of the agreement;

(c) The portion(s) of the agreement that prohibit or limit Watson or Carlsbad's ability to relinquish;

(d) The name, title, and division of any employee, officer, or director of Watson and the other company involved in the discussions;

(e) The name and address of the current employer of any Watson employee, officer, or director involved in the discussions, but no longer employed by Watson; and

(f) The agreement(s) and/or subject matter with respect to which the individual was involved in decision making.

SPECIFICATION 4: Identify each company with which Watson had contact relating to: the '346 patent; Watson or Carlsbad's First Filer status for Generic Provigil; eligibility to claim 180-day Marketing Exclusivity for Generic Provigil; or the relinquishment thereof. For each such company, identify:

(a) The name and address of the company;

(b) The dates of discussions;

(c) The name, title, and division of any employee, officer, or director of Watson and the other company involved in the discussions;

(d) The name and address of the current employer of any Watson employee, officer, or director involved in the discussions, but no longer employed by Watson;

(e) The substance of the discussions;

(f) Whether Watson entered into an agreement as a result of the discussions, and the reasons for Watson's decision.

SPECIFICATION 5: Identify whether Watson had any communications with Cephalon relating to the '346 patent; Watson or Carlsbad's First Filer status for Generic Provigil; eligibility to claim 180-day Marketing Exclusivity for Generic Provigil; or the relinquishment thereof. If so, identify:

(a) The dates of discussion(s);

(b) The name, title, and division of any employee, officer, or director of Watson and Cephalon involved in the discussions;

(c) The name and address of the current employer of any Watson employee, officer, or director involved in the discussions, but no longer employed by Watson;

(d) The substance of the discussions;

(e) Whether Watson entered into an agreement as a result of the discussions, and the reasons for Watson's decision.

SPECIFICATION 6: Provide one copy of each document constituting or relating to a communication concerning: the '346 patent; Watson or Carlsbad's First Filer status for Generic Provigil; eligibility to claim 180-day Marketing Exclusivity for Generic Provigil; or the relinquishment thereof.

SPECIFICATION 7: Identify and provide one copy of each and every forecast or analysis of projected revenues or profits from Watson's sales of Generic Provigil.

SPECIFICATION 8: Beginning January 1, 2000, identify all drug products for which Watson has relinquished or has agreed to relinquish its eligibility to claim 180-day Marketing Exclusivity. For each drug product, identify:

(a) The name of the drug product;

(b) The date of relinquishment;

(c) The revenues or profits Watson made as a result of relinquishment; and

(d) The reasons for Watson's decision to relinquish.

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Deborah Platt Majoras, Chairman
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

RESOLUTION AUTHORIZING USE OF COMPULSORY PROCESS IN A NONPUBLIC INVESTIGATION

File No. 0610182

Nature and Scope of Investigation:

To determine whether Cephalon, Inc., Teva Pharmaceutical Industries, Inc. (and its affiliate Teva Pharmaceuticals USA, Inc.), Barr Laboratories, Inc., Ranbaxy Laboratories, Inc., Mylan Pharmaceuticals, Inc., Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding any modafinil products.

The Federal Trade Commission hereby resolves and directs that any and all compulsory processes available to it be used in connection with this investigation.

Authority to Conduct Investigation:

Sections 6, 9, 10, and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; FTC Procedures and Rules of Practice, 16 C.F.R. *et. seq.*, and supplements thereto.

By direction of the Commission.

Donald S. Clark

Donald S. Clark
Secretary

ISSUED: August 30, 2006

Exhibit G

SUBPOENA AD TESTIFICANDUM

1. TO	2. FROM
David Buchen, Esq., General Counsel Watson Pharmaceuticals, Inc. c/o Steven C. Sunshine, Esq. Skadden, Arps, Slate, Meagher & Flom, LLP 1440 New York Ave. NW, Washington, DC 20005	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoena requires you to appear and testify at the request of the Federal Trade Commission at a hearing [or deposition] in the proceeding described below (Item 6).

3. LOCATION OF HEARING	4. YOUR APPEARANCE WILL BE BEFORE
Federal Trade Commission 601 New Jersey Ave. NW Washington, DC 20001 Rm 7100	Saralisa Brau
	5. DATE AND TIME OF HEARING OR DEPOSITION
	June 10, 2009 at 10:00am

6. SUBJECT OF INVESTIGATION

See attached resolution, File No. 0610182

7. RECORDS CUSTODIAN/DEPUTY RECORDS CUSTODIAN	8. COMMISSION COUNSEL
Markus H. Meier, Records Custodian Saralisa C. Brau, Deputy Records Custodian	Saralisa Brau, Mark Woodward, Ellen Connelly, Alpa Gandhi

DATE ISSUED	COMMISSIONER'S SIGNATURE
MAY 19 2009	William E. Kovacic

GENERAL INSTRUCTIONS

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

PETITION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any petition to limit or quash this subpoena be filed within 20 days after service or, if the return date is less than 20 days after service, prior to the return date. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission. Send one copy to the Commission Counsel named in Item 8.

TRAVEL EXPENSES

Use the enclosed travel voucher to claim compensation to which you are entitled as a witness for the Commission. The completed travel voucher and this subpoena should be presented to Commission Counsel for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from Commission Counsel.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

RETURN OF SERVICE

I hereby certify that a duplicate original of the within subpoena was duly served; (check the method used)

○ *in person.*

○ *by registered mail.*

○ *by leaving copy at principal office or place of business, to wit:*

on the person named herein on:

(Month, day, and year)

(Name of person making service)

(Official title)

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Deborah Platt Majoras, Chairman
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

RESOLUTION AUTHORIZING USE OF COMPULSORY PROCESS IN A NONPUBLIC INVESTIGATION

File No. 0610182

Nature and Scope of Investigation:

To determine whether Cephalon, Inc., Teva Pharmaceutical Industries, Inc. (and its affiliate Teva Pharmaceuticals USA, Inc.), Barr Laboratories, Inc., Ranbaxy Laboratories, Inc., Mylan Pharmaceuticals, Inc., Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding any modafinil products.

The Federal Trade Commission hereby resolves and directs that any and all compulsory processes available to it be used in connection with this investigation.

Authority to Conduct Investigation:

Sections 6, 9, 10, and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; FTC Procedures and Rules of Practice, 16 C.F.R. *et seq.*, and supplements thereto.

By direction of the Commission.

Donald S. Clark
Secretary

ISSUED: August 30, 2006

Exhibit H

SUBPOENA AD TESTIFICANDUM

1. TO	2. FROM
Paul Bisaro President/CEO, Watson Pharmaceuticals, Inc. c/o Steven C. Sunshine, Esq. Skadden, Arps, Slate, Meagher & Flom, LLP 1440 New York Ave. NW, Washington, DC 20005	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoena requires you to appear and testify at the request of the Federal Trade Commission at a hearing [or deposition] in the proceeding described below (Item 6).

3. LOCATION OF HEARING	4. YOUR APPEARANCE WILL BE BEFORE
Federal Trade Commission 601 New Jersey Ave. NW Washington, DC 20001 Rm 7100	Markus Meier
	5. DATE AND TIME OF HEARING OR DEPOSITION
	June 22, 2009 at 10:00am

6. SUBJECT OF INVESTIGATION

See attached resolution, File No. 0610182

7. RECORDS CUSTODIAN/DEPUTY RECORDS CUSTODIAN	8. COMMISSION COUNSEL
Markus H. Meier, Records Custodian Saralisa C. Brau, Deputy Records Custodian	Saralisa Brau, Mark Woodward, Ellen Connelly, Alpa Gandhi

DATE ISSUED	COMMISSIONER'S SIGNATURE
5/22/09	D. Tim Rosch

GENERAL INSTRUCTIONS

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

PETITION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any petition to limit or quash this subpoena be filed within 20 days after service or, if the return date is less than 20 days after service, prior to the return date. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission. Send one copy to the Commission Counsel named in Item 8.

TRAVEL EXPENSES

Use the enclosed travel voucher to claim compensation to which you are entitled as a witness for the Commission. The completed travel voucher and this subpoena should be presented to Commission Counsel for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from Commission Counsel.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

RETURN OF SERVICE

I hereby certify that a duplicate original of the within subpoena was duly served: (check the method used)

☐ *in person.*

☐ *by registered mail.*

☐ *by leaving copy at principal office or place of business, to wit:*

.....

.....

.....

.....

on the person named herein on:

.....
(Month, day, and year)

.....
(Name of person making service)

.....
(Official title)

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Deborah Platt Majoras, Chairman
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

RESOLUTION AUTHORIZING USE OF COMPULSORY PROCESS IN A NONPUBLIC INVESTIGATION

File No. 0610182

Nature and Scope of Investigation:

To determine whether Cephalon, Inc., Teva Pharmaceutical Industries, Inc. (and its affiliate Teva Pharmaceuticals USA, Inc.), Barr Laboratories, Inc., Ranbaxy Laboratories, Inc., Mylan Pharmaceuticals, Inc., Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding any modafinil products.

The Federal Trade Commission hereby resolves and directs that any and all compulsory processes available to it be used in connection with this investigation.

Authority to Conduct Investigation:

Sections 6, 9, 10, and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; FTC Procedures and Rules of Practice, 16 C.F.R. *et seq.*, and supplements thereto.

By direction of the Commission.

Donald S. Clark
Secretary

ISSUED: August 30, 2006

Exhibit I

United States of America
Federal Trade Commission

CIVIL INVESTIGATIVE DEMAND

1. TO

Carlsbad Technology, Inc.
c/o Steven C. Sunshine
Skadden, Arps, Slate, Meagher, & Flom, LLP
1440 New York Avenue NW
Washington, DC 20005

This demand is issued pursuant to Section 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1, in the course of an investigation to determine whether there is, has been, or may be a violation of any laws administered by the Federal Trade Commission by conduct, activities or proposed action as described in Item 3.

2. ACTION REQUIRED

☐ You are required to appear and testify.

LOCATION OF HEARING	YOUR APPEARANCE WILL BE BEFORE
	No appearance required.
	DATE AND TIME OF HEARING OR DEPOSITION

☒ You are required to produce all documents described in the attached schedule that are in your possession, custody, or control, and to make them available at your address indicated above for inspection and copying or reproduction at the date and time specified below.

☒ You are required to answer the interrogatories or provide the written report described on the attached schedule. Answer each interrogatory or report separately and fully in writing. Submit your answers or report to the Records Custodian named in Item 4 on or before the date specified below.

DATE AND TIME THE DOCUMENTS MUST BE AVAILABLE

Return date is 15 (fifteen) days from date of CID.

3. SUBJECT OF INVESTIGATION

See attached resolution, File No. 0610182.

4. RECORDS CUSTODIAN/DEPUTY RECORDS CUSTODIAN	5. COMMISSION COUNSEL
Markus H. Meier, Records Custodian Saralisa C. Brau, Deputy Records Custodian	Saralisa Brau, Mark Woodward, Ellen Connelly, Alpa Gandhi

DATE ISSUED	COMMISSIONER'S SIGNATURE
MAY 19 2009	William E. Kovacic

INSTRUCTIONS AND NOTICES

The delivery of this demand to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply. The production of documents or the submission of answers and report in response to this demand must be made under a sworn certificate, in the form printed on the second page of this demand, by the person to whom this demand is directed or, if not a natural person, by a person or persons having knowledge of the facts and circumstances of such production or responsible for answering each interrogatory or report question. This demand does not require approval by OMB under the Paperwork Reduction Act of 1980.

