IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION **Petitioner**, v. **PAUL M. BISARO**, **Respondent**.	)	Misc. Action No. 10-289 (CKK)

PETITIONER'S REPLY MEMORANDUM IN SUPPORT OF PETITION FOR AN ORDER ENFORCING ADMINISTRATIVE SUBPOENA *AD TESTIFICANDUM* AND OPPOSITION TO RESPONDENT'S MOTION TO COMPEL

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This is a subpoena enforcement proceeding to require Respondent, Paul M. Bisaro, CEO of Watson Pharmaceuticals, Inc., ("Watson") to appear and testify under oath. The Federal Trade Commission ("FTC" or "Commission") seeks to determine whether Watson is a party to an unlawful agreement to preclude generic competition to branded modafinil – an arrangement that would cost consumers hundreds of millions of dollars each year. Respondent is concededly one of only two individuals with knowledge of the relevant events. The subpoena is a reasonable and necessary mechanism to obtain crucial information which, thus far, Watson has not provided. In conducting its investigation, the Commission has acted in good faith and with a lawful purpose. Having engaged in protracted efforts to avoid providing the requested testimony and aired his objections to the full Commission, it is time for Respondent to fulfill his responsibility to assist the Commission in its investigation by sitting for an investigational hearing, as the Commission directed.

ARGUMENT

I. RESPONDENT MUST TESTIFY PURSUANT TO THE LAWFULLY AUTHORIZED SUBPOENA

As discussed in the Commission's opening memorandum, an investigatory subpoena must be upheld "if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant." *United States v. Morton Salt Co.*, 338 U.S. 632, 652, 70 S. Ct. 357, 369 (1950); *accord, FTC v. Invention Submission Corp*., 1991 WL 47104, *1, 1991-1 Trade Cas. (CCH) ¶ 69,338 (D.D.C. 1991) ("so long as the agency acts within its authority, requests information relevant to the lawful inquiry, and makes reasonable demands, the court must uphold the validity of the administrative subpoena"), *aff'd*, 965 F.2d 1086 (D.C. Cir. 1992). Respondent's opposition falls far short of the showing he must make to justify his refusal to appear and testify in a government law enforcement investigation. Furthermore, nothing in Respondent's motion to compel demonstrates that this is an "extraordinary case" justifying discovery.[1]

A. The FTC Needs Respondent's Testimony to Determine Whether Watson Is a Party to an Unlawful Agreement.

Respondent argues first that the subpoena requesting his testimony is "unreasonable" because it demands information that is already in the Commission's possession. Opp. 16. As the Commission found in denying Respondent's petition to quash, this assertion is baseless.

The purpose of the current investigation is to determine whether Watson has entered into

[1] We note that Respondent's opposition brief was untimely, having been filed – without leave of court – on May 22, 2010, instead of May 21, 2010, as directed by the Court's Order to Show Cause.

an unlawful agreement that restricts it from relinquishing marketing exclusivity for generic Provigil.[2] In connection with this inquiry, the Commission issued narrowly targeted CIDs to Watson and its development partner, Carlsbad. The CIDs required them to produce certain documents and information regarding their potential eligibility for marketing exclusivity under the Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

Watson, however, provided incomplete and evasive responses, and failed again to respond fully when FTC staff asked its counsel to correct the deficiencies. The Commission's efforts to inquire into this matter were blocked yet again when Watson's Senior Vice President, General Counsel, and Secretary, David Buchen, failed to respond fully to questions at his June 25, 2009 investigative hearing. Thus, in denying Respondent's petition to quash, the Commission categorically rejected the proposition that Watson had responded "fully" to its inquiries. *See* Pet. Exh. 7 at 6.

