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

Office of the Secretary

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

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[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).