PETITION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any petition to limit or quash this demand be filed within 20 days after service, or, if the return date is less than 20 days after service, prior to the return date. The original and twelve copies of the petition must be filed with the Secretary of the Federal Trade Commission, and one copy should be sent to the Commission Counsel named in Item 5.

YOUR RIGHTS TO REGULATORY ENFORCEMENT FAIRNESS

The FTC has a longstanding commitment to a fair regulatory enforcement environment. If you are a small business (under Small Business Administration standards), you have a right to contact the Small Business Administration's National Ombudsman at 1-888-REGFAIR (1-888-734-3247) or www.sba.gov/ombudsman regarding the fairness of the compliance and enforcement activities of the agency. You should understand, however, that the National Ombudsman cannot change, stop, or delay a federal agency enforcement action.

The FTC strictly forbids retaliatory acts by its employees, and you will not be penalized for expressing a concern about these activities.

TRAVEL EXPENSES

Use the enclosed travel voucher to claim compensation to which you are entitled as a witness for the Commission. The completed travel voucher and this demand should be presented to Commission Counsel for payment. If you are permanently or temporarily living somewhere other than the address on this demand and it would require excessive travel for you to appear, you must get prior approval from Commission Counsel.

Form of Certificate of Compliance*

I/We do certify that all of the documents and information required by the attached Civil Investigative Demand which are in the possession, custody, control, or knowledge of the person to whom the demand is directed have been submitted to a custodian named herein.

If a document responsive to this Civil Investigative Demand has not been submitted, the objections to its submission and the reasons for the objection have been stated.

If an interrogatory or a portion of the request has not been fully answered or a portion of the report has not been completed, the objections to such interrogatory or uncompleted portion and the reasons for the objections have been stated.

Signature _____

Title _____

Sworn to before me this day

_____ _____

_____
Notary Public

_____

*In the event that more than one person is responsible for complying with this demand, the certificate shall identify the documents for which each certifying individual was responsible. In place of a sworn statement, the above certificate of compliance may be supported by an unsworn declaration as provided for by 28 U.S.C. § 1746.

CIVIL INVESTIGATIVE DEMAND TO CARLSBAD TECHNOLOGY, INC.

DEFINITIONS

A. The term "'346 patent" means U.S. Patent No. 7,297,346.

B. The term "180-day Marketing Exclusivity" means the period of time established by the Hatch-Waxman Act which awards the initial generic challenger(s) 180 days of marketing exclusivity during which the Food and Drug Administration (FDA) may not approve a potential competitor's ANDA, as defined in 21 U.S.C. § 355(j)(5)(B)(iv).

C. The term "ANDA" means Abbreviated New Drug Application, as defined in 21 U.S.C. § 355(j).

D. The term "Carlsbad" means Carlsbad Technology, Inc., its successors, predecessors, divisions, wholly or partially owned subsidiaries, domestic or foreign parents, affiliates, partnerships, and joint ventures; and all the directors, officers, employees, consultants, agents, and representatives of the foregoing.

E. The term "Cephalon" means Cephalon, Inc., its successors, predecessors, divisions, wholly or partially owned subsidiaries, domestic or foreign parents, affiliates, partnerships, and joint ventures; and all the directors, officers, employees, consultants, agents, and representatives of the foregoing.

F. The term "communication" is used in the broadest possible sense and means every conceivable manner or means of disclosure, transfer, or exchange of oral, written, or electronic information between one or more persons or entities.

G. The term "document" means all written, recorded, or graphic materials of every kind, prepared by any person, that are in the Company's possession, custody, or control. The term "document" includes the complete original document (or a copy thereof if the original is not available), all drafts, whether or not they resulted in a final document, and all copies that differ in any respect from the original, including any notation, underlining, marking, or information not on the original. Documents covered by this CID include, but are not limited to, the following: Electronically Stored Information; letters; memoranda; all papers filed with a court in litigation and relating to litigation settlement; reports; contracts, including patent license agreements; studies; plans; notes; entries in calendars; publications, including the publication entitled "Datamonitor"; facsimiles; tabulations; ledgers and other records of financial matters or commercial transactions; audio and video tapes; recorded voice mail messages and computer printouts.

H. The term "Electronically Stored Information" refers to any portion of data found only on a computer or other device capable of storing electronic data, where such data is capable of being manipulated as an entry. "Electronically Stored Information" includes, but is

not limited to, e-mail, spreadsheets, databases, word processing documents, images, presentations, application files, executable files, log files, and all other files present on any type of device capable of storing electronic data. Devices capable of storing Electronically Stored Information include, but are not limited to: servers, desktop computers, portable computers, handheld computers, flash memory devices, wireless communication devices, pagers, workstations, minicomputers, mainframes, and any other forms of online or offline storage, whether on or off company premises.

I. The term "First Filer" means the initial generic challenger(s) to certify to the FDA that a brand drug company's patent is invalid or not infringed, as defined in 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

J. The term "Generic Provigil" means a product sold or projected to be sold pursuant to an ANDA which references New Drug Application 20-717.

K. The term "identify," when used in reference to a natural person, shall mean to state the person's (1) full name; (2) present or last known business address and telephone number; (3) present or last known employer and job title; and (4) the nature (including job title) and dates of any affiliation, by employment or otherwise, with Carlsbad. For any person identified, if any of the above information was different during the time period relevant to the CID, supply both the current information and such different information as applies to the time period relevant to the CID. Once a natural person has been identified properly, it shall be sufficient thereafter when identifying that same person to state the name only.

The term "identify," when used in reference to a corporation or other non-natural person, shall mean (1) to state that entity's name; (2) to describe its nature (*e.g.*, corporation, partnership, etc.); (3) to state the location of its principal place of business; and (4) to identify the natural person or persons employed by such entity whose actions on behalf of the entity are responsive to the CID. Once such a person has been identified properly, it shall be sufficient thereafter when identifying that same person to state the name only.

The term "identify," when used in reference to facts, acts, events, occurrences, meetings, or communications, shall mean to describe with particularity the fact, act, event, occurrence, meeting, or communication in question, including but not limited to (1) identifying the participants and witnesses of the fact, act, event, occurrence, meeting, or communication; (2) stating the date or dates on which the fact, act, event, occurrence, meeting, or communication took place; (3) stating the location or locations at which the fact, act, event, occurrence, meeting, or communication took place; and (4) providing a description of the substance of the fact, act, event, occurrence, meeting, or communication.

L. The term "relating to" is used in the broadest possible sense and means, in whole or in part, addressing, analyzing, concerning, constituting, containing, commenting, in

connection with, dealing with, discussing, describing, embodying, evidencing, identifying, pertaining to, referring to, reflecting, reporting, stating, or summarizing.

M. The term "relinquish" or "relinquishment" is used in the broadest possible sense and means a First Filer's agreement or unilateral action to inform the FDA that it relinquishes any claim to eligibility for 180-day Marketing Exclusivity for a particular drug product.

N. The term "Watson" means Watson Pharmaceuticals, Inc., its successors, predecessors, divisions, wholly or partially owned subsidiaries, domestic or foreign parents, affiliates, partnerships, and joint ventures; and all the directors, officers, employees, consultants, agents, and representatives of the foregoing.

INSTRUCTIONS

1. Unless otherwise indicated, each specification in this CID covers information and documents dated, generated, received or in effect from November 9, 2006 to the present.

2. For procedures applicable to the search for and production of documents responsive to this CID, the Instructions contained in the Federal Trade Commission Subpoena dated November 9, 2006 are incorporated herein by reference.

3. Where Carlsbad has previously produced documents responsive to this CID, Carlsbad need not produce another copy of the document but may instead identify responsive documents by Bates number.

4. Carlsbad is required to submit all information and documents demanded by this CID on or before the return date, which is 15 days from the date of the CID. Carlsbad should comply with this CID by submitting all responsive information and documents to Saralisa Brau, Federal Trade Commission, Bureau of Competition, 601 New Jersey Avenue, N.W., Room 7225, Washington, D.C. 20001. Please contact Saralisa Brau at (202) 326-2774 with any questions.

[remainder of page intentionally left blank]

SPECIFICATIONS

SPECIFICATION 1: Identify whether Carlsbad believes it is eligible to claim 180-day Marketing Exclusivity for Generic Provigil. Identify each and every reason for Carlsbad's view.

SPECIFICATION 2: Identify which company, Carlsbad or Watson, has the authority to relinquish any eligibility to claim 180-day Marketing Exclusivity for Generic Provigil. Identify each and every reason for Carlsbad's view.

SPECIFICATION 3: Identify and provide one copy of each agreement, written or oral, that prohibits, blocks, prevents, compromises, or limits in any way Carlsbad or Watson's ability to relinquish its eligibility to claim 180-day Marketing Exclusivity for Generic Provigil. For each agreement, identify:

(a) The name and address of the parties to the agreement;

(b) The date of the agreement;

(c) The portion(s) of the agreement that prohibit or limit Carlsbad or Watson's ability to relinquish;

(d) The name, title, and division of any employee, officer, or director of Carlsbad and the other company involved in the discussions;

(e) The name and address of the current employer of any Carlsbad employee, officer, or director involved in the discussions, but no longer employed by Carlsbad; and

(f) The agreement(s) and/or subject matter with respect to which the individual was involved in decision making.

SPECIFICATION 4: Identify each company with which Carlsbad had contact relating to: the '346 patent; Carlsbad or Watson's First Filer status for Generic Provigil; eligibility to claim 180-day Marketing Exclusivity for Generic Provigil; or the relinquishment thereof. For each such company, identify:

(a) The name and address of the company;

(b) The dates of discussions;

(c) The name, title, and division of any employee, officer, or director of Carlsbad and the other company involved in the discussions;

(d) The name and address of the current employer of any Carlsbad employee, officer, or director involved in the discussions, but no longer employed by Carlsbad;

(e) The substance of the discussions;

(f) Whether Carlsbad entered into an agreement as a result of the discussions, and the reasons for Carlsbad's decision.

SPECIFICATION 5: Identify whether Carlsbad had any communications with Cephalon relating to the '346 patent; Carlsbad or Watson's First Filer status for Generic Provigil; eligibility to claim 180-day Marketing Exclusivity for Generic Provigil; or the relinquishment thereof. If so, identify:

(a) The dates of discussion(s);

(b) The name, title, and division of any employee, officer, or director of Carlsbad and Cephalon involved in the discussions;

(c) The name and address of the current employer of any Carlsbad employee, officer, or director involved in the discussions, but no longer employed by Carlsbad;

(d) The substance of the discussions;

(e) Whether Carlsbad entered into an agreement as a result of the discussions, and the reasons for Carlsbad's decision.

SPECIFICATION 6: Provide one copy of each document constituting or relating to a communication concerning: the '346 patent; Carlsbad or Watson's First Filer status for Generic Provigil; eligibility to claim 180-day Marketing Exclusivity for Generic Provigil; or the relinquishment thereof.

SPECIFICATION 7: Identify and provide one copy of each and every forecast or analysis of projected revenues or profits from Carlsbad or Watson's sales of Generic Provigil.

SPECIFICATION 8: Beginning January 1, 2000, identify all drug products for which Carlsbad has relinquished or has agreed to relinquish its eligibility to claim 180-day Marketing Exclusivity. For each drug product, identify:

(a) The name of the drug product;

(b) The date of relinquishment;

(c) The revenues or profits Carlsbad made as a result of relinquishment; and

(d) The reasons for Carlsbad's decision to relinquish.

