IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION 600 Pennsylvania Ave., N.W. Washington, D.C. 20580, Petitioner, v. PAUL M. BISARO President and CEO, Watson Pharmaceuticals, Inc. 360 Mt. Kemble Avenue, Morristown, NJ 07962 Respondent.	Misc. No.: 1:10-mc-00289 (CKK)

RESPONDENT'S OPPOSITION TO PETITION
OF FEDERAL TRADE COMMISSION FOR AN ORDER ENFORCING
ADMINISTRATIVE SUBPOENA *AD TESTIFICANDUM*

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

PRELIMINARY STATEMENT 1

FACTUAL BACKGROUND 4

A. The Present Dispute Arises out of the FTC's Campaign Against Reverse-Payment Settlements 4

B. The FTC's Modafinil Investigation 6

1. The Initial Phase of the FTC's Investigation 6

2. A New Provigil Patent is Listed in the Orange Book 8

3. The FTC Reopens its Modafinil Investigation 9

(a) The FTC Attempts to Broker a Business Deal and Threatens a Renewed Investigation 9

(b) The FTC Issues Compulsory Process while Watson Evaluates its Options, but Agrees to Defer Initial Subpoena Issued to Respondent 10

(c) The FTC Issues a New Subpoena 14

(d) Respondent Seeks to Quash and the FTC Files this Action 14

LEGAL ARGUMENT 16

A. The Subpoena Unreasonably Demands Information already in the FTC's Possession 16

B. The Subpoena Should Not Be Enforced because it Unreasonably Seeks Testimony from the Apex of Watson's Organization 21

C. The Subpoena Should Not be Enforced Because it Was Issued for an Improper Purpose 24

1. The 2006 Resolution Does Not Provide a Legitimate Basis to Investigate Conduct Occurring after its Issuance 24

2. The Court Must Consider Respondent's Ample Evidence Demonstrating that the Subpoena Was Issued for an Improper Purpose.....25

(a) Respondent Has Satisfied His Burden of Showing Improper Purpose.....25

(b) The Proffer of a "Legitimate Purpose" Does Not End the Inquiry.....29

D. Respondent Should be Allowed Discovery into the FTC's *Ultra Vires* Activity 30

CONCLUSION.....31

TABLE OF AUTHORITIES

CASES

Adamowicz v. United States,
531 F.3d 151 (2d Cir. 2008).....21

In re AndroGel Antitrust Litigation (No. II),
No. 1:09-MD-2084-TWT, 2010 WL 668291 (N.D. Ga. Feb. 22, 2009).....6

**Baine v. General Motors Corp.*,
141 F.R.D. 332 (M.D. Ala. 1991).....22, 23, 24

In re Ciprofloxacin Hydrochloride Antitrust Litigation,
544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009).....4

Donaldson v. United States,
400 U.S. 517 (1971).....29

**FEC v. Committee to Elect Lyndon La Rouche*,
613 F.2d 849 (D.C. Cir. 1979).....16, 25, 29

FTC v. Carter,
636 F.2d 781 (D.C. Cir. 1980).....29

FTC v. Watson Pharmaceuticals, Inc.,
611 F. Supp. 2d 1081 (C.D. Cal. 2009).....6

In re K-Dur Antitrust Litigation,
No. 01-1652, 2010 WL 1172995 (D.N.J. Mar. 25, 2010).....4

In re K-Dur Antitrust Litigation,
No. 01-1652, 2009 WL 508869 (D.N.J. Feb. 6, 2009).....4

**Salter v. Upjohn Co.*,
593 F.2d 649 (5th Cir. 1979).....22

Schering-Plough Corp. v. FTC,
402 F.3d 1056 (11th Cir. 2005).....4

**SEC v. Wheeling-Pittsburgh Steel Corp.*,
648 F.2d 118 (3d Cir. 1981).....25

**Six West Retail Acquisition, Inc. v. Sony Theater Management Corp.*,
203 F.R.D. 98 (S.D.N.Y. 2001).....22, 23

In re Tamoxifen Citrate Antitrust Litigation,
466 F.3d 187 (2d Cir. 2006).....4

**Thomas v. IBM*,
48 F.3d 478 (10th Cir. 1995) 21

United States v. Aero Mayflower Transit Co.,
831 F.2d 1142 (D.C. Cir. 1987).....25, 29

United States v. Berkowitz,
355 F. Supp. 897 (E.D. Pa. 1973).....21

**United States v. Fensterwald*,
553 F.2d 231 (D.C. Cir. 1977).....26

**United States v. Markwood*,
48 F.3d 969 (6th Cir. 1995) 25, 29

United States v. Monumental Life Insurance Co.,
440 F.3d 729 (6th Cir. 2006) 21

**United States v. Morton Salt Co.*,
338 U.S. 632 (1950).....16, 21

**United States v. Powell*,
379 U.S. 48 (1964)..... *passim*

STATUTES

21 C.F.R. § 20.61(b)–(c) (2010) 27

21 C.F.R. § 20.85 (2010) 27

21 C.F.R. § 314.430 (2010) 9, 27

21 C.F.R. § 314.95(a), (d) (2010) 8

21 U.S.C. § 355(j)(5)(B).....5

15 U.S.C. § 45(a)(2).....26

15 U.S.C. § 57b-2 27

*Fed. R. Civ. P. 26(b)(2)(C)(i) 22

*Fed. R. Civ. P. 26(c)(1).....22

Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) 4

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.....5

MISCELLANEOUS

Jon Leibowitz, Commissioner, Federal Trade Commission, Remarks at Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust, *Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck! (The Role of the Commission, Congress, and the Courts)* (Apr. 24, 2006), *available at* http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf.....5

Jon Leibowitz, Chairman, Federal Trade Commission, Remarks at the Center for American Progress: "Pay for Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution) (June 23, 2009), *available at* http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf 5

The Generic Drug Maze: Speeding Access to Affordable, Life Saving Drugs, Hearing Before the S. Special Comm. on Aging, 109th Cong. 35, 39-41 (2006) (statement of Jon Leibowitz, Commissioner, Federal Trade Commission), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_senate_hearings&docid=f:30710.pdf 6

PRELIMINARY STATEMENT

Petitioner the Federal Trade Commission ("FTC") seeks enforcement of a subpoena *ad testificandum* issued to Respondent Paul M. Bisaro ("Respondent"), President and Chief Executive Officer of Watson Pharmaceuticals, Inc. ("Watson" or "the Company"), on July 22, 2009 (the "Subpoena"). While the FTC's Petition for an Order Enforcing Administrative Subpoena *Ad Testificandum* ("Petition") and accompanying Memorandum of Law ("Petitioner's Brief") attempt to portray this matter as a garden-variety enforcement action, the truth is quite different.

At its core, this matter arises from the FTC's improper attempt to broker a new business deal between Watson and another generic pharmaceutical manufacturer that would "improve" the market—rather than any legitimate pursuit of the FTC's statutory mission of policing anticompetitive deals. When Watson exercised its unilateral business judgment in not entering into the FTC's proposed deal, the FTC threatened and then issued multiple subpoenas for documents and testimony. After Watson complied fully with the FTC's demands for information, this matter came to a head when the FTC insisted on compelling Watson's CEO to travel to Washington for a deposition even though: (1) Respondent had *no* relevant documents; (2) Respondent had *no discussions* with any third party regarding this matter; (3) Respondent's knowledge of this matter is derivative and based on *fewer than five* brief updates by Watson's General Counsel—who was the executive responsible for this business decision (and already subject to a detailed deposition by FTC Staff); and (4) the questions the Petition identifies about Watson's 2006 settlement of patent litigation all occurred prior to Respondent's first day of employment at the Company. At this point, Respondent and Watson have had enough and respectfully request that the Court deny the Petition.

