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

Office of the Secretary

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.