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Deborah Platt Majoras, Chairman
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

RESOLUTION AUTHORIZING USE OF COMPULSORY PROCESS IN A NONPUBLIC INVESTIGATION

File No. 0610182

Nature and Scope of Investigation:

To determine whether Cephalon, Inc., Teva Pharmaceutical Industries, Inc. (and its affiliate Teva Pharmaceuticals USA, Inc.), Barr Laboratories, Inc., Ranbaxy Laboratories, Inc., Mylan Pharmaceuticals, Inc., Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding any modafinil products.

The Federal Trade Commission hereby resolves and directs that any and all compulsory processes available to it be used in connection with this investigation.

Authority to Conduct Investigation:

Sections 6, 9, 10, and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; FTC Procedures and Rules of Practice, 16 C.F.R. *et. seq.*, and supplements thereto.

By direction of the Commission.

Donald S. Clark
Secretary

ISSUED: August 30, 2006

Exhibit J

SUBPOENA AD TESTIFICANDUM

1. TO	2. FROM
Robert Wan, Chief Financial Officer Carlsbad Technology, Inc. c/o Steven C. Sunshine Skadden, Arps, Slate, Meagher, & Flom, LLP 1440 New York Avenue NW, Washington, DC 20005	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoena requires you to appear and testify at the request of the Federal Trade Commission at a hearing [or deposition] in the proceeding described below (Item 6).

3. LOCATION OF HEARING	4. YOUR APPEARANCE WILL BE BEFORE
Federal Trade Commission 601 New Jersey Ave. NW Washington, DC 20001 Rm 7100	Markus Meier
	5. DATE AND TIME OF HEARING OR DEPOSITION
	June 18, 2009 at 10:00am

6. SUBJECT OF INVESTIGATION

See attached resolution, File No. 0610182

7. RECORDS CUSTODIAN/DEPUTY RECORDS CUSTODIAN	8. COMMISSION COUNSEL
Markus H. Meier, Records Custodian Saralisa C. Brau, Deputy Records Custodian	Saralisa Brau, Mark Woodward, Ellen Connelly, Alpa Gandhi

DATE ISSUED	COMMISSIONER'S SIGNATURE
MAY 19 2009	William E. Kovacic

GENERAL INSTRUCTIONS

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PETITION TO LIMIT OR QUASH

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TRAVEL EXPENSES

Use the enclosed travel voucher to claim compensation to which you are entitled as a witness for the Commission. The completed travel voucher and this subpoena should be presented to Commission Counsel for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from Commission Counsel.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

FTC Form 68-A (rev. 10/93)

RETURN OF SERVICE

I hereby certify that a duplicate original of the within subpoena was duly served: (check the method used)

☐ *in person.*

☐ *by registered mail.*

☐ *by leaving copy at principal office or place of business, to wit:*

on the person named herein on:

(Month, day, and year)

(Name of person making service)

(Official title)

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Deborah Platt Majoras, Chairman
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

RESOLUTION AUTHORIZING USE OF COMPULSORY PROCESS IN A NONPUBLIC INVESTIGATION

File No. 0610182

Nature and Scope of Investigation:

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By direction of the Commission.

Donald S. Clark
Secretary

ISSUED: August 30, 2006

Exhibit K

SUBPOENA AD TESTIFICANDUM

1. TO	2. FROM
Lanie Wang, Supervisor Regulatory Affairs Carlsbad Technology, Inc. c/o Steven C. Sunshine Skadden, Arps, Slate, Meagher, & Flom, LLP 1440 New York Avenue NW, Washington, DC 20005	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoena requires you to appear and testify at the request of the Federal Trade Commission at a hearing [or deposition] in the proceeding described below (Item 6).

3. LOCATION OF HEARING	4. YOUR APPEARANCE WILL BE BEFORE
Federal Trade Commission 601 New Jersey Ave. NW Washington, DC 20001 Rm 7100	Alpa Gandhi
	5. DATE AND TIME OF HEARING OR DEPOSITION
	June 11, 2009 at 10:00am

6. SUBJECT OF INVESTIGATION

See attached resolution, File No. 0610182

7. RECORDS CUSTODIAN/DEPUTY RECORDS CUSTODIAN	8. COMMISSION COUNSEL
Markus H. Meier, Records Custodian Saralisa C. Brau, Deputy Records Custodian	Saralisa Brau, Mark Woodward, Ellen Connelly, Alpa Gandhi

DATE ISSUED	COMMISSIONER'S SIGNATURE
MAY 19 2009	William E. Kovacic

GENERAL INSTRUCTIONS

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PETITION TO LIMIT OR QUASH

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Use the enclosed travel voucher to claim compensation to which you are entitled as a witness for the Commission. The completed travel voucher and this subpoena should be presented to Commission Counsel for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from Commission Counsel.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

FTC Form 68-A (rev. 10/93)

RETURN OF SERVICE

I hereby certify that a duplicate original of the within subpoena was duly served: (check the method used)

☐ *in person.*

☐ *by registered mail.*

☐ *by leaving copy at principal office or place of business, to wit:*

on the person named herein on:

(Month, day, and year)

(Name of person making service)

(Official title)

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Deborah Platt Majoras, Chairman
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

RESOLUTION AUTHORIZING USE OF COMPULSORY PROCESS IN A NONPUBLIC INVESTIGATION

File No. 0610182

Nature and Scope of Investigation:

To determine whether Cephalon, Inc., Teva Pharmaceutical Industries, Inc. (and its affiliate Teva Pharmaceuticals USA, Inc.), Barr Laboratories, Inc., Ranbaxy Laboratories, Inc., Mylan Pharmaceuticals, Inc., Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding any modafinil products.

The Federal Trade Commission hereby resolves and directs that any and all compulsory processes available to it be used in connection with this investigation.

Authority to Conduct Investigation:

Sections 6, 9, 10, and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; FTC Procedures and Rules of Practice, 16 C.F.R. *et. seq.*, and supplements thereto.

By direction of the Commission.

Donald S. Clark

Donald S. Clark
Secretary

ISSUED: August 30, 2006

Exhibit L

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Bureau of Competition
Health Care Division

Saralisa C. Brau
Deputy Assistant Director

Direct Dial
(202) 326-2774
sbrau@ftc.gov

June 2, 2009

By Electronic Mail

Maria Raptis, Esq.
Skadden, Arps, Slate, Meagher & Flom LLP
Four Times Square
New York, New York 10036

Re: Cephalon, Inc., FTC File No. 061-0182

Dear Maria:

I write to confirm our agreement to the following modifications to the May 19, 2009 Civil Investigative Demands (CIDs) and Subpoenas Ad Testificandum (SATs) issued to Watson Pharmaceuticals, Inc., and Carlsbad Technologies, Inc. in the above-referenced investigation.[1]

The FTC agrees to your request to extend the date for the CID responses from June 3, 2009 to June 10, 2009 with the understanding that Watson and Carlsbad intend to produce substantially all relevant, non-privileged documents and narrative responses by that date. The FTC is willing to defer the production of a privilege log by June 10, 2009, but reserves the right to request the production of such log at a future date.[2] We have discussed, and will continue to discuss, potential limitations to the scope of CID Specification 6, as necessary.

---

[1]The first set of CIDs and SATs were served on Watson and Carlsbad care of counsel at Skadden Arps. Because you indicated concern about whether you were authorized to accept investigative demands on behalf of your clients, for the avoidance of doubt about perfection of service, the FTC issued the same set of CIDs and SATs to Watson and Carlsbad directly on May 26, 2009.

[2]You have indicated that Watson and Carlsbad aim to produce the privilege log on June 10, 2009, and that this extension may not be necessary.

The FTC also agrees to your request for new hearing dates and, in two cases, new locations for the SATs. You have agreed to abide by new deadlines for filing any petitions to quash the SATs. Our agreements are reflected in the following chart:

Name	Title	Original Hearing Date & Quash Deadline/ Location	New Hearing Date /Location	New Deadline for Petition for Motion to Quash
David Buchen	Watson General Counsel	June 10 in DC	June 25 in LA	June 17
Paul Bisaro	Watson CEO	June 22 in DC	June 30 in NJ	June 29
Robert Wan	Carlsbad CFO	June 18 in DC	July 2 in DC	June 29

Based on your representation that Lanie Wang, the Carlsbad Supervisor of Regulatory Affairs, has not been employed by Carlsbad since September 2007, we hereby withdraw our SAT for her hearing (originally scheduled for June 11, 2009).

Please let me know at your earliest convenience if this letter misstates any aspect of our agreement. Please feel free to call me with any questions.

Sincerely,

Saralisa C. Brau

Approved:

Markus H. Meier
Assistant Director

Exhibit M

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
1440 NEW YORK AVENUE, N.W.
WASHINGTON, D.C. 20005-2111

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CONFIDENTIAL

June 30, 2009

Markus H. Meier, Esq.
Assistant Director
Bureau of Competition
Health Care Division
Federal Trade Commission
601 New Jersey Avenue, N.W.
Washington, D.C. 20580

Re: Cephalon, Inc., FTC File No. 061-0182

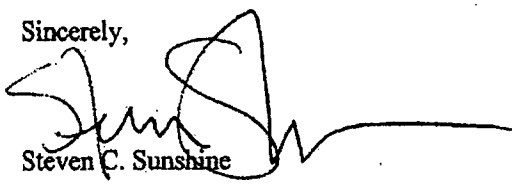
Dear Markus:

I write to confirm our agreement to modify the subpoena *ad testificandum* issued on May 19, 2009 to Mr. Paul Bisaro, President and Chief Executive Officer of Watson Pharmaceuticals, Inc. ("Watson"), in connection with the above-referenced investigation.

The Federal Trade Commission ("FTC") agrees to indefinitely postpone the hearing date for Mr. Bisaro. This agreement is without prejudice to all the rights of both parties, including our right to petition to quash Mr. Bisaro's subpoena at a later date. Moreover, while you indicated that the FTC has no present intention to conduct an investigational hearing of Mr. Bisaro, this agreement would also not preclude the FTC from enforcing the subpoena at a later date.

Please let me know at your earliest convenience if this letter does not accurately reflect any aspect of our agreement.

Sincerely,



Steven C. Sunshine

Agreed:

_____

Markus H. Meier
Assistant Director

Exhibit N

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
4 TIMES SQUARE
NEW YORK, NEW YORK 10036-6522

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CONFIDENTIAL

July 21, 2009

Saralisa C. Brau, Esq.
Federal Trade Commission
601 New Jersey Avenue, N.W.
Washington, D.C. 20001

Re: FTC File No. 0610182

Dear Saralisa:

I write on behalf of Watson Pharmaceuticals, Inc. ("Watson") to reiterate our attempt to reach a mutually acceptable agreement with regard to the subpoena *ad testificandum* issued to Mr. Paul Bisaro, President and Chief Executive Officer of Watson, in connection with the Federal Trade Commission's ("FTC") investigation relating to the modafinil patent settlements.