There are three independent legal reasons why enforcement must be denied:

1. The FTC cannot demonstrate that "the information sought [from Respondent] is not already within [the FTC's] possession," a prerequisite to agency subpoena enforcement. *United States v. Powell*, 379 U.S. 48, 57-58 (1964). The Petition states that the question in the FTC's investigation is whether Watson entered into any agreement that prevents or restricts the relinquishment of certain of its statutory rights. Watson has already answered this question in the negative multiple times during the investigation and it is abundantly clear from the record that Respondent has no additional information. Indeed, despite repeatedly stating that Watson's response to a single interrogatory in one of the several subpoenas was "deficient," the FTC fails to explain how it is deficient or identify any appropriate information whatsoever that Watson has refused to provide. Remarkably, the FTC suggests that Watson has never provided a legal analysis of Watson's 2005 agreement with Cephalon and asserts that Respondent, as CEO, can provide further information on the legal interpretation of this agreement. The FTC's argument here conveniently ignores the facts, including that Watson's General Counsel stated under oath that the settlement agreement does not restrict relinquishment; that the settlement predates Respondent's employment by Watson; that Respondent, while trained as a lawyer, has never acted in any legal capacity for Watson; and that any information he might have on the legal interpretation of the document—if any at all—would have come from Watson's General Counsel and be protected by privilege.

2. The FTC's Subpoena unreasonably seeks testimony from Respondent, who as Watson's President and Chief Executive Officer is the apex of Watson's organization. Respondent's knowledge of this matter stems from a very limited number of updates from Watson's General Counsel. Yet the FTC has already deposed Watson's General Counsel, who is

the individual at the Company with direct knowledge and who had decision-making authority over the issues under investigation. In such a situation, courts routinely hold that burdening a company's most senior executive who has no personal knowledge is improper, particularly when those employees with direct knowledge are available.

3. Perhaps most importantly, this Court should deny the Petition because enforcement of the Subpoena would amount to an abuse of this Court's process. The FTC has been on an avowed mission to ban, through litigation and/or legislation, so-called "reverse-payment" patent litigation settlements between brand-name drug manufacturers and their generic counterparts. In this case, the FTC is unhappy with Cephalon for its settlement with the four first-filing generic manufacturers regarding modafinil. Having met with little success in either Congress or the courts, in March 2009 the FTC undertook an attempt to engineer generic entry into the modafinil market. To accomplish this, the FTC exceeded its statutory law-enforcement mission by seeking to broker a business deal between Watson and Apotex, Inc. ("Apotex"), improperly using its privileged access to confidential information from the Food and Drug Administration ("FDA") in the process, and apparently providing Watson's confidential information to Apotex. When Watson failed to pursue the FTC's suggested business deal, the FTC first threatened to investigate Watson and then issued compulsory process, including the Subpoena at issue here, claiming authority under a then three-year-old Commission resolution that, by its express terms, is retrospective and predates the period under investigation. The record demonstrates that the Subpoena was issued as a means to pressure Watson to enter into a business relationship with Apotex and/or retaliate against Watson for failing to do so—clearly an improper purpose under prevailing Supreme Court precedent. Moreover, the FTC's pursuit of the Subpoena demonstrates that its conduct is nothing short of harassment.

In a separate application filed concurrently herewith, Respondent moves to compel the FTC to respond to limited discovery demands regarding the FTC's external contacts with the FDA and Apotex to further support Respondent's position that the FTC is acting with an improper purpose. In that motion, Respondent respectfully requests the right to supplement its briefing to the Court upon completion of this highly limited discovery.

FACTUAL BACKGROUND

Respondent is Watson's President and Chief Executive Officer. Watson, together with its subsidiaries and affiliates, is a leading generic pharmaceutical company engaged in the research, development, manufacture, sale, marketing and distribution of generic versions of brand-name pharmaceutical drugs. *See* Declaration of Steven C. Sunshine ¶ 3 ("Sunshine Decl.").

A. The Present Dispute Arises out of the FTC's Campaign Against Reverse-Payment Settlements.

At all times relevant to the events underlying this enforcement action, the FTC has been engaged in a crusade to outlaw so-called "reverse payment" settlements between brand-name pharmaceutical companies and their generic counterparts, even though three Circuit Courts of Appeal and various lower courts have found such settlements to be legal.[1] Following its 2005 loss in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (vacating FTC administrative decision holding reverse-payment settlement to be illegal), and spurred by the

[1] "Reverse-payment" settlements are settlements of patent infringement litigation brought pursuant to the Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), involving settlement payments from the patent holder (usually a branded pharmaceutical company) to the alleged infringer (typically a generic pharmaceutical company). *See, e.g.*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1073-74 (11th Cir. 2005). The Hatch-Waxman Act grants generic companies standing to mount a validity challenge to a patent without incurring the cost of entry or risking damages flowing from any possible infringement, thereby "essentially redistribut[ing] the relative risk assessments and explain[ing] the flow of settlement funds [to the generic manufacturers] and their magnitude." *Id*. at 1074. The three Circuit Courts and several lower courts have found such settlements to be legal where the anticompetitive effects of the settlement remain within the patent's terms. *See id*. at 1076; *In re Ciprofloxacin Hydrochloride Antitrust Litig*., 544 F.3d 1323, 1333 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009); *In re Tamoxifen Citrate Antitrust Litig*., 466 F.3d 187, 212-213 (2d Cir. 2006); *In re K-Dur Antitrust Litig*., No. 01-1652, 2010 WL 1172995 (D.N.J. Mar. 25, 2010) (adopting Special Master Report and Recommendation, *In re K-Dur Antitrust Litig*., No. 01-1652, 2009 WL 508869 (D.N.J. Feb. 6, 2009)).

subsequent decisions that effectively immunize from antitrust liability reverse-payment settlements within the patent's scope, the FTC has been on a mission to ban them. Through their speeches and testimony, the FTC's senior officials have made clear that achieving such a ban, whether through Congress or the courts, is "one of the Federal Trade Commission's highest priorities."[2] The FTC has, however, met with little success in any quarter.

The FTC's litigation strategy has involved the filing of two high-profile lawsuits of its own challenging reverse-payment settlements in federal court. The FTC filed the first of these suits against Cephalon, Inc., in February 2008 in connection with patent litigation settlements that Cephalon had entered into with four generic companies relating to Provigil, Cephalon's brand-name modafinil drug.[3] By March 2009 (which marked the beginning of the time frame

[2] Jon Leibowitz, Chairman, Federal Trade Commission, Remarks at the Center for American Progress: "Pay for Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution), at 1 (June 23, 2009), *avail. at* http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf; *see also, e.g.*, Jon Leibowitz, Commissioner, F.T.C, Remarks at Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust, *Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck! (The Role of the Commission, Congress, and the Courts),* at 1, 3-4 (Apr. 24, 2006), *available at* http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf; *The Generic Drug Maze: Speeding Access to Affordable, Life Saving Drugs, Hearing Before the S. Special Comm. on Aging,* 109th Cong. 35, 39-41 (2006) (statement of Jon Leibowitz, Commissioner, F.T.C.), *avail. at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_senate_hearings&docid=f:30710.pdf. Thus far, Congress has failed to enact any legislation banning reverse-payment settlements.

[3] The relevant regulatory regime allows manufacturers of generic drugs to gain early entry into the market through the filing of an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA"). Hatch-Waxman's truncated procedure avoids the duplication of expensive safety and efficacy studies, so long as the generic manufacturer proves that its drug is bioequivalent to the already-approved brand-name/pioneer drug. As part of the application process, the generic applicant must certify that the relevant patent(s) on the brand-name drug that are listed in the U.S. Food and Drug Administration's Book of Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book") are either invalid or will not be infringed. This is commonly known as a "Paragraph IV certification." The patent holder is then notified of the ANDA, and if the patent holder sues for infringement within forty-five days of receiving the notice, the FDA automatically institutes a thirty-month delay on the generic manufacturer's ANDA approval. *See* 21 U.S.C. § 355(j)(5)(B)(iii). In order to provide generic companies an incentive to incur the expense and risk of a potential infringement suit by the patent holder, the first ANDA filer is awarded an exclusivity period of 180 days. *Id.* § 355(j)(5)(B)(iv). During this period, the FDA cannot approve any other generic manufacturer's ANDA until 180 days after the earlier of (1) the date of the first ANDA filer's commercial marketing of its generic drug, or (2) the date of a court decision that the patent is invalid or not infringed. *Id.* § 355(j)(5)(B)(iii)(I). Following the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 ("MMA"), if more than one generic company filed on the same day, there could be multiple first filers that would share this exclusivity. *See* MMA section 1102(a)(1) (codified at 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb)).

relevant to the present action), the FTC's case against Cephalon had barely progressed; Cephalon's motion to dismiss the action had been fully briefed and pending for nine months.

The FTC's second suit was filed in January 2009 against Watson and three other defendants in connection with settlements of patent litigation related to the drug AndroGel, following an FTC investigation of more than two years. The FTC initially filed its AndroGel case in the Ninth Circuit to avoid the Eleventh Circuit's *Schering-Plough* precedent, but in April 2009 lost a key transfer motion that sent the case to the Eleventh Circuit. *See FTC v. Watson Pharms, Inc.*, 611 F. Supp. 2d 1081 (C.D. Cal. 2009). In light of *Schering-Plough*, this transfer ultimately proved fatal to the FTC's case; the transferee judge granted Watson's motion to dismiss the FTC's action in February 2010. *See In re AndroGel Antitrust Litig. (No. II)*, No. 1:09-MD-2084-TWT, 2010 WL 668291, at *5-7 (N.D. Ga. Feb. 22, 2009) (Thrash, J.) (to be published in F. Supp. 2d). The FTC is expected to appeal.

B. The FTC's Modafinil Investigation.

1. The Initial Phase of the FTC's Investigation.

In December 2004 Watson and its development partner, Carlsbad Technologies, Inc. ("Carlsbad"), filed an Abbreviated New Drug Application ("ANDA") for a generic version of Provigil.[4] *See* Sunshine Decl. ¶ 4. The ANDA contained a Paragraph IV certification as to the patents that were then listed in the FDA's Book of Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book"), including U.S. Reissued Patent No. 37,516 (reissued Jan. 15, 2002) (the "'516 Patent"). *Id.* ¶ 6. The Watson/Carlsbad ANDA was filed approximately two years after the ANDAs filed by the first-filing generic companies (the "First

[4] Pursuant to Watson and Carlsbad's development agreement, Carlsbad and its majority shareholder are responsible for the development of generic modafinil and the preparation of the ANDA. Among other things, Watson is responsible for any legal costs arising out of the modafinil ANDA and has the right to make all decisions regarding commercialization of generic modafinil. Sunshine Decl. ¶ 5.

Filers"); Watson therefore could not claim any marketing exclusivity in connection with that ANDA.

Cephalon sued the four First Filers and Carlsbad for infringement of the '516 Patent, but settled those suits with the First Filers over the course of 2005-2006. *See* Complaint for Injunctive Relief, *FTC v. Cephalon, Inc.*, No. 08-cv-2141, ¶¶ 60, 64, 69, and 72 (E.D. Pa. Compl. filed Feb. 13, 2008). On August 2, 2006, after all First Filer settlements, Watson, Carlsbad and Cephalon entered into a Settlement and License Agreement (the "Settlement Agreement") pursuant to which Watson obtained a license to market generic modafinil prior to patent expiry. *See* Sunshine Decl. ¶ 8.

In August 2006, the FTC initiated a non-public inquiry by resolution dated August 30, 2006, "to determine whether Cephalon, Inc. [and the ANDA filers] have engaged in any unfair methods of competition … by entering into agreements regarding any modafinil products." *See* Exhibit A to the Declaration of Julia K. York ("York Declaration"; all exhibits to the York Declaration are hereinafter referred to as "Opposition Exhibit" or "Opp. Ex."). The investigation focused on Cephalon's alleged use of the 2005-2006 patent settlements as a means to delay generic competition for Provigil. *See* Sunshine Decl. ¶ 9.

On November 9, 2006, the FTC issued a subpoena *duces tecum* to Watson, demanding voluminous documents relating to Provigil, generic modafinil, and the Settlement Agreement. *See id*. ¶ 11; *see also* Opp. Ex. B (Subpoena *Duces Tecum* dated November 9, 2006). On May 18, 2007, the FTC issued a further request for information and documents—a Civil Investigative Demand ("CID") consisting of 17 different specifications regarding generic modafinil, the Settlement Agreement and the '516 patent litigation. *See* Opp. Ex. C (CID dated May 18, 2007). Carlsbad received a similar request dated June 5, 2007—a CID containing 7 different

specifications on these same subjects. *See* Pet. Ex. 4 (CID dated June 5, 2007).

Watson and Carlsbad cooperated fully with each of the FTC's inquiries, providing thousands of documents and extensive information relevant to the investigation. Sunshine Decl. ¶¶ 11-12. 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. *Id*. ¶ 13. Counsel for Watson also twice met with FTC Staff and provided detailed presentations regarding the Settlement Agreement. *Id*. 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 three-and-a-half years.

As noted above, 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. *FTC v. Cephalon, Inc.*, No. 08-cv-2141 (E.D. Pa. filed Feb. 13, 2008). None of the First Filers were named in the FTC's complaint. Of course, Watson and Carlsbad, as late filers, were also not named in the FTC's complaint.

2. A New Provigil Patent is Listed in the Orange Book.

On December 19, 2007, Cephalon listed a new patent, U.S. Patent No. 7,297,346 (issued Nov. 20, 2007) (the "'346 Patent"), for Provigil in the Orange Book. Sunshine Decl. ¶ 14. Although Watson's and Carlsbad's ANDA for a generic version of Provigil was already pending, under the prevailing FDA rules Watson and Carlsbad were required to file a Paragraph IV certification as to the newly-listed patent. *See* 21 C.F.R. § 314.95(a),(d) (2010). Watson and Carlsbad filed a supplement to their pending ANDA on the same day the patent was listed in the

Orange Book. Sunshine Decl. ¶ 15.

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 any other generic companies had also filed on the first possible day, making the exclusivity status for Watson highly uncertain. *See* Opp. Ex. D at 27-28 (Excerpt from Transcript, *In the Matter of Cephalon, Inc.*, FTC File No. 0610182, dated June 25, 2009 ("Buchen Dep.")). Moreover, because Watson and Carlsbad were late to file the original application challenging the '516 Patent, Watson's ability to take advantage of its possible first-filer status on the '346 Patent ANDA would require assessment of facts unknown to Watson, including whether it was the lone first filer on December 19, 2007, and whether all of the original four First Filers had relinquished their exclusivity as to the '516 Patent. Many of these facts were confidential information held by the FDA. *See* 21 C.F.R. § 314.430 (2010).

3. The FTC Reopens its Modafinil Investigation.

(a) The FTC Attempts to Broker a Business Deal and Threatens a Renewed Investigation.

On March 4, 2009, Markus H. Meier, Assistant Director in the FTC Bureau of Competition Health Care Division, 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. Sunshine Decl. ¶ 16. 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. *Id.* 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. *Id.* ¶ 17. Mr. Meier also discussed whether Watson would be interested in receiving a call from

another company that may be prepared to launch a generic modafinil product. *Id*. ¶ 18.