Background

By resolution dated August 30, 2006, the FTC initiated a non-public inquiry "to determine whether Cephalon, Inc. [and others] engaged in any unfair methods of competition...by entering into agreements regarding any modafinil products." Watson cooperated fully with all phases of the FTC's inquiry, including responding to one subpoena *duces tecum* issued on November 9, 2006 and one Civil Investigative Demand ("CID") issued on May 18, 2007 in connection with the matter. Watson also made its Senior Vice President, General Counsel and Secretary, Mr. David Buchen, available for an investigational hearing on a voluntary basis during the pre-complaint stage of the FTC's investigation. On February 13, 2008, the FTC brought an action against Cephalon, Inc. ("Cephalon"), alleging anticompetitive conduct in preventing generic competition to its branded modafinil product. None of the first filers – at least some of whom had maintained their Hatch-Waxman exclusivity – were named in the FTC's complaint. Watson, and its development

partner Carlsbad Technology, Inc. – the actual ANDA applicant – were also not named in the complaint.

More recently, using the same August 2006 resolution that culminated in a suit against Cephalon only, the FTC has taken steps to continue its investigation in response to the listing of a new patent relating to modafinil – U.S. Patent No. 7,297,346 (the "'346 Patent"). On May 19, 2009, the FTC issued a new CID requesting information and documents pertaining to the '346 Patent and any marketing exclusivity Watson may have obtained as a result of filing a Paragraph IV certification with respect to the patent. In addition, the FTC issued two subpoenas *ad testificandum*, one to Mr. Buchen, and one to Mr. Bisaro. Through discussions with FTC Staff, Watson learned that the FTC is interested in understanding whether Watson has reached any agreements regarding relinquishment of any marketing exclusivity associated with the '346 Patent, and the basis for any decision not to waive exclusivity.

Watson submitted its response to the May 19, 2009 CID on June 10, 2009. In its response, Watson confirmed that it had not reached any agreements or decisions regarding relinquishment. Watson also identified and described the full extent of its limited contacts with third parties on the subject of relinquishment. Moreover, Watson submitted all documents relevant to these topics together with its written response to the CID. Notably, Mr. Bisaro had no responsive documents, and did not have any contacts with any company on the subject of relinquishment. For these reasons, we informed you that Watson would in all likelihood resist an investigational hearing with respect to Mr. Bisaro. We also informed you that deposing Mr. Buchen was unlikely to yield significant additional information, but in the interest of avoiding a dispute, agreed to go forward with his hearing.

On June 25, 2009, Mr. Buchen provided sworn testimony in this matter in an investigational hearing conducted by Mr. Markus H. Meier, Assistant Director in the Health Care Division at the FTC. Mr. Buchen testified that Watson had not reached any agreement or decision with any party relating to relinquishment.[1] Mr. Buchen also testified that he was the only individual at Watson involved in any discussions with third parties relating to this topic, and that he was the primary decision-maker with respect to relinquishment.[2] Moreover, to the extent Mr. Buchen kept Mr. Bisaro informed of his discussions relating to relinquishment,

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[1] *See* Transcript, In the Matter of Cephalon, Inc., FTC File No. 0610182, dated June 25, 2009, pages 40, 67

[2] *Id.* at 29, 40, 51 and 66 – 67.

they had had "fewer than five" conversations, all of which would implicate legal advice because of Mr. Buchen's role as General Counsel of the company.[3]

The Subpoena Ad Testificandum Issued to Mr. Bisaro

At the time of Mr. Buchen's investigational hearing, the subpoena *ad testificandum* issued to Mr. Bisaro was still pending. Therefore, Mr. Meier and Mr. Steven C. Sunshine, Watson's counsel at Skadden, Arps, Slate, Meagher & Flom LLP, reached an agreement on the record extending the return date for Mr. Bisaro's subpoena to July 2, 2009. Mr. Meier further stated that, in the interim, he would "talk with people at the FTC about whether it's even necessary to do an investigational hearing of Mr. Bisaro."[4] Mr. Sunshine reiterated that Watson would petition to quash the subpoena issued to Mr. Bisaro if the FTC determined to enforce the subpoena.

Shortly thereafter, Mr. Meier telephoned Mr. Sunshine and indicated that the FTC had no present intention of conducting an investigational hearing of Mr. Bisaro. Mr. Meier agreed to indefinitely postpone the hearing, but preserved the right to seek to enforce the subpoena at a later date. Watson also preserved its right to petition to quash Mr. Bisaro's subpoena. A letter memorializing this agreement was provided to Mr. Meier for his countersignature or comment.[5] We understand that Mr. Meier was traveling when the letter was transmitted on June 30, 2009. While he was therefore unable to sign the letter, during subsequent telephone calls he twice reiterated that the parties had an agreement and that his workload was the only factor preventing him from providing a countersigned copy of the letter.

On the afternoon of Friday, July 17, 2009, Mr. Meier telephoned Mr. Sunshine to discuss the status of Mr. Bisaro's subpoena. Mr. Sunshine was traveling but returned the call late that same afternoon. Mr. Meier stated that the FTC had determined to proceed with Mr. Bisaro's investigational hearing. Mr. Sunshine informed Mr. Meier that Watson would in all probability petition to quash the subpoena. Mr. Meier asked Mr. Sunshine to telephone you on the following Monday, July 20, 2009, to agree on a schedule.

On Monday, July 20, 2009, we spoke by telephone and I proposed that we set a return date of August 21, 2009. You indicated that the FTC's preferred

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[3] *Id.* at 37 – 38.
[4] *Id.* at 71.
[5] *See* Letter dated June 30, 2009 from Steven C. Sunshine to Markus H. Meier.

return date was Friday, July 24, 2009 (*i.e.*, four days later) or Monday, July 27, 2009, and that a return period of roughly a month was a non-starter. At best, you suggested a return date of August 3, 2009. I explained that due to vacation schedules during the month of August, and Mr. Sunshine's absence during this period, Watson would not be able to agree to this date.

On Tuesday, July 21, 2009, I telephoned you to propose August 17, 2009 as an alternative date. However, you indicated that despite the existence of an indefinite extension on the return date for Mr. Bisaro's subpoena, the FTC did not need to negotiate this matter and could issue a new subpoena more in line with its preferred timing. I then proposed August 14, 2009. You declined to consider this new proposal, and notwithstanding the present agreement between the FTC and Watson, indicated you felt no need to reach an agreement with Watson. You further stated that FTC Staff would recommend to the Commission that it issue a new subpoena and that the FTC would act unilaterally to achieve an acceptable return date. Nevertheless, I write to reiterate our proposal that we reach an agreement on a return date of August 14, 2009. Please call me at (212) 735-2425 if you wish to discuss this proposal further.

Very truly yours,

/Maria A. Raptis/

Maria A. Raptis

cc: Markus H. Meier, Esq.

Exhibit O

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Bureau of Competition
Health Care Division

Saralisa C. Brau
Deputy Assistant Director

Direct Dial
(202) 326-2774
sbrau@ftc.gov

July 22, 2009

By Electronic Mail

Maria A. Raptis, Esq.
Skadden, Arps, Slate, Meagher & Flom LLP
Four Times Square
New York, New York 10036

Re: Cephalon, Inc., FTC File No. 061-0182

Dear Maria:

I write to express disagreement with the characterizations in your letter of July 21, 2009 in the above-referenced matter, including but not limited to those relating to the subpoenas ad testificandum issued to Mr. Paul Bisaro, President and Chief Executive officer of Watson Pharmaceuticals, Inc.

We believe that a two week period – from the date FTC staff called Mr. Sunshine on July 17, 2009 informing him of the decision to conduct an investigational hearing of Mr. Bisaro, until July 31, 2009 – is a reasonable amount of time for Watson to file a petition to quash Mr. Bisaro's subpoena. This is particularly true here, where Watson has been on notice of the FTC's potential interest in speaking with Mr. Bisaro for two months (since mid-May),[1] and counsel from your

[1]Watson has been on notice concerning the FTC's interest in speaking with Mr. Bisaro since May 19, 2009, when the Commission issued the first subpoena for Mr. Bisaro's testimony. The first subpoena ad testificandum to Mr. Bisaro was issued care of counsel at Skadden Arps. Because you expressed concern about your firm's authorization to accept service, for the avoidance of doubt about perfection of service, the FTC issued the same subpoena to Mr. Bisaro directly on May 26, 2009. Because we were unable to come to an agreement on a date in this matter after our conversations of July 17, 20, and 21, 2009, the Commission issued a third subpoena to Mr. Bisaro dated July 21, 2009 with a "return date" of July 31, 2009.

firm informed FTC staff on multiple occasions that Watson would petition to quash any subpoena to Mr. Bisaro.[2] In light of these circumstances and the ongoing harm to consumers of Provigil, FTC staff is not prepared to accept your proposal that Watson enjoy a prolonged four-or-five week period to file a petition to quash.

Of course, if Watson were willing to allow Mr. Bisaro to appear and testify at an investigational hearing, FTC staff would be willing to discuss a mutually convenient return date.

Please feel free to call me with any questions at (202) 326-2774.

Sincerely,

Saralisa C. Brau

[2]Indeed, your own letter specifically cites to at least two such examples, including: (1) the June 25, 2009 investigational hearing of Watson's General Counsel, Mr. David Buchen, at which, according to your letter: "Mr. Sunshine informed Mr. Meier that Watson would in all probability petition to quash the subpoena."; and (2) the July 17, 2009 telephone call from FTC staff to Mr. Sunshine informing Mr. Sunshine of the decision to enforce the subpoena, during which, according to your letter: "Mr. Sunshine informed Mr. Meier that Watson would in all probability petition to quash the subpoena." Raptis Letter to Brau (July 21, 2009) at 3.

Petition Exhibit 5

Office of the Secretary

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

November 13, 2009

VIA FACSIMILE AND EXPRESS MAIL **Non-Public**

Watson Pharmaceuticals, Inc.
c/o Steven C. Sunshine, Esquire
Skadden Arps, Slate, Meagher & Flom LLP
1440 New York Ave., N.W.
Washington, DC 20005

Re: *Petition to Quash Subpoena* Ad Testificandum *Dated July 22, 2009*, File No. 091-0182

Dear Mr. Sunshine:

On July 30, 2009, Paul M. Bisaro (Petitioner), the President and Chief Executive Officer of Watson Pharmaceuticals, Inc. ("Watson"), filed a Petition to Quash Subpoena *Ad Testificandum* Dated July, 22, 2009 ("Petition"). The challenged subpoena was issued in the Commission's ongoing investigation to determine whether Watson, or others, are depriving consumers of access to lower-cost, generic modafinil drug products through any unfair method of competition in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

In the course of the investigation, a subpoena was issued for Petitioner's testimony at an investigational hearing ("IH") to be held on July 31, 2009 at the Commission's offices at 601 New Jersey Ave., N.W. in Washington, DC.[1] Petitioner did not provide the requested testimony. Instead, he filed a Petition asking the Commission to quash the subpoena on the grounds that (a) the Commission already has all the information that it might obtain from his responses to any questions propounded in such an investigational hearing; [2] (b) the subpoena is unreasonable in that it seeks the testimony of a high-level corporate executive;[3] and (c) the subpoena purportedly

[1] Petition, Exhibit A at 1 (Subpoena *Ad Testificandum* issued to Paul Bisaro on July 27, 2009).

[2] *Id.* at 15-17.

[3] *Id. at 17-19.*

was issued for an improper purpose.[4] The record does not support these claims. Therefore, the relief requested by the Petition is denied.