Within a week, Watson received a telephone call from Apotex, a third party generic pharmaceutical company, seeking to negotiate a transaction with Watson involving the Company's purported first-to-file rights. *Id*. In response to these contacts, Watson considered its alternatives. Responsibility for the business decision of whether to partner with Apotex lay with Mr. Buchen, Watson's Senior Vice President and General Counsel, and a member of the Executive Committee. Opp. Ex. D at 67 (Buchen Dep.).

Apparently frustrated by Watson's failure to quickly relinquish its rights, 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. Sunshine Decl. ¶ 17.

(b) The FTC Issues Compulsory Process while Watson Evaluates its Options, but Agrees to Defer Initial Subpoena Issued to Respondent.

While Mr. Buchen was still considering Watson's options, the FTC on May 19, 2009, issued a CID to Watson and a subpoena *ad testificandum* to Mr. Buchen. Sunshine Decl. ¶ 19; Opp. Ex. D at 33, 40, 67 (Buchen Dep.). This was followed on May 22, 2009 by a first subpoena *ad testificandum* issued to Respondent. *Id*. The CIDs 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 FTC Staff, counsel for Watson learned that the FTC was primarily interested in understanding whether Watson had reached any agreements with Cephalon regarding relinquishment of any marketing exclusivity associated with the '346 Patent. Opp. Ex. E ¶ 6 (Declaration of Maria A. Raptis ("Raptis Decl.")). 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 events. Pet. Ex. 4 (Carlsbad CIDs). Pursuant to Watson

and Carlsbad's development agreement, Watson is responsible for any legal costs arising out of the modafinil ANDA. Sunshine Decl. ¶ 5.

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. Opp. Ex. E ¶ 6 (Raptis Decl.). Watson's counsel informed Ms. Brau that Watson had not reached any agreements regarding relinquishment and further sought to limit Watson's response to the CID and subpoenas to narrative responses that would confirm that Watson had not reached any agreements whatsoever on relinquishment. *Id*. ¶ 7. Watson's counsel also sought a deferral of the investigatory hearing subpoenas until such time as the FTC reviewed Watson's response to the CID and thereby confirmed the absence of any agreements or decisions regarding relinquishment. *Id*. The FTC declined. *Id*.

Watson and the FTC Staff agreed that Watson would respond to the CID in its entirety by June 10, 2009, and also 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. *Id*. ¶ 10; *see also* Opp. Ex. F at 2 (Letter dated June 2, 2009 from Saralisa C. Brau to Maria A. Raptis). The FTC also agreed to conduct its investigational hearing of Respondent in New Jersey, Respondent's principal place of business. *See* Opp. Ex. F at 2 (June 2, 2009 Brau Letter).

On June 10, 2009, Watson submitted its response to the May 19, 2009 CID. Opp. Ex. E ¶ 11 (Raptis Decl.). In its response, Watson once again informed FTC Staff that it had not reached any agreements or decisions regarding relinquishment. *Id*. Watson also identified its limited contacts with one third-party generic company (Apotex) on the subject of relinquishment (which the FTC Staff was already aware of owing to the fact that it initiated them). *Id*. Notably, the

CID response certified that Respondent had *no responsive documents*, and *did not have any contacts with Cephalon, Apotex, or any other company on the subject of relinquishment*.

Counsel for Watson 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 agreements on relinquishment. *Id*. ¶ 12. Watson's counsel suggested that the subpoena for Respondent's testimony should be withdrawn but agreed to proceed with the Buchen investigational hearing in hopes of providing enough information to end the investigation. *Id*.

On June 25, 2009, Mr. Buchen provided sworn testimony in a hearing conducted by Mr. Meier. The FTC traveled to California, Mr. Buchen's state of residence, for the hearing. Mr. Buchen categorically testified that Watson had not reached any agreement or decision with any party relating to relinquishment. Opp. Ex. D at 40-41; 51-52 (Buchen Dep.). In fact, Mr. Buchen testified that the FTC's CID and subpoenas caused Watson to suspend consideration of relinquishment. *Id*. at 39-40. Mr. Buchen also testified that he was the only individual at Watson involved in any discussions with third parties relating to this topic (*i.e.*, Apotex), that he had no discussions with Cephalon, and that he was the primary decision-maker with respect to relinquishment. *Id*. at 30-31, 40, 51, 66-67. Mr. Buchen testified that he spoke with Respondent about this matter "fewer than five" times, and only for the purposes of keeping Respondent generally informed. *Id*. at 37-38, 67.

At the time of Mr. Buchen's investigational hearing, the first subpoena *ad testificandum* issued to Respondent was still pending. Given Mr. Buchen's testimony regarding Respondent's marginal familiarity with the relevant topics, Mr. Meier and Mr. Sunshine reached an agreement on the record extending the return date for Respondent's subpoena to July 2, 2009. *Id.* at 70-71. 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 Respondent." *Id.* (emphasis added).

Shortly thereafter, Mr. Meier telephoned Mr. Sunshine and indicated that the FTC had no present intention of conducting an investigational hearing of Respondent. Sunshine Decl. ¶ 22. 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 Respondent's subpoena. A letter memorializing this agreement was provided to Mr. Meier for his countersignature on June 30, 2009.[5] *Id.*; *see also* Opp. Ex. G (Letter dated June 30, 2009 from Steven C. Sunshine to Markus H. Meier).

During this time period, Mr. Jack Kay, President and COO of Apotex, tried to engage Respondent in a direct discussion of this matter but Respondent refused. *See* Sunshine Decl. ¶ 23. On July 15, 2009, Mr. Kay then forwarded to Respondent an internal Apotex e-mail indicating that Mr. Buchen had told Apotex that Watson would not discuss a business deal while the FTC investigation was ongoing. Opp. Ex. H (E-mail from Jack Kay to Paul Bisaro dated July 15, 2009). The e-mail also confirmed that the FTC Staff and Apotex were in close communication and that the Staff was apparently sharing certain of Watson's statements with Apotex. *Id*. ("Watson refuses to talk to us about a deal to relinquish exclusivity so that we can market modafinil (US). Watson is oddly saying that it cannot talk to us due to FTC investigation relating to modafinil (US). Yet FTC is investigating because Watson refuses to talk to us. … In my call with FTC enforcement this morning, I indicated and [the FTC] confirmed that Watson is

[5] 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 it was only his workload that prevented him from providing a countersigned copy of the letter. Sunshine Decl. ¶ 22.

just mum about deal making. The reason for silence truly evades us and the FTC.").[6]

(c) The FTC Issues a New Subpoena.

On Friday, July 17, 2009, Mr. Meier telephoned Mr. Sunshine to inform him that the FTC had determined to proceed with Respondent's investigational hearing. Sunshine Decl. ¶ 23. On Monday, July 20, 2009, counsel for Watson contacted Ms. Brau to discuss a new return date for the Subpoena, but ultimately the parties were unable to agree on a reasonable date. Opp. Ex. E ¶ 15 (Raptis Decl.); *see also* Opp. Ex. I (Letter dated July 21, 2009 from Maria A. Raptis to Saralisa C. Brau) *and* Opp. Ex. J (Letter dated July 22, 2009 from Saralisa C. Brau to Maria A. Raptis). Ms. Brau in fact terminated these discussions, indicating that despite the agreement, the FTC would simply issue a new subpoena to unilaterally set its own schedule. *Id.* On July 22, 2009, the FTC issued a second subpoena *ad testificandum* to Respondent (the Subpoena at issue here), which was received on July 23, 2009 and carried a return date of July 31, 2009. Opp. Ex. E ¶ 17 (Raptis Decl.); Opp. Ex. K (Subpoena).

(d) Respondent Seeks to Quash and the FTC Files this Action.

On July 30, 2009, Respondent filed a petition to quash the Subpoena. *See* Opp. Ex. L (Petition to Quash). Despite the purported urgency and its refusal to negotiate a reasonable schedule with Respondent, the FTC waited almost four months, until November 13, 2009, to issue a letter ruling denying the petition. *See* Opp. Ex. M at 1 (Nov. 13 Letter Ruling). On November 27, 2009, Respondent requested review by the full Commission. *See id.* at 2, *see also* Sunshine Decl. ¶ 26; *see also* Opp. Ex. N (Nov. 27 Letter). Again, with apparent disregard for timing, another four months passed before the FTC issued the April 2, 2010 letter ruling denying full Commission review. The FTC once more set a short deadline, ordering Respondent to

[6] The scope of these non-privileged discussion between the FTC and Apotex is a key focus of Respondent's discovery requests. *See infra* at 30.

appear for an investigational hearing on April 15, 2010. *See* Opp. Ex. O at 9 (April 2 Letter Ruling).

Counsel for Watson and Respondent next met with the Director of the FTC's Bureau of Competition, as well as members of the FTC Staff, and, as a means of resolving any questions about Respondent's knowledge of the relevant facts, offered to provide the FTC with a sworn affidavit. *See* Sunshine Decl. ¶ 28. Although the Director indicated that he would consider an affidavit, he stated that it would be just as efficient to depose Respondent as it would be to discuss an affidavit with Respondent's counsel. *Id*. Five days later, on April 23, 2010, FTC Staff informed Respondent's counsel that the Bureau of Competition had referred the matter to the FTC's Office of the General Counsel ("FTC OGC"), recommending that an enforcement action be brought. *Id*. ¶ 29. Respondent's counsel contacted the FTC OGC the same day, leaving a voicemail with an offer to meet to discuss the merits of such an action, or in the alternative discuss next steps. York Decl. ¶ 3. By April 28, 2010, the call had not been returned, prompting counsel to send a follow-up letter to reiterate the offer to meet, and to request a discussion of next steps. *Id*. ¶ 4; *see also* Opp. Ex. P at 2 (Letter dated April 28, 2010 from Julia K. York to Michael Bergman). FTC staff did not have the courtesy to return the call until April 30, 2010 (a full week later), when FTC OGC attorneys indicated that a petition to file an enforcement action had already been tendered to the Court "earlier in the week," but refusing to state exactly when it had been tendered. York Decl. ¶ 5. Respondent's counsel learned, to its surprise, that the clerk's date stamp reflected a filing date of April 23, 2010, the same day that FTC Staff had said the Bureau had recommended an action, and a full week before the FTC OGC contacted Respondent's counsel (and clearly not "earlier in the week" as suggested by FTC Staff). *See* Redacted Pet. 1 (Doc. No. 5). Following the April 30, 2010, telephone call,

Respondent's counsel requested unredacted versions of the papers filed with the Court (counsel had obtained the public filings from the Court), but these were not provided. York Decl. ¶ 5. FTC counsel refused, in fact, to provide any papers to Respondent's counsel unless and until counsel accepted service on behalf of Respondent. York Decl. ¶ 6.

LEGAL ARGUMENT

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 that must be met by an agency to obtain enforcement of compulsory agency process: (i) that the investigation will be conducted pursuant to a legitimate purpose; (ii) that the inquiry may be relevant to the purpose; (iii) that the information sought is not already within the [agency's] possession; and (iv) that the administrative steps required by the [agency's statutes or rules] have been followed. *United States v. Powell*, 379 U.S. 48, 57-58 (1964). Even if the FTC is able to make out a prima facie case under *Powell*, enforcement of the subpoena may nevertheless be denied where the recipient of agency process demonstrates that enforcement would amount to abuse of the court's process, for example "if the summons had been issued for *an improper purpose*, such as to harass the [recipient of the summons] 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 (emphasis added); *accord, FEC v. Comm. to Elect Lyndon La Rouche*, 613 F.2d 849, 864 (D.C. Cir. 1979).

A. The Subpoena Unreasonably Demands Information already in the FTC's Possession.

Because the FTC already possesses the information being sought by the Subpoena, it

cannot make out its prima facie case for enforcement under *Powell*.[7] *Powell*, 379 U.S. at 57-58. The FTC claims that it requires Respondent's testimony to determine whether Watson has an agreement with Cephalon "that limits or restricts the exercise of any marketing rights or exclusivities [Watson] may have now or obtain in the future vis-à-vis modafinil." Opp. Ex. O at 2 and n.1 (April 2 Letter Ruling). Further, the FTC has argued that Respondent's testimony is necessary because "Watson has identified [Respondent] as one of only two people who has knowledge of the relevant events, the Commission has already taken the testimony of the other person, and the critical question of whether Watson has reached a potentially unlawful agreement remains unanswered." *Id*. at 2; *see also* Petition ¶ 14. In fact, this "critical question" has by now been answered at least eight times, including in sworn testimony and statement.

Watson told the FTC that it has not reached any agreements on relinquishment—and particularly that no agreement exists with Cephalon that would preclude Watson from relinquishing any exclusivity it may have—on at least the following occasions:

- on a May 26, 2009 telephone call with Saralisa Brau, Deputy Assistant Director of the FTC's Health Care Division, *see* Opp. Ex. E ¶ 6 (Raptis Decl.);
- in the June 10, 2009 CID Response, sworn under penalty of perjury, *see* Opp. Ex. E ¶ 11 (Raptis Decl.);
- at a June 12, 2009 meeting with Ms. Brau and other FTC Staff members; *see* Opp. Ex. L at 10-11 (Petition to Quash);
- in Mr. Buchen's sworn testimony at his investigational hearing, *see* Opp. Ex. D at 40-41, 51-52, 67 (Buchen Dep.);
- in the Petition to Quash, *see* Opp. Ex. L at 9-11 (Petition to Quash);

[7] The FTC focuses on whether Respondent's testimony is relevant to its investigation. *See* Pet. Br. 8, 11-12. However, even if relevant, under *Powell* the agency must also show that the information is not already in its possession. *Powell*, 379 U.S. at 57-58. The FTC cannot satisfy its burden with mere speculation, particularly where the record evidence indicates otherwise. *See* Pet. Br. 12 ("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.") (emphasis added).

- in Watson's November 27, 2009 letter to the FTC requesting full Commission review, *see* Opp. Ex. N at 2 (Nov. 27 Letter);
- in a letter from Watson's counsel to James Rhilinger of the FTC Staff, *see* Opp. Ex. Q (April 13, 2010 Letter to Rhilinger); and
- at a meeting with the Director of the FTC's Bureau of Competition on April 19, 2010. *See* Sunshine Decl. ¶ 28.

Despite all of this evidence, the FTC asserts that Respondent's testimony is still necessary because (i) Watson's response to the May 19, 2009 CID was incomplete, since Watson supposedly provided "only partial responses to the CID questions," Pet. ¶ 8, and (ii) because Mr. Buchen purportedly "failed to provide complete answers" at his investigational hearing. *Id.*; *see also* Pet. Br. 6.

As for Watson's CID responses, tellingly, the FTC fails to identify any specific responses that were incomplete. In fact, Watson provided a complete response to each and every CID inquiry. To the extent it possessed documents that were responsive to the CID, Watson produced them. As the FTC is well aware, Respondent had *no responsive documents* and was not even employed by Watson at the time the Settlement Agreement with Cephalon was entered into, or, for that matter, at the time the FTC issued its August 2006 Resolution. *See* Opp. Ex. M n.24 (Nov. 13 Letter Ruling, citing Watson press release); Opp. Ex. N at 2 (Nov. 27 Letter to FTC). As for its written CID responses, Watson likewise provided complete responses, informing the FTC, *inter alia*, that (i) Watson does not have definitive information regarding its eligibility for exclusivity; (ii) as between Watson and Carlsbad, Watson has the right to make all decisions regarding the commercialization of generic modafinil; (iii) there is no agreement between Watson and any other party preventing Watson from relinquishing any first-to-file rights it may have; (iv) 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 (v) Watson

has not reached any decision about whether or not to relinquish exclusivity. *See* Opp. Ex. R (CID Responses). Out of an abundance of caution, Watson in its CID response identified the Settlement Agreement as "possibly relating" to the issue of relinquishment. At his investigational hearing, Mr. Buchen explained that the Settlement Agreement is related to relinquishment by the very existence of the FTC's investigation, and the fact that it triggered Cephalon's obligation under the indemnification provision of the Settlement Agreement. Opp. Ex. D at 43-44 (Buchen Dep.). At no point, however, did Watson say that the Settlement Agreement prevented relinquishment —in fact, Mr. Buchen testified categorically that it does not. Opp. Ex. D at 51-52 (Buchen Dep.).