This letter advises you of the Commission's disposition of the Petition.[5] This ruling was made by Commissioner Pamela Jones Harbour, acting as the Commission's delegate. *See* 16 C.F.R. § 2.7(d)(4). Pursuant to 16 C.F.R. § 2.7(f), Petitioner has the right to request review of this matter by the full Commission. Such a request must be filed with the Secretary of the Commission within three days after service of this letter.[6]

Background and Summary

Watson develops, manufactures, and markets generic versions of brand-name drugs. In December 2004, Watson and its development partner (Carlsbad Technology, Inc.), filed an abbreviated new drug application ("ANDA") for a modafinil product with the United States Food and Drug Administration ("FDA"). Modafinil is the active ingredient in a wakefulness-enhancing drug that at present is distributed in the United States exclusively by Cephalon, Inc. under the brand name Provigil®. Provigil is covered by two Cephalon patents that are relevant to the Petition: U.S. Reissued Patent No. 37,516 ("the '516 Patent"); and U.S. Patent No. **[7,297,346 ("the '346]** Patent"). Petition at 3, 6.

On December 22, 2002, four manufacturers of generic drugs (the so-called four "first filers" for the '516 Patent) filed Paragraph IV ANDAs for modafinil – the first step in opening

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[4] *Id.* at 19-20. Watson also suggests (without supporting authority) that the investigatory resolution cited by staff as authority for issuing the instant subpoena expired when the Commission instituted a civil action against Cephalon in February 2008. *Id.* at 15 note 73. This claim is without merit. This is a continuing resolution that contains no time or other limitations. The Commission's litigation against Cephalon has no effect on the Commission's ability to continue the investigation of other parties for potential acts of wrongdoing covered by the resolution. Watson also claims the subpoena is unreasonably burdensome because it is returnable in Washington, DC rather than New Jersey, Mr. Bisaro's place of residence. *Id.* at 14 note 72, 19. Petitioner, however, provides no factual basis for this claim of burden.

[5] The request for confidential treatment in the Petition is under review by the Commission Office of General Counsel. Pending the completion of that review, the bracketed material in boldface print in this letter ruling will be redacted from the public record version of this letter ruling. The public record version of this letter ruling will be placed on the public record, including the public Commission Website, at or after 9 a.m. on November 30, 2009.

[6] This letter ruling is being delivered by facsimile and express mail. The facsimile copy is provided as a courtesy. Computation of the time for appeal, therefore, should be calculated from the date you received the original by express mail. In accordance with the provisions of 16 C.F.R. § 2.7(f), the timely filing of a request for review of this matter by the full Commission shall not stay the return date established pursuant to this decision.

the U.S. market for modafinil to generic competition. Under the Hatch-Waxman Act (the Drug Price Competition and Patent Restoration Act of 1984, Pub. L. 98-417, as amended), the first firm(s) to file a Paragraph IV ANDA for a generic version of a branded drug are eligible for a 180-day period of marketing exclusivity before the FDA can approve later filed ANDAs. Petition at 3. The first-filers' ANDAs certified that their generic versions of modafinil products either did not infringe Cephalon's patents listed in the FDA's Orange Book, or that those patents were invalid. *Id*.[7] Watson and Carlsbad filed their ANDA for modafinil on August 2, 2006, and were not first filers on the '516 patent; however, they were sued by Cephalon for patent infringement and did obtain a license to market generic modafinil as part of the settlement agreement for that suit. Sunshine Decl. at ¶ 7. Under that license, Watson may commence modafinil marketing on April 6, 2012. Petition at 4 n.6.

[On December 19, 2007, Cephalon listed a new patent for modafinil in the FDA's Orange Book (the '346 Patent). Watson and Carlsbad thereafter filed "a Paragraph IV certification as to the '346 Patent," claiming that because they already had "a license from Cephalon" to produce modafinil, its generic version of modafinil would not infringe the '346 Patent.] Sunshine Decl. at ¶¶ 13-14.[8]

On February 13, 2008, the FTC filed an action against Cephalon, alleging that its settlements of the ensuing patent infringement litigation with the four first filers for the '516 Patent prevented generic competition to Provigil® in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. "None of the four first filers for the '516 Patent – at least some of whom had maintained their Hatch-Waxman exclusivity – were named in the FTC's complaint." Petition at 5-6.

I. The Subpoena is Within the Commission's Authority To Seek Relevant Information in a Law Enforcement Investigation

The Congress provided the Commission with the power to issue subpoenas because law enforcement investigations, like this one, frequently require the FTC "to get information from those who best can give it and who are most interested in not doing so." *United States v. Morton Salt Co.*, 338 U.S. 632, 643 (1950). The scope of information that may be required in response to a subpoena is broad. As a general matter, "it is sufficient if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably necessary," *id.* at 652, and the information sought can be produced without being "unduly burdensome" or disruptive. *Fed. Trade Comm'n v. Texaco, Inc.*, 555 F.2d 862, 882 (D.C. Cir. 1977). Further, the party who moves to quash an FTC administrative subpoena bears the burden of demonstrating

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[7] At that time, Cephalon's listing in the FDA's "Orange Book" included the '516 Patent, but did not **[include the later-issued '346 Patent.]** *Id.* at 3, Sunshine Decl. at ¶ 13.

[8] **[Watson and Carlsbad are potential First Filers for the '346 Patent]**, but not for the '516 Patent.

that the subpoena is unreasonable. "[T]he burden of showing that an agency subpoena is unreasonable remains with the respondent, . . . and where, as here, the agency inquiry is authorized by law and the materials sought are relevant to the inquiry, that burden is not easily met. [citations omitted]." *Fed. Trade Comm'n v. Rockefeller*, 591 F.2d 182, 190 (2nd Cir. 1979), *quoting Sec. and Exchange Comm'n v. Brigadoon Scotch Distributing Co.*, 480 F.2d 1047, 1056 (2nd Cir. 1973), *cert. denied*, 415 U.S. 915 (1974). As shown below, Petitioner has not demonstrated that the subpoena issued to Mr. Bisaro fails to meet these criteria. Nothing in *United States v. Powell*, 379 U.S.48 (1964), is to the contrary.

Specifically, an earlier civil investigative demand (CID) asked whether Watson's settlement agreement with Cephalon prevented it from **[relinquishing any claim of exclusivity regarding the '346 Patent]**; whether Watson would agree with a third party to facilitate earlier entry of a generic modafinil product; and, if not, why not.[9] The Petition effectively acknowledges that Watson's prior responses regarding these issues have been incomplete. Watson's CID response stated unequivocally, "**[There is no agreement between Watson and any other party preventing Watson from relinquishing any first-to-file rights it may have.]**"[10] But at the same time, the Petition confirms that Watson's CID response regarding the absence of a potentially illegal agreement was qualified such that its completeness, and accuracy, was questionable. See Petition at 16 n.75.[11]

On June 11, 2009, FTC staff advised Watson that its responses to the Commission's CID were deficient in that the responses failed, among other things, to indicate "the portion(s) of [each] agreement that prohibit or limit" **[relinquishment]**, or provide reasons for failing to have reached an agreement with a third party regarding **[relinquishment]**.[12] Watson declined to supplement its CID responses, stating that the FTC has a copy of the Settlement Agreement, and "The Agreement speaks for itself."[13] Citing attorney-client privilege, Watson declined to state the reasons for its failure to have reached an agreement with a third party regarding **[relinquishment]** because "the decision whether to **[relinquish marketing exclusivity]** and enter into **[a license with another company]** is inextricably intertwined with legal matters; Watson's internal deliberations regarding this matter implicate legal advice and are protected from disclosure by the attorney-client privilege."[14]

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[9] Petition at 15.

[10] *Id.* at 16.

[11] *Id.* at 16 note 75.

[12] Letter from Saralisa Brau to Maria Raptis (June 11, 2009) at 1-2.

[13] Letter from Maria Raptis to Saralisa Brau (June 17, 2009) at 2.

[14] *Id.* Mr. Buchen's unproductive negotiations of a possible business deal with a third-party **[generic drug manufacturer]** appear to have been conducted in the ordinary course of

Likewise, when FTC counsel asked Mr. Buchen at his investigational hearing on June 25, 2009, whether the patent settlement agreement with Cephalon limited Watson's right to **[relinquish]**, counsel instructed Mr. Buchen not to answer because the Commission was asking **"[for a lawyer's analysis of a legal agreement]."**[15] FTC counsel attempted to elicit additional information regarding particular provisions of the patent settlement agreement between Watson and Cephalon that related to **[relinquishment]**, but Mr. Buchen's counsel again instructed him not to answer because, **"[You [the FTC] have a copy of the settlement agreement; you're entitled to have a copy of the settlement agreement. It is something else to say how is that legally analyzed]."**[16]

It is not necessary to address the validity of Watson's privilege claims to rule on this Petition. *See Petition of Hoechst Marion Roussel, Inc.*, 128 F.T.C. 798, 804 (Nov. 1, 1999) ("The issue here is simply whether Spears must appear for a hearing, not the validity of any privileges Hoechst might claim in response to questions asked during the hearing. Indeed, no assessment of privilege claims is even possible because as yet, no questions have been posed and no proper assertions of privilege have been lodged."). In the event Mr. Bisaro appears and testifies at an investigational hearing, any unresolved dispute between the FTC and Mr. Bisaro concerning the validity of any privilege asserted will be resolved by the district court, if the Commission elects to challenge particular claims of privilege. See 16 C.F.R. § 2.13.

To summarize, the record clearly shows that fully responsive answers to the Commission's questions regarding **[relinquishment]** have not been provided either by Watson or Mr. Buchen. The Commission understands that Mr. Bisaro is the only other Watson employee who possesses any knowledge regarding these issues.[17] Thus, Mr. Bisaro's testimony is necessary in order for the Commission to satisfy itself that the law is not being violated.[18] Furthermore,

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business. Likewise, his reports on the progress of those negotiations to his corporate superior, Mr. Bisaro, also appear to be ordinary course of business discussions. Petitioner has cited no authority to support a claim that a corporation can shield its day-to-day business activities from scrutiny merely by having those activities discharged by lawyers. *See Fine v. Facet Aerospace Products Co.*, 133 F.R.D. 439, 444 (S.D. NY 1990) (The attorney-client "privilege covers communications made in connection with the rendering of legal advice, it does not extend to the provision of business and management advice.").

[15] Buchen IH 44:22-24, Jun. 25, 2009.

[16] Buchen IH 48:9-12. This privilege claim, however, fails to account for the Commission's right to obtain information regarding Watson's understanding of the duties and limitations that Watson, or its managers believe were imposed upon the firm by reason of this contract.

[17] Petition at 17; Buchen IH 39:1.

[18] *Morton Salt Co.*, 338 U.S. at 642-43.

Watson's claim that its settlement with Cephalon "speaks for itself,"[19] lacks all merit. Mr. Bisaro's knowledge of the document and its meaning has independent evidentiary value. Thus, contrary to Petitioner's claims, the instant subpoena does not seek information that is already in the Commission's possession. Furthermore, whether the materials and testimony that have been made available to the Commission thus far satisfy its investigative needs is a matter for the Commission to determine, not Petitioner. *See Sec. and Exchange Comm'n v. Arthur Young & Co.*, 584 F.2d 1018, 1031 (D.C. Cir. 1978) ("The breadth of an investigation is for the investigators to determine."). There is therefore no apparent justification for Mr. Bisaro to refuse to answer questions regarding his understanding of Watson's settlement agreement with Cephalon.