Mr. Buchen also provided complete responses to the FTC's questions. The FTC is apparently frustrated that it cannot compel Mr. Buchen to provide his legal analysis of the Settlement Agreement. *See, e.g.*, Pet. ¶ 9 (characterizing Mr. Buchen's testimony as incomplete on the basis that the FTC's questions called for responses that are protected by the attorney-client privilege—but importantly *not* contending that Mr. Buchen's testimony was inappropriately cloaked under a claim of privilege); Opp. Ex. O at 6 (April 2 Letter Ruling expressing dissatisfaction with Watson's position that the Settlement Agreement speaks for itself and that Watson is not required to perform a legal analysis of an agreement in the FTC's possession); and Opp. Ex. M at 5, n.16 (Nov 13 Letter Ruling stating that the FTC has a right to obtain information regarding "Watson's understanding" of provisions of the contract). But as General Counsel and an active member of the California Bar, Mr. Buchen's analysis is privileged. *See* Opp. Ex. D at 5 (Buchen Dep.). A proper invocation of attorney-client and work product privileges does not render his responses incomplete.

As its last piece of circumstantial evidence supposedly warranting further discovery

regarding the potential existence of an anticompetitive agreement between Watson and Cephalon, the FTC cites Watson's failure to pursue the supposedly "potentially lucrative" Apotex deal. Opp. Ex. O at 6 (April 2 Letter Ruling). However, Mr. Buchen—the executive responsible for the decision—fully explained why he thought the Apotex deal would not be a good business proposition for Watson. *See* Opp. Ex. D at 67-69. In particular, he testified that he believed it would be more profitable for Watson to retain any statutorily-granted exclusivity rights it might have and enter the market itself in 2012 rather than accept a limited royalty stream from Apotex. *Id*. While the FTC may believe that Watson would be better off partnering with Apotex, the Court should not countenance the FTC's attempt to substitute its own business judgment for that of Watson.

Not surprisingly, Mr. Buchen's analysis has proven correct because Apotex, the FTC's favored partner, has received several FDA citations over the past year for violations of the FDA's rules on manufacturing practices, leading the FDA to impose an import ban on Apotex products manufactured in its Canadian facility, which would include generic modafinil if it were launched. *See* Opp. Ex. S (Letter dated March 29, 2010 from the FDA to Apotex) (citing "serious and repeat violations" of manufacturing rules and affirming continued denial of entry of Apotex products from entering the United States) *and see generally* Opp. Ex. T (Defendant Cephalon, Inc.'s Request for Conference Concerning Significant Regulatory Developments (Redacted Version), *Apotex, Inc. v. Cephalon, Inc.*, No. 2:06-cv-02768-MSG (E.D. Pa. April 20, 2010) (Doc. No. 241)). Thus, the FTC's preferred business deal is in fact no deal at all.

Well aware of these facts, the FTC resorts to the excuse that it now requires Respondent's testimony to inquire about matters which, if Respondent even has any knowledge, clearly fall within the attorney-client privilege. Commissioner Jones Harbour in her letter ruling went so far

as to suggest that because "[Respondent] is not the General Counsel of Watson … [but] is an attorney" he is competent to answer questions interpreting the Cephalon Settlement Agreement. *See id*. at 7. This statement shows how much the FTC is willing to turn the doctrine of privilege on its head to try to justify its pursuit of Respondent.

In short, the record evidence clearly demonstrates that the FTC's "critical question" has already been answered: Watson did not enter into any agreement on relinquishment with any third party. Respondent's testimony will not shed any further light on this matter, given his limited (and wholly derivative) knowledge about the relinquishment issue. Because enforcing the Subpoena can only yield information that the FTC already possesses, the FTC cannot make out a prima facie case for enforcement under *Powell*, and its Petition should be denied.[8]

B. The Subpoena Should Not Be Enforced because it Unreasonably Seeks Testimony from the Apex of Watson's Organization.

A second independent basis for denial of the FTC's Petition is that the Subpoena unreasonably seeks testimony from Respondent, the apex of Watson's organization, thus running afoul of the Supreme Court's mandate in *Morton Salt* that "'the disclosure sought shall not be unreasonable.'" *Morton Salt*, 338 U.S. at 652-53 (citation omitted). 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 relevant information that cannot be obtained through other means. *See, e.g., Thomas v. IBM*, 48 F.3d 478, 483 (10th Cir. 1995) (upholding

[8] 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 Subpoena. *See Adamowicz v. United States*, 531 F.3d 151, 159 (2d Cir. 2008) (finding that "if the bulk of the materials" sought is not in the agency's possession, then some overlap between what is requested and what the agency already possesses does not render the subpoena unenforceable (citation omitted)). Nor did the FTC issue 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) (noting that 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).

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, 335-36 (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).

Although these cases address discovery conducted pursuant to the Federal Rules of Civil Procedure, the underlying justification for the "apex" doctrine found in Federal Rule of Civil Procedure 26 is mirrored in the language of *Powell*, which sets out the standard for enforcing agency process. *See Powell*, 379 U.S. at 57-58. 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 applicable to agency process address those same concerns, such as that the information sought must not already be in the agency's possession, and that agency process should not be enforced if issued for an improper purpose such as harassment. *See Powell*, 379 U.S. at 57-58. The concerns underlying restrictions on apex depositions conducted pursuant to the Federal Rules of Civil Procedure should therefore apply to assess the reasonableness of an apex deposition in this context.

The FTC argues that "high-level corporate executives have discovery obligations," and in its April 2 Letter Ruling cited *Six West Retail Acquisition, Inc. v. Sony Theater Management*

Corp., 203 F.R.D. 98, 102 (S.D.N.Y. 2001) for the proposition that high-ranking executives are not insulated from discovery. *See* Pet. Br. 13, Opp. Ex. O at 8 (April 2 Letter Ruling). In fact, *Six West* reaffirms the points Respondent makes here, namely that "a court may place limits on discovery demands that are 'unreasonably cumulative or duplicative,'" and that "unless it can be demonstrated that a corporate official has 'some unique knowledge' of the issues in the case, 'it may be appropriate to preclude a redundant deposition of [this] highly-placed executive' while allowing other witnesses with the same knowledge to be questioned." *Six West*, 203 F.R.D. at 102 (citations omitted) (alteration in original). Indeed, in *Six West* it was shown that the CEO in question did likely have "*some* unique knowledge," in that he was "well-informed" about a challenged pricing arrangement, was present at a board of directors meeting where key decisions were made, and was "substantially involved," or had "hands-on involvement" in other relevant matters. *Id*. at 103-05; *see also Baine*, 141 F.R.D. at 334-35 (citing case law requiring party seeking testimony to show that would-be deponent has "'unique personal knowledge" of the matter in issue that is "truly unique" and that information could not be had through interrogatories or deposition testimony of other persons; and that president could not be deposed "if he could contribute nothing new to the information provided by the alternative deponents").

In light of the record, the FTC cannot demonstrate that Respondent has any unique or superior knowledge as to whether there exists any agreement regarding relinquishment. Mr. Buchen, the only individual at Watson who participated in the limited discussions between Watson and Apotex, has already provided sworn testimony. Mr. Buchen testified that while he kept Respondent informed, Respondent did not participate in any discussions first-hand. *See* Opp. Ex. D at 67 (Buchen IH). Any non-privileged information told to Respondent by Mr. Buchen was discoverable during Mr. Buchen's investigational hearing. Under these

circumstances, there is no reasonable basis to expend valuable time and resources on the deposition of Watson's Chief Executive Officer.[9]

Moreover, even if the FTC could articulate a good-faith basis for believing that Respondent 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*, 141 F.R.D. at 334-36. Even more tellingly, the FTC refused to accept a confirmatory affidavit from Respondent. Sunshine Decl. ¶ 29.

C. The Subpoena Should Not be Enforced Because it Was Issued for an Improper Purpose.

The Supreme Court in *Powell* requires that the agency, as part of its prima facie case, demonstrate that the investigation is being conducted pursuant to a "legitimate purpose." *Powell*, 379 U.S. at 57. Even if the FTC makes out a prima facie case, enforcement must still be denied if the Subpoena was issued for an improper purpose. *Id*. at 58. The FTC's Petition fails on both counts.

1. The 2006 Resolution Does Not Provide a Legitimate Basis to Investigate Conduct Occurring after its Issuance.

The FTC argues that the purpose of the investigation giving rise to the Subpoena is grounded in the August 2006 Resolution. Opp. Ex. M at 7 (Nov. 13 Letter Ruling); *accord* Opp. Ex. O at 8 (April 2 Letter Ruling). The Resolution is, however, by its express terms clearly retrospective. *See* Opp. Ex. A (the nature and scope of the investigation is "[t]o determine whether [the named entities] *have engaged* in any unfair methods of competition . . . " (emphasis

[9] The FTC contends that Respondent has not explained the burden of having to travel to Washington, D.C. to testify. *See* Pet. Br. at 9. The FTC overlooks the fact that Respondent is the President and CEO of a major multinational pharmaceutical company who works in New Jersey; it is obvious that his schedule would be extremely busy, and that travel to Washington D.C. to attend an investigational hearing would be disruptive. The FTC implicitly acknowledged this burden when it initially agreed to conduct Mr. Bisaro's investigational hearing in New Jersey. *See* Opp. Ex. F at 2 (June 2, 2009 Brau Letter). In the event that the Court were to grant the Petition, Respondent respectfully requests at a minimum that the Court direct that the examination occur close to his principal place of business in New Jersey.

added)). The conduct the FTC purports to investigate here—*i.e.* whether Watson entered into an agreement with Cephalon regarding relinquishment of its rights relating to the '346 Patent—necessarily post-dates the August 2006 Resolution by well over a year. The Watson/Carlsbad ANDA supplement that gives rise to whatever exclusivity rights Watson may have under the '346 Patent was not filed until December 2007. Therefore, assuming, *arguendo*, that an agreement on relinquishment were to exist (which it does not), logically Watson could not have entered into such an agreement until at least December 2007. The 2006 Resolution cannot provide the FTC with a "legitimate purpose" to investigate events that did not even occur until over a year after the Resolution's issuance.[10]

2. The Court Must Consider Respondent's Ample Evidence Demonstrating that the Subpoena Was Issued for an Improper Purpose.

(a) Respondent Has Satisfied His Burden of Showing Improper Purpose.

Powell holds that even where an agency can point to a "legitimate purpose" for its investigation, the recipient of agency process may nevertheless contest enforcement as improper where enforcement would amount to an abuse of the court's process. *See Powell*, 379 U.S. at 58; *accord United States v. Aero Mayflower Transit Co.*, 831 F.2d 1142, 1145 (D.C. Cir. 1987) *and La Rouche*, 613 F.2d at 862; *United States v. Markwood*, 48 F.3d 969, 978 (6th Cir. 1995) (explaining that *Powell* provides subpoena recipients with an "*additional* defense against enforcement (in addition to the defense that one or more of [the *Morton Salt* and *Powell*] standards weren't met)," namely that the agency acted in "bad faith") (emphasis added); *SEC v. Wheeling-Pittsburgh Steel Corp.*, 648 F.2d 118, 125 (3d Cir. 1981) (finding that allegations in

[10] Note that if the FTC asserts here that it is only continuing its investigation of whether the 2005 Settlement Agreement prevents relinquishment in 2009, then the Petition must be denied because Respondent had no participation in the execution or negotiation of the Agreement and can provide no information not already in the FTC's possession. *See supra* at p. 18.

case, if proven, would be sufficient to transcend any judicial deference to the agency); *see also United States v. Fensterwald*, 553 F.2d 231, 232 (D.C. Cir. 1977) (finding allegations of agency harassment sufficient, if proven, to take recipient of agency process out of the category of an ordinary respondent).

There is ample evidence demonstrating that the FTC initiated its renewed investigation into modafinil, and issued and pursued the Subpoena, as a means either to pressure Watson or to retaliate against Watson in connection with the FTC's improper attempt to engineer its preferred outcome in the modafinil market. In either case, the Subpoena is nothing more than a means to harass Respondent and Watson, and enforcement is therefore improper under *Powell*. A number of facts demonstrate the existence of the FTC's improper purpose.

First, the FTC's attempt to facilitate a transaction relating to Watson's purported exclusivity rights, and use its investigatory authority to that end, exceeds the FTC's statutory mandate. The Federal Trade Commission Act ("FTC Act") empowers the FTC "to prevent [persons or corporations] . . . from using unfair methods of competition in or affecting commerce." 15 U.S.C. § 45(a)(2). The FTC Act does not empower the FTC to use its investigatory power to broker business deals in hopes of engineering particular market outcomes that it views as desirable.

Second, Respondent has reason to believe that the FTC obtained confidential information regarding Watson's regulatory status from the FDA, and then improperly shared that information to put Watson and Apotex in communication. The FTC confirmed to Watson's counsel that it had been in touch with the FDA, suggested to Watson that it might be interested in speaking with another pharmaceutical company regarding relinquishment issues, and apparently spoke to

Apotex about this same question.[11] *See* Sunshine Decl. ¶¶ 16, 18. The FDA would not have shared this information with either Apotex or Watson. *See, e.g.*, 21 C.F.R. 314.430(b)-(c) (2010) (prohibiting FDA from disclosing the existence of an ANDA, and from disclosing any data or information within the ANDA, before tentative approval is sent to the filer); 21 C.F.R. 20.61(b)-(c) (2010) (exempting from public disclosure by FDA information that is privileged and confidential commercial or financial information).

Third, in another apparent breach, it appears that the FTC may have violated confidentiality obligations imposed upon it by the FTC Act when it communicated to Apotex confidential information obtained from Watson during the course of the FTC's investigation. *See* 15 U.S.C. §§ 57b-2(b)(3)(C), 57b-2(c), 57b-2(f)(1). This possible wrongful sharing of information is suggested by an Apotex e-mail wherein an Apotex executive confirms that he is in contact with the FTC about Watson and states that "Watson refuses to talk to us about a deal to relinquish exclusivity so that we can market modafinil (US). Watson is oddly saying that it cannot talk to us due to FTC investigation relating to modafinil (US). Yet FTC is investigating because Watson refuses to talk to us. … In my call with FTC enforcement this morning, I indicated and [the FTC] confirmed that Watson is just mum about deal making. The reason for silence truly evades us and the FTC." *See* Opp. Ex. H (E-mail from Jack Kay to Paul Bisaro dated July 15, 2009).

Fourth, the FTC's tactics in pursuit of the Subpoena demonstrate that the FTC is using the Subpoena as a means to harass Respondent and Watson. FTC Staff called Watson repeatedly to urge the Apotex deal. In these conversations, Staff *told* Watson's counsel that the FTC "Front

[11] Although the FDA regulations permit the FDA to disclose to other government agencies information exempted from the public record, the regulations set out that the FDA and the receiving agency must enter into a written agreement that the information would not be further disclosed without the written permission of the FDA. *See* 21 C.F.R. 20.85 (2010).