II. Exhaustion of Other Investigational Avenues Is Not Required

There is no support for Petitioner's claim that the FTC may only take testimony from Watson's CEO when it can show that he has personal information that is not obtainable through other means.[20] The initial mistake lies in Petitioner's assumption that the Commission's investigational hearings should be governed, by analogy, by discretionary limitations that may be placed on depositions conducted pursuant to the Federal Rules of Civil Procedure. Counsel has not provided appropriate authority to support its claim that the Commission can only take testimony from Mr. Bisaro regarding relinquishment as a last resort, and then only if the Commission can show that he has personal knowledge of the subjects that will be examined during the investigational hearing.[21]

More importantly, only Mr. Buchen and Mr. Bisaro possess relevant knowledge regarding the **[relinquishment]** issues being investigated by the Commission.[22] Counsel has instructed Mr. Buchen not to tell the FTC which provisions of the Cephalon settlement agreement related to

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[19] Letter from Maria Raptis to Saralisa Brau (June 17, 2009) at 2.

[20] Petitioner's reliance on cases holding that a district court judge has discretion to defer discovery depositions of a company's CEO until after other discovery means have been exhausted is not relevant to resolving the Petition. Petition at 17-20. Many of the cases relied upon by Petitioner appear to involve claims asserted by lower level employees in remote company offices about which the CEO was unlikely to have been either involved or informed. For instance, in *Thomas v. Internat'l Bus. Mach.*, 48 F.3d 478 (10th Cir. 1995), a wrongful termination suit, the court affirmed the district court's grant of a protective order where a former clerical employee in IBM's Oklahoma City marketing office sought to compel the CEO, located in New York, to appear in Oklahoma City for a deposition on five days notice. The record in that case indicated that the CEO did not have any knowledge of the employee, the quality of her prior work, or the reasons for her termination.

[21] Petition at 17-18.

[22] Buchen IH at 39:1.

[relinquishment] other than a provision regarding Cephalon's obligation to **[reimburse certain of Watson's legal fees]**.[23]

Unlike Mr. Buchen, Mr. Bisaro is not the General Counsel of Watson; rather, he is Watson's CEO. Mr. Bisaro is an attorney with significant prior business experience as both the general counsel and chief operating officer of another generic drug company.[24] Mr. Bisaro appears to be competent to answer questions regarding the Cephalon settlement agreement without having to disclose any privileged communications that he might have had with Mr. Buchen.

III. The Subpoena Was Issued for A Proper Purpose.

Petitioner claims that the subpoena should be quashed because it was issued by the FTC for an improper purpose – namely, "**[to pressure Watson to relinquish any exclusivity rights it may have, and thereby attempt to engineer generic entry into the modafinil market]**."[25]

The analysis of the purpose for the issuance of this subpoena must begin by an examination of the resolution authorizing staff to use compulsory process in conducting this investigation.[26] The Commission's resolution of August 30, 2006 authorized FTC staff to use compulsory process to "determine whether Cephalon, Inc., . . . Watson . . ., or others have engaged in any unfair methods of competition" in violation of the FTC Act "by entering into agreements regarding any modafinil product."[27] Watson does not claim that an agreement not to **[relinquish any exclusivity it might have]** regarding modafinil products is beyond the scope of the resolution, nor does it claim that its patent settlement and license with Cephanol would be beyond the scope of the resolution. Further, Watson does not claim that the Bisaro investigational hearing is beyond the scope of the resolution. Thus, the subpoena to Mr. Bisaro is authorized by the resolution, and Petitioner has the burden of establishing the existence of "extraordinary

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[23] *Id.* at 47:10-11. The relationship between Cephalon's **[reimbursement]** obligations to Watson and **[relinquishment]** are not obvious. This is especially true in light of other provisions in that agreement that appear more likely to be related to **[relinquishment]**; provisions about which Mr. Buchen was instructed by counsel not to testify. *Id.* at 51:6.

[24] Press Release, Watson, Watson Announces CEO Succession Plan (Aug. 2, 2007), available at: http://ir.watson.com/phoenix.zhtml?c=65778&p=irol-newsArticle&ID=1035647&highlight= (Last Visited Oct. 2, 2009).

[25] Petition at 19.

[26] *Fed. Trade Comm'n v. Invention Submission Corp.*, 965 F.2d 1086, 1092 (D.C. Cir. 1992), citing *Fed. Trade Comm'n v. Carter*, 636 F.2d 781, 789 (D.C. Cir. 1980).

[27] Petition, Exhibit B.

circumstances" before a further inquiry into the *bona fides* of this subpoena would be appropriate. *Carter*, 636 F.2d at 789.[28]

Petitioner speculates that the "**[only conceivable reason for the FTC to insist on [the Bisaro hearing] at this stage is to pressure Watson to relinquish any exclusivity rights it might have].**"[29] Rather than cooperate in the investigation, Watson has chosen to rely instead on incomplete and contradictory answers, and on dubious claims of privilege.[30] These stratagems deprive Petitioner's speculations of probative value. Petitioner acknowledges that FTC staff have expressed concerns that certain provisions of the settlement agreement with Cephalon might delay consumer access to lower-cost generic drugs and violate the FTC Act.[31] Those concerns, even without considering Watson's incomplete and contradictory responses to CIDs and subpoenas, provide ample grounds for asking Mr. Bisaro to sit for an investigational hearing as part of the Commission's continuing investigation.

CONCLUSION AND ORDER

For all the foregoing reasons, **IT IS ORDERED THAT** the Petition be, and it hereby is, **DENIED.**

IT IS FURTHER ORDERED THAT Commission staff may reschedule the investigational hearing of Mr. Bisaro at such date and time as they may direct in writing, in accordance with the powers delegated to them by 16 C.F.R. § 2.9(b)(6).

By direction of the Commission.

Donald S. Clark
Secretary

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[28] The full scope of Petitioner's burden is demonstrated by the D.C. Circuit's reliance on *Donaldson v. United States*, 400 U.S. 517, 534-35 (1971), for the proposition that an administrative subpoena must be enforced whenever a valid purpose appears, even if an otherwise improper purpose also appeared.

[29] Petition at 19-20.

[30] This record lends a hollow ring to any claim that Watson has "cooperated fully" throughout this investigation. Petition at 5, Sunshine Decl. at ¶ 12.

[31] Petition, Exhibit N at 2 (Letter from Maria Raptis to Saralisa Brau, dated July 21, 2009).

Petition Exhibit 6

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HIGHLY CONFIDENTIAL

November 27, 2009

By Hand Delivery
Mr. Donald S. Clark
Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW
Room H135
Washington, DC 20580

Re: FTC File No. 0610182

Dear Mr. Clark:

I write on behalf of Mr. Paul M. Bisaro, President and Chief Executive Officer of Watson Pharmaceuticals, Inc. ("Watson" or the "Company"), and Watson to request review by the full Federal Trade Commission ("FTC" or the "Commission") of the Petition to Quash Subpoena *Ad Testificandum* dated July 22, 2009 (the "Petition") filed in connection with the matter referenced above. A copy of the Petition is attached as Appendix A.

Acting as the Commission's delegate, Commissioner Pamela Jones Harbour denied the Petition by letter dated November 13, 2009 (attached as Appendix B). Pursuant to 16 C.F.R. § 2.7(f), a request for review of this matter by the full Commission must be filed with the Secretary of the Commission within three business days after service of the letter ruling. The letter ruling was received by counsel for Mr. Bisaro via hand delivery on November 23, 2009.

We believe that the Commission's ruling overlooks the key basis for the Petition: that Watson has already responded fully to the Commission's inquiries, and the subpoena issued to Mr. Bisaro is not calculated to obtain additional relevant information. In particular, the Commission seeks information regarding: (i) whether Watson's settlement agreement with Cephalon prevented it from relinquishing

exclusivity relating to the '346 Patent; and (ii) whether Watson has agreed with a third party to relinquish its exclusivity, and if not, why not.[1] Watson has repeatedly stated – including through the sworn testimony of its General Counsel – that there is no agreement preventing Watson from relinquishing any exclusivity associated with the '346 Patent, and that the Company has not reached any agreements with third parties to relinquish such exclusivity.[2] Moreover, Watson's General Counsel has fully explained the Company's business rationale for not unilaterally relinquishing its rights.

The Commission disregards these responses in its letter ruling, characterizing Mr. Bisaro's testimony on these issues as "necessary" despite the fact that Mr. Bisaro has *no* responsive documents and *no* contacts with any third party regarding relinquishment,[3] and indeed was not even employed by Watson at the time the Company entered into its settlement agreement with Cephalon. Enforcement of the subpoena under these circumstances is not calculated to yield information that the FTC does not already possess.

Thus, notwithstanding the General Counsel's testimony that Watson is free to relinquish any exclusivity, but has not made a decision regarding whether to relinquish its rights, the Commission's letter ruling strongly suggests that the Commission is entitled to something more than this information – *i.e.*, Watson's detailed legal interpretation of various provisions of the settlement agreement. This type of legal analysis is protected by privilege and its disclosure is not an appropriate goal of the Commission's investigatory process.[4] Likewise, to the extent they implicate legal analysis, Watson's internal deliberations regarding relinquishment (to the extent they occurred) are not appropriate subjects of the FTC's subpoena power. As the Commission's letter ruling makes clear, these are the only conceivable topics remaining for the Commission to attempt to probe. Under these circumstances, the Commission's continued insistence on deposing Mr. Bisaro, together with the circumstances and staff communications with Watson surrounding the issuance and enforcement of compulsory process as detailed in the Petition, leads to a strong inference that the subpoena was issued for an improper purpose.

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[1] *See* Letter dated November 13, 2009 at 4.
[2] *See* Petition at 11, 16-17. *See also* Letter dated November 13, 2009 at 4, n. 10.
[3] *See* Petition at 10.
[4] *See* Letter dated November 13, 2009 at 5, n. 16, stating that the Commission has a right to obtain information regarding "Watson's understanding" of provisions of the contract. *See also id.* at 7, stating that because "Mr. Bisaro is an attorney" he can answer questions regarding the Cephalon settlement agreement.

Accordingly, we request full Commission review of the entire Petition and all the issues presented therein (which are hereby incorporated by reference), including Petitioner's arguments that:

(i) the subpoena demands information that the Commission already possesses;

(ii) the subpoena unreasonably seeks testimony from the Chief Executive Officer of Watson when the information it demands has already been obtained elsewhere;

(iii) the Commission resolution authorizing compulsory process in connection with the above-referenced matter has already culminated in a lawsuit, and may not now be resurrected to burden Watson with additional process;

(iv) the subpoena was likely issued for an improper purpose as described in the Petition; and

(v) compelling Petitioner to travel to Washington, D.C. to undergo an investigational hearing under these circumstances would be unduly burdensome.

Please do not hesitate to contact me if you should have any questions regarding this request for review by the full Commission.

Very truly yours,

Steven C. Sunshine

Steven C. Sunshine

cc: Saralisa Brau, Esq.

Enclosures

Appendix A

Appendix A is Respondent's Petition to Quash, which is Petition Exhibit 4

Appendix B

Appendix B is the Commission decision of November 13, 2009 denying Respondent's Petition to Quash, which is Petition Exhibit 5

Petition Exhibit 7

Office of the Secretary

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

April 2, 2010

Watson Pharmaceuticals, Inc.
c/o Steven C. Sunshine, Esq.
Skadden, Arps, Slate, Meagher & Flom LLP
1440 New York Avenue NW
Washington, DC 20005

RE: Request for Review of Ruling Denying Petition to Quash Subpoena *Ad Testificandum* Dated July 22, 2009, File No. 091-0182

Dear Mr. Sunshine:

This letter responds to your November 27, 2009 Request for Review ("Request"), by the full Commission, of the November 13, 2009 ruling by Commissioner Pamela Jones Harbour, denying the Petition to Quash the Subpoena *Ad Testificandum*, dated July 22, 2009, and issued to Paul M. Bisaro ("Petition"). Mr. Bisaro is the President and Chief Executive Officer of Watson Pharmaceuticals, Inc. ("Watson"), and the Commission seeks his testimony in connection with an investigation of whether certain pharmaceutical companies, including Watson, have entered into any agreements to forego relinquishing any eligibility or rights they may have to market the generic drug modafinil – *i.e.*, whether these companies, including Watson, have entered into any agreements that potentially constitute an "unfair method of competition" in violation of the Federal Trade Commission Act. As you know, the market for modafinil (a/k/a Provigil) exceeds $800 million a year. So, if multiple generic companies enter the marketplace, consumers could save hundreds of millions of dollars per year.

The information the Commission may subpoena is broad in scope. As a general matter, "it is sufficient if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably necessary." *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950). Thus, in a petition to quash, the petitioner bears the burden to show that a subpoena is unreasonable, and where "'the agency inquiry is authorized by law and the materials sought are relevant to the inquiry, that burden is not easily met.'" *FTC v. Rockefeller*, 591 F.2d 182, 190 (2d Cir. 1979), *quoting SEC v. Brigadoon Scotch Distributing Co.*, 480 F.2d 1047, 1056 (2d Cir. 1973), *cert. denied*, 415 U.S. 915 (1974). Despite the Commission's broad authority, Watson refuses to produce Mr. Bisaro for an investigational hearing.

The Commission has more than a sufficient basis to seek Mr. Bisaro's testimony under *Morton Salt*. At issue in the Petition is whether the Commission can examine Mr. Bisaro to discover his knowledge about any agreement Watson may have that limits or restricts the exercise of any marketing rights or exclusivities it may have now or obtain in the future vis-à-vis modafinil. Such an agreement, if it exists, could be delaying generic entry to the detriment of consumers.[1] Despite the Petition's repeated assertions that Watson has reached no such agreement and that it has confirmed to the Commission that no such agreement exists, other facts raise questions about whether such an agreement exists. For example, in its response to the Commission's civil investigative demand ("CID"), Watson identified an agreement that it said "may relate to" its ability to relinquish any exclusivity rights relating to generic modafinil. Watson, however, has repeatedly refused to clarify – either through written responses or testimony – whether that agreement would prevent or otherwise limit its ability to relinquish. Further, although a company has approached Watson about relinquishing any potential exclusivity rights, Watson appears disinterested, and, according to one witness, would prefer to wait until 2012 to launch its own product. The extent to which this decision is inconsistent with Watson's economic interest is likely to shed light on whether Watson has entered into a potentially illegal agreement. Mr. Bisaro is a logical person to question on this issue that goes to the core of the Commission's investigation. Watson has identified him as one of only two people who has knowledge of relevant events, the Commission has already taken the testimony of the other person, and the critical question of whether Watson reached a potentially unlawful agreement remains unanswered.

Against this factual background and given the Commission's broad power to compel information in investigations conducted pursuant to its law enforcement efforts, we find that conducting an investigational hearing of Mr. Bisaro is proper. Accordingly, and as explained more fully below, we therefore deny the Request.

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[1] Courts have expressed great skepticism of agreements in which a generic manufacturer who is eligible for the 180-day exclusivity agrees with the branded manufacturer not to relinquish or waive that exclusivity. *See, e.g. In re Ciprofloxacin*, 544 F.3d 1323, 1339 (Fed. Cir. 2008) (agreeing that "the only legitimate allegation by the plaintiffs was that the 180-day exclusivity period had been manipulated."); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 401 (2d Cir. 2005) ("[W]e think that an agreement to time the deployment of the exclusivity period to extend a patent monopoly power might well constitute anticompetitive action outside the scope of a valid patent."); *Andrx v. Elan*, 421 F.3d 1227, 1235 (11th Cir. 2005) (holding that delayed licensed plus putative agreement to refrain from ever marketing a generic barred any competitors from entering "would exceed the scope of the patent"); *FTC v. Cephalon, Inc.*, No. 2:08-cv-2141, mem. op. (E.D. Pa. Mar. 29, 2010) (declining to dismiss complaint alleging that agreement to settle patent litigation and affecting relinquishment of exclusivity rights is anticompetitive).

Background

The Petition and Request relate to a Commission investigation,

> [t]o determine whether Cephalon, Inc., Teva Pharmaceuticals, Inc. (and its affiliate Teva Pharmaceuticals USA, Inc.), Barr Laboratories, Inc., Ranbaxy Laboratories, Inc., Mylan Pharmaceuticals, Inc., Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding modafinil products.[2]

Modafinil is a "wakefulness-enhancing" drug that Cephalon, Inc. ("Cephalon") has developed and marketed under the brand name Provigil.[3] Each of the other entities identified in the compulsory process resolution has developed and sought to market generic modafinil. The controversy giving rise to the Petition concerns the investigation of certain facts relating to Watson Pharmaceuticals, Inc. ("Watson") and its development partner, Carlsbad Technologies, Inc. ("Carlsbad") – in particular, obtaining the testimony of Paul Bisaro ("Petitioner"), Watson's President and Chief Executive Officer.

To that end, Commission staff is interested in any agreements between Cephalon and entities identified in the Commission's compulsory process resolution to settle patent litigation associated with modafinil. Cephalon sued most of the entities named in the resolution, alleging that they were infringing U.S. Reissued Patent No. 37,516 ("'516 Patent") relating to Provigil. These patent infringement allegations were based on each of the entities named in the resolution having filed Abbreviated New Drug Applications ("ANDA") with the Food and Drug Administration ("FDA") for generic modafinil, with a "Paragraph IV" certification that generic modafinil would not infringe the '516 Patent.[4] Each of the entities other than Watson/Carlsbad filed their ANDA on the same day, and before any other parties. As "first filers," these entities were eligible under applicable law for 180 days of joint marketing exclusivity at such time that the ANDA is approved. Watson/Carlsbad were not "first filers," but Cephalon also sued Carlsbad for patent infringement after Watson/Carlsbad filed their ANDA and Paragraph IV certification. Cephalon settled each of the suits between late 2005 and 2006, with the Carlsbad settlement occurring on August 2, 2006.[5] On February 13, 2008, the Commission filed a complaint against Cephalon, alleging that its settlement agreements, which provided compensation to the generic firms for foregoing generic entry, were anticompetitive, an abuse of

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[2] Resolution Authorizing Use of Compulsory Process in a Nonpublic Investigation, File No. 06110182 (Aug. 30, 2006).

[3] Petition at 3.

[4] ANDAs reflect a streamlined FDA approval process that enables manufacturers of generic drugs (*i.e.*, those that are the "bioequivalent" of branded drugs) to rely on the safety and efficacy studies relating to the branded drug. When a branded drug is covered by one or more patents, the company that seeks to market the generic drug prior to the expiration of any of those patents may proceed to seek FDA approval, but certify that the generic version does not infringe the patents on the brand-name drug, or that the patents are invalid. This certification is a "Paragraph IV" certification.

[5] Petition at 3-4.

monopoly power, and unlawful under Section 5 of the FTC Act. *FTC v. Cephalon, Inc.*, 08-cv-2141-MSG (E.D. Pa.).[6]

In December 2007, Cephalon listed a new patent with the FDA relating to modafinil: U.S. Patent No. 7,297,346 ("'346 Patent"). The subsequent listing of the '346 Patent required the existing ANDA applicants for modafinil to make a certification vis-à-vis the '346 Patent. Watson/Carlsbad filed a Paragraph IV certification on the same day that the FDA listed the new patent, identifying the Cephalon/Carlsbad settlement agreement as the basis for non-infringement of the '346 Patent. According to the Petition, if Watson were a "first filer" on the '346 Patent, it would be eligible for the 180-day marketing exclusivity for generic modafinil.[7]

Following these developments, Commission staff contacted Watson in March 2009 about its ANDA. Commission staff informed Watson that they were primarily interested in determining whether Watson had reached any agreement relating to relinquishment of any exclusivity rights it might have with respect to generic modafinil, and, if not, the basis for any decision not to waive such rights.[8] On May 19, 2009, the Commission issued a new CID to Watson and a subpoena *ad testificandum* to David A. Buchen, Watson's Senior Vice President, General Counsel, and Secretary. On May 22, 2009, the Commission issued a subpoena *ad testificandum* to Petitioner. The Commission also issued a CID and two subpoenas *ad testificandum* to Carlsbad executives.[9]

Controversies, discussed more below, ensued about the adequacy of Watson's CID responses, the necessity of investigational hearings for the Watson executives, and the schedule of the same. As a result of these discussions, Mr. Buchen ultimately appeared for a hearing. In contrast, Mr. Bisaro refused to appear and filed a petition to quash, which Commissioner Harbour denied on November 13, 2009. Pursuant to Commission Rule 2.6(f), 16 C.F.R. § 2.6(f), Mr. Bisaro has now asked the full Commission to review Commissioner Harbour's ruling.

Analysis of Petitioner's Legal Objections to Subpoena

The Supreme Court made clear that the Commission has a right to conduct an investigation "if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant." *U.S. v. Morton Salt Co.*, 338 U.S. 632, 652 (1950). This standard applies to administrative subpoenas issued by the Commission. *See, e.g., FTC v. Texaco, Inc.*, 555 F.2d 862, 872 (D.C. Cir. 1977) (en banc); *Adams v. FTC*, 296 F.2d 861, 866 (8th Cir. 1961), *cert. denied*, 369 U.S. 864 (1962). In the context of a Commission investigatory subpoena, "[t]he law on this issue is well-established: so long as an agency acts within its authority, requests information relevant to the lawful inquiry, and makes

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[6] The district court recently denied Cephalon's motion to dismiss the complaint. *FTC v. Cephalon, Inc.*, 08-cv-2141, mem. op. (E.D. Pa. Mar. 29, 2010).
[7] Petition at 6-7.
[8] Raptis Decl., at 2.
[9] Petition at 7-8.

reasonable demands, the court must uphold the validity of the administrative subpoena." *FTC v. Invention Submission Corp.*, 1991 WL 47104, *1 (D.D.C. 1991), *aff'd* 965 F.2d 1086 D.C. Cir 1992), *cert. denied*, 507 U.S. 910 (1993). Petitioner carries a heavy burden to show that the subpoena should not be enforced.

Petitioner does not challenge the Commission's authority to issue the subpoena. Nor does the Petition claim that the discovery sought is not "reasonably relevant" or too indefinite. Rather, Petitioner claims that the Commission is improperly using its compulsory process by being "unreasonable" in seeking his testimony. Petitioner raises five objections to the subpoena: (1) the resolution authorizing the compulsory process has already produced one lawsuit against Cephalon, and now cannot be used for the additional investigatory process directed to Watson; (2) the subpoena unreasonably demands information that the Commission already possesses; (3) the subpoena unreasonably seeks testimony from the "apex" of Watson's organization; (4) the subpoena was likely issued for an improper purpose; and (5) compelling Petitioner to travel to the Commission offices in Washington, DC to undergo an investigational hearing is unduly burdensome.[10]

Because we find that none of these arguments is persuasive, we deny the Petition and Request in their entirety. We address each of Petitioner's five specific challenges below.

I.