Office" would open an investigation if Watson did not pursue the Apotex deal. The FTC then issued multiple subpoenas to Watson and Carlsbad. The FTC refused all reasonable attempts to make the investigation efficient. *See supra* at p. 10-14. After acknowledging that a hearing of Respondent might not even be necessary, *see* Opp. Ex. D at 70-71 (Buchen Dep.), the FTC reversed course and then simply issued the instant Subpoena on July 22, 2009, abandoning any pretext of negotiating a schedule. *See* Opp. Ex. E ¶¶ 15-16 (Raptis Decl.). The FTC permitted Respondent only one week to file a Petition to Quash with the FTC, but then took nine months to finally act on Respondent's Petition to Quash and file this enforcement action, belying any claim as to the urgency.

Fifth, when Respondent's counsel offered a confirmatory affidavit from Respondent as a means of resolving the matter, the Director of the FTC's Bureau of Competition contended that it would be just as efficient to require Respondent, Watson's CEO, to appear for a deposition ordered to take place in Washington, D.C., as it would be to discuss such an affidavit with Respondent's counsel. *See* Sunshine Decl. ¶ 28; *see also* Opp. Ex. P (April 28, 2010 Letter to Bergman). The same day that the FTC rejected Respondent's proposal it filed this enforcement action. *See* Sunshine Decl. ¶ 28; York Decl. ¶ 5. Despite repeated requests, the FTC waited a week to inform Respondent's counsel that it had filed an enforcement action, and then refused to provide non-public versions of its filings unless counsel accepted service of the Order to Show Cause. York Decl. ¶¶ 5-6.

The FTC's tactics cast serious doubt upon its *bona fides* in issuing and seeking to enforce the Subpoena, and demonstrate that the FTC has an ulterior purpose in continuing to seek Respondent's deposition. *See Powell*, 379 U.S. at 58. The FTC's crusade against reverse-payment settlements has already resulted in the nearly year-long investigation of Watson and

Carlsbad in connection with modafinil in 2006-2007 (culminating in the suit against Cephalon only), the renewed investigation in May 2009, and the three-year ordeal for Watson in connection with the FTC's failed attempt to overturn the AndroGel settlement. It is clear that in the present case, the FTC has learned all it can regarding the subject of relinquishment, and is seeking either to continue its pursuit of its *ultra vires* goal, or is simply attempting to punish Watson.

(b) The Proffer of a "Legitimate Purpose" Does Not End the Inquiry.

The FTC apparently believes that any inquiry into its *bona fides* in issuing the Subpoena begins and ends with its 2006 Resolution. *See* Pet. Br. 11 (quoting *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1091-92 (D.C. Cir. 1992) (quoting *FTC v. Carter*, 636 F.2d 781, 789 (D.C. Cir. 1980) for the proposition that "the validity of Commission subpoenas is to be measured against the purpose stated in the resolution, and not by reference to extraneous evidence")); *see also* Opp. Ex. M at 7 (Nov. 13 Letter Ruling); Opp. Ex. O at 8 (April 2 Letter Ruling). Such a position, however, flatly contradicts the clear mandate of *Powell*. *See Powell*, 379 U.S. at 58; *accord Aero Mayflower Transit Co.*, 831 F.2d 1142, 1145 (D.C. Cir. 1987); *La Rouche*, 613 F.2d at 862; *Markwood*, 48 F.3d 969, 978 (6th Cir. 1995). While it is Respondent's burden to demonstrate the illegitimate purpose, the FTC is not shielded from all inquiry merely because it has issued a facially legitimate resolution.[12]

[12] The FTC cited *Carter* for the proposition that "an administrative subpoena must be enforced whenever a valid purpose appears, even if an otherwise improper purpose also appeared." Opp. Ex. M at 8 n.28 (Nov. 13 Letter Ruling, citing *Carter's* reliance on *Donaldson v. United States*, 400 U.S. 517, 534-35 (1971)). The FTC's interpretation of this proposition cannot be squared with the Supreme Court's mandate in *Powell*. Such an interpretation of *Carter* implies that an agency subpoena could *never* be challenged as an abuse of process, so long as there is a hint of legitimacy in the resolution authorizing the use of compulsory process. This would allow an agency tactically to issue compulsory process to achieve all manner of questionable goals, so long as it is acting under the aegis of a nominally legitimate resolution. This is precisely what *Powell* shields against by providing recipients of agency process the opportunity to demonstrate an improper purpose, even where the agency has made out its prima facie case. *See Powell*, 379 U.S. at 58. Nor does *Donaldson* support the FTC's argument. *See Carter*, 636 F.2d at 789 (citing *Donaldson*, 400 U.S. at 534-35). *Donaldson* does not purport to overrule *Powell* and does not stand for the proposition attributed to it. *See Donaldson*, 400 U.S. at 526-27 (citing *Powell*, 400 U.S. at 526-27,

The FTC has thus far not squarely addressed Respondent's ample evidence of improper purpose, instead conclusorily dismissing Respondent's allegations variously as "groundless," "speculative," and "baseless." Pet. Br. 11; Opp. Ex. O at 8 (April 2 Letter Ruling). Tellingly, the FTC admitted in passing that FTC Staff may "explore or suggest certain actions that might negate any anticompetitive concerns identified," *id.*, although in this case the anticompetitive acts the FTC is trying to negate were allegedly committed by Cephalon and not Watson. Moreover, any supposedly anticompetitive concerns the FTC sought to remedy through a deal with Apotex relate to the FTC's inability to achieve its desired market outcome in its lawsuit against Cephalon. That matter is before Judge Mitchell S. Goldberg in the Eastern District of Pennsylvania and any attempts at fixing the modafinil market should be addressed to that Court.

D. Respondent Should be Allowed Discovery into the FTC's *Ultra Vires* Activity.

Concurrently with the filing of this brief, Respondent is filing a motion to compel the FTC to respond to limited discovery relating to its purpose in prosecuting the Subpoena. To the extent the Court has any doubt that Respondent has made out a prima facie case of improper purpose, Respondent respectfully requests that the Court grant Respondent's motion to compel to garner additional evidence concerning the FTC's contacts with the FDA and Apotex.

approvingly). In *Donaldson*, the Court faced a situation where no improper purpose was yet apparent at the time the agency process was issued, *see id*. at 534-36, and is therefore not analogous to the present case, where the circumstantial evidence shows the FTC reopened the modafinil investigation, and issued the Subpoena, to aid it in accomplishing an already-extant *ultra vires* objective.

CONCLUSION

For these reasons, Respondent respectfully requests that the Court enter an order denying the FTC's Petition.

Respectfully submitted,

Dated: May 21, 2010

/s/ Steven C. Sunshine
Steven C. Sunshine (D.C. Bar No. 450078)
Julia K. York (D.C. Bar No. 478001)
Skadden, Arps, Slate, Meagher & Flom LLP
1440 New York Avenue, N.W.
Washington, DC 20005
202-371-7000
steven.sunshine@skadden.com

Paul M. Eckles (Of Counsel)
Skadden, Arps, Slate, Meagher & Flom LLP
Four Times Square
New York, New York 10036
212-735-3000
paul.eckles@skadden.com

Attorneys for Respondent Paul M. Bisaro.

CERTIFICATE OF SERVICE

I hereby certify that on May 21, 2010, a true and correct copy of the foregoing Opposition to Petition of Federal Trade Commission for an Order Enforcing Administrative Subpoena *Ad Testificandum* was filed electronically in the United States District Court for the District of Columbia using the CM/ECF system.

Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing.

/s/ Julia K. York
Attorney for Respondent Paul M. Bisaro