We first address Petitioner's threshold argument that the subpoena is improper because the resolution authorizing the compulsory process has already culminated in one enforcement action.[11] Petitioner provides no legal support for this proposition. A Commission resolution authorizing compulsory process for an investigation does not, as a matter of law, expire automatically upon the filing of an enforcement action or because some litigation regarding related subjects may have commenced. *See, e.g., Linde Thomson Langworthy Kohn & Van Dyke, P.C. v. Resolution Trust Corp.*, 5 F.3d 1508 (D.C. Cir. 1993). To the contrary, multiple actions might be taken as a result of information obtained through compulsory process stemming from such a resolution. Moreover, as indicated above, the concerns that prompted the Commission's current investigation relating to the '346 Patent differ in scope from those that prompted its investigation of the "pay-for-delay" settlement agreements relating to the '516 Patent. However, both components of the investigation clearly fall within the broad parameters of the compulsory process resolution, *i.e.*, "[t]o determine whether ... Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec 45, as amended, by entering into agreements regarding modafinil products." As a result, we reject Petitioner's argument that because "the Commission resolution authorizing compulsory process in connection with the above-referenced matter has already culminated in a lawsuit," it "may not now be resurrected to burden Watson with additional process."[12]

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[10] Request at 3.
[11] Request at 3.
[12] Request at 3.

II.

We turn next to Petitioner's argument that the subpoena compelling his testimony is unreasonable because it demands information that, he contends, the Commission already possesses. While Watson has provided the Commission information relating to the '346 Patent, Petitioner has not shown that his testimony will shed no additional light on matters that fall within the scope of the Commission's investigatory concerns. As a key executive of Watson, Petitioner's testimony may well be useful in elaborating on the information or explaining relevant circumstances. Under the broad standard applicable to the investigatory process, Commission staff is entitled to question Petitioner to determine if he has any additional relevant information.

As indicated above, the investigation related to the '346 Patent focuses on two critical questions: (1) whether the company has entered into any agreements that restrict it from relinquishing any exclusivity it may have in connection with that patent, and (2) if not, why the company is not pursuing potentially lucrative arrangements with third parties concerning relinquishment. In connection with these issues, and as indicated above, the Commission issued CIDs to Watson and Carlsbad on May 19, 2009, and subpoenas *ad testificandum* to two executives at each company, including Petitioner. Petitioner contends that Watson "fully" responded to "each and every" inquiry in the CID directed to it, and that because Mr. Buchen confirmed the company's responses during his investigational hearing, Petitioner's testimony is unnecessary.[13] The record, however, leaves certain open questions.

On the first issue of interest, one of the CID specifications directed to Watson required the company to "[i]dentify and provide one copy of each agreement, whether written or oral, that prohibits, blocks, prevents, compromises, or limits in any way Watson or Carlsbad's ability to relinquish eligibility to claim 180-day Marketing Exclusivity for Generic Provigil," and to identify "[t]he portion(s) of the agreement that prohibit or limit Watson or Carlsbad's ability to relinquish."[14] In response, Watson identified its settlement agreement with Cephalon as the only agreement that "may relate" to its ability to relinquish, but failed to identify the portions that prohibit or limit its ability to relinquish.[15] In response to follow-up questions by staff designed to elicit complete answers, Watson simply stated that the settlement agreement "speaks for itself," and, citing attorney-client privilege, refused to provide any information about Watson's understanding of how that agreement might relate to marketing exclusivity.[16] As for Mr. Buchen's investigational hearing, he identified an indemnification provision in the Cephalon settlement agreement that "might relate to the investigation," but declined to answer questions about any other provisions, including whether the settlement agreement limits Watson's ability to relinquish exclusivity.[17] Against this backdrop, it is reasonable for the Commission to seek

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[13] Petition at 16.
[14] CID to Watson, FTC File No. 0610182 (issued May 19, 2009).
[15] Watson Responses to CID, FTC File No. 0610182 (June 10, 2009).
[16] Letter from Maria A. Raptis to Saralisa Brau (June 17, 2009).
[17] Buchen Transcript at 47, 50-51.

testimony from additional witnesses on these issues. Watson has identified Petitioner as the only other person other than Mr. Buchen who is knowledgeable about the issues and it is therefore logical to seek his testimony.

On the second issue of interest, one of the CID specifications required Watson to "[i]dentify each company with which Watson had contact relating to ... eligibility to claim 180-day Marketing Exclusivity for Generic Provigil; or the relinquishment thereof," and "[w]hether Watson entered into an agreement as a result of these discussions, and the reasons for Watson's decision."[18] In response, Watson identified a particular company with which it had discussions, stated that specific terms were not discussed and that no agreement or decision had been reached, but failed to provide any rationale.[19] In response to follow-up questions by staff designed to elicit complete answers, Watson again failed to provide the information sought, based on attorney-client privilege.[20] Yet at Mr. Buchen's investigational hearing, he provided at least two rationales for not pursuing relinquishment: (1) discussions with the company stopped after issuance of the Commission's process, and (2) his own business view that Watson would be in a better position to launch its own product.[21] Given this information, after Watson's initial response failed to explain its decision and its follow-up response failed to provide the requested information based on privilege, we again find that it is reasonable for the Commission to pose questions to Petitioner to determine what he knows.

We recognize that questions directed to Petitioner about whether Watson has an agreement that in some way limits its ability to relinquish any marketing exclusivity rights it has, as well as about the basis for any decision of Watson not to relinquish any such rights, *may* implicate privileged communications. However, that does not provide a basis upon which to quash the subpoena for his testimony in its entirety. Rather, the proper procedure is for (1) the investigational hearing to take place; (2) Petitioner to assert the privilege (as he believes it to be applicable); and (3) Commission staff to establish facts through questioning to determine whether Petitioner's assertion is proper.

III.

Petitioner also suggests that the subpoena directed to him is unreasonable because, as President and CEO of Watson, there is no reason to believe that he has personal knowledge of relevant information that cannot be obtained through other means.[22] Petitioner provides no case law indicating that the so-called "apex doctrine" applies in an administrative investigation. Even assuming, without deciding, that the principle might apply, we find that it does not provide an adequate basis to quash the subpoena here.

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[18] CID to Watson, FTC File No. 0610182 (issued May 19, 2009).
[19] Watson Responses to CID, FTC File No. 0610182 (June 10, 2009).
[20] Letter from Maria A. Raptis to Saralisa Brau (June 17, 2009).
[21] Buchen Transcript at 33, 67-68.
[22] Petition at 17-19; Request at 3.

As a preliminary matter, we note that high-ranking executives are, of course, not insulated from discovery. *Six West Retail Acquisition, Inc. v. Sony Theatre Mgmt. Corp.*, 203 F.R.D. 98, 102 (S.D.N.Y. 2001). Even when such an executive denies having personal knowledge of relevant issues, the examining party may test such a claim. *Id.*

In the current investigation, the Commission has already sought information through a CID to Watson, through a CID to Carlsbad, through an investigational hearing of Mr. Buchen, and through an investigational hearing of a Carlsbad executive. Petitioner is another logical, possible source of relevant information, since Mr. Buchen identified him as the only person with whom Mr. Buchen had discussions regarding potential relinquishment. In addition, Petitioner has personal knowledge of conversations that he had with Mr. Buchen, as well as other factual information that may not have been discovered yet and may not be privileged. Therefore, even under the stringent standards Petitioner suggests apply to administrative investigations, the investigational hearing requested here is warranted.

To summarize, we find no basis for Petitioner's assertion that the subpoena is "unreasonable" in requesting Mr. Bisaro's testimony. Accordingly, we reject Petitioner's arguments to the contrary.

IV.

Petitioner further contends that the subpoena is improper because it was issued for an improper purpose, *i.e.*, "to pressure Watson to relinquish any exclusivity rights it may have, and thereby attempt to engineer generic entry into the modafinil market."[23] In particular, Petitioner asserts that Commission staff threatened to continue its investigation of Watson if the company did not relinquish any exclusivity rights it has, and carried out that threat by issuing the process at issue in the Petition.

These allegations are baseless and do not support the Petition's assertion that the subpoena was issued for an improper purpose. The subpoena was issued pursuant to a valid and extant resolution "[t]o determine whether Cephalon, Inc., ... Carlsbad Technology, Inc., Watson Pharmaceuticals, or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding modafinil products." Pursuant to that resolution, the Commission is authorized to investigate whether Watson has entered into any agreements relating to relinquishment of any marketing exclusivity rights that it may have for generic modafinil, and, if not, whether it intends to relinquish such rights. In such an investigation, Commission staff may explore or suggest certain actions that might negate any anticompetitive concerns identified. We find that issuing a subpoena for the testimony of the President and CEO of Watson about any company agreements and discussions with third parties with regard to relinquishment – after first issuing CIDs to the company and receiving the testimony of another of its executives – is clearly a proper purpose.

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[23] Petition at 19.

V.

Finally, Petitioner contends that if his investigational hearing is to proceed, it is "unduly burdensome" for him to appear at FTC offices in Washington, D.C. as opposed to his place of residence.[24] Petitioner provides nothing more than a generalized assertion of burden, and does not explain how his travel to and participation in an investigational hearing in Washington, D.C. is unduly burdensome. On the current record, we therefore reject Petitioner's request that the investigational hearing proceed at a location other than the FTC's offices in Washington.

Conclusion and Order

For all of the foregoing reasons, **IT IS HEREBY ORDERED THAT** the Request be, and it hereby is, **DENIED**.

IT IS FURTHER ORDERED THAT Petitioner appear on April 15, 2010, for an investigational hearing in Washington, D.C., unless otherwise agreed to by Commission staff.

By direction of the Commission.

Donald S. Clark
Secretary

[24] Petition at 19; Request at 3.

Petition Exhibit 8

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CONFIDENTIAL

April 13, 2010

James Rhilinger, Esq.
Federal Trade Commission
601 New Jersey Avenue, N.W.
Washington, D.C. 20580

RE: Cephalon, Inc., FTC File No. 061-0182

Dear James:

I write to memorialize the substance of our telephone conversation yesterday afternoon. As I stated on the call, Watson Pharmaceuticals, Inc. ("Watson") has determined not to produce its President and Chief Executive Officer, Mr. Paul Bisaro, for an investigational hearing on April 15, 2010 in connection with the Federal Trade Commission's ("FTC") subpoena *ad testificandum* dated July 22, 2009. We have taken this step in order to preserve our position that the FTC's subpoena should be quashed. Nevertheless, we expect to work cooperatively with the FTC in addressing the next steps to be taken, including a dialogue on whether any resolution is possible, or alternatively, efficiently scheduling any ensuing litigation. I understand that you will let us know whether we should discuss those next steps either with the management of the Health Care Division or with the FTC's Office of the General Counsel.

More generally, Watson is aware that the interface between brand-name and generic pharmaceutical manufacturers is currently a topic of great interest at the FTC. Watson has, however, confirmed to the FTC on various occasions that it has not reached any agreements or decisions regarding relinquishment of any marketing exclusivity associated with the '346 Patent, and in particular that there is no agreement that would preclude Watson from relinquishing any exclusivity rights

it may have. Moreover, as the record in the case clearly indicates, Mr. Bisaro has had *no* contacts with any third party regarding this subject. Indeed, his knowledge is limited to less than a handful of brief updates from Watson's general counsel. Given these facts, we can see no practical purpose in pursing Mr. Bisaro's testimony.

I look forward to hearing from you regarding next steps.

Sincerely,

Steven C. Sunshine