The Commission explained that Watson's responses were evasive and incomplete in the following specific respects:

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[2] As explained in the Commission's opening memorandum, Pet. Mem. at 5-6, by filing a Paragraph IV certification on the same day that Cephalon filed its '346 patent, Watson may be eligible for first-filer marketing exclusivity under FDA rules. Watson's eligibility for exclusivity could, in turn, prevent other generic firms from receiving final FDA approval and launching their own generic versions of Provigil. Some courts have held such agreements to be illegal *per se* because, *inter alia*, the continued presence of first-filer exclusivity acts as a bar to other generic competition. *See In re Cardizem*, 332 F.3d 896, 907-08 (6th Cir. 2003). Other courts have agreed in *dicta*. *See In re Ciprofloxacin*, 544 F.3d 1323, 1334 (Fed. Cir. 2008)*; In re Tamoxifen*, 429 F.3d 370, 398 (2d Cir. 2005); *Valley Drug Co. v. Geneva Pharms., Inc*. 344 F.3d 1294, 1311 n.26 (11th Cir. 2003); *Andrx Pharms., Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005).

- **Omissions in Watson's CID Responses**

Specification 3 of the CID required Watson to identify:

> "[E]ach agreement, 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 "[t]he portion(s) of the agreement that prohibit or limit Watson's or Carlsbad's ability to relinquish."

See Supp. Pet. Exh. 2. Watson, in its response, identified its Settlement Agreement with Cephalon as the only agreement that "may relate" to its ability to relinquish, and stated that "[a]ny relevant limitations or restrictions are contained therein." Watson, however, failed to identify the relevant portions of its agreement, as required by the CID. Supp. Pet. Exh. 2.

Specification 4 required Watson to identify:

> "[E]ach 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."

See Supp. Pet. Exh. 2. Watson, in its response, stated that it had discussed a "[p]roposal by Apotex that Watson relinquish eligibility to claim 180-day Marketing Exclusivity in exchange for a royalty on sales," but that "specific terms were not discussed," and that "[n]o agreement or decision [had] been reached." Supp. Pet. Exh. 2. Watson, however, did not provide the reasons for not entering into such an agreement, as required by the CID. *Id.*

- **Follow-up Inquiries to Watson's Counsel Were Fruitless**

After receiving incomplete responses to the CID, FTC staff asked Watson's counsel to correct the deficiencies. For example, as to Specification 3, FTC staff asked (again) which specific provisions of the Settlement Agreement "may relate" to Watson's ability to relinquish marketing exclusivity. Supp. Pet. Exh. 3. Watson's counsel, however, did not provide the requested information. Instead, she claimed that the "[t]he Agreement speaks for itself." Supp.

Pet. Exh. 4. She also asserted that "Watson's analysis of * * * how the Agreement may relate to FDA marketing exclusivity" was privileged. *Id.* As for the omissions in Watson's response to Specification 4, Watson's counsel responded to FTC staff's request for clarification by invoking attorney-client privilege for information regarding Watson's business "decision whether to relinquish marketing exclusivity." *Id.*

- **Mr. Buchen's Testimony Did Not Satisfy the Commission's Investigational Needs**

In June 2009, Watson's General Counsel, David Buchen, sat for an investigational hearing. Again, FTC staff inquired about the relationship between Watson's Settlement Agreement with Cephalon and Watson's ability to relinquish marketing exclusivity. In response, Mr. Buchen identified a provision not mentioned previously by Watson – namely, a provision that indemnifies Watson for legal fees that "might relate to the investigation."[3] Mr. Buchen, however, refused to respond to any inquiries about whether other provisions in the Settlement Agreement related to, prohibited, or limited Watson's ability to relinquish marketing exclusivity. Supp. Pet. Exh. 5 at 46-51.[4]

[3] Thus, it appears that Watson bears none of the costs of a government investigation relating to the Settlement Agreement, including the current FTC investigation and related litigation.

[4] There is therefore no merit to Respondent's assertion that Mr. Buchen testified "categorically" that the Settlement Agreement does not prevent relinquishment. Opp. 19. In the portion of the transcript cited by Respondent, Mr. Buchen testified that neither he nor anyone else at Watson had conversations with anyone at Cephalon regarding whether the Settlement Agreement preventing relinquishment, and that he was unaware of any discussions between Watson and Cephalon about relinquishment in the negotiations leading up to the Settlement Agreement. Exh. Supp. Pet. Exh. 5 at 51-52.. However, Mr. Buchen did not answer the *relevant* question – namely, whether Watson's Settlement Agreement with Cephalon in any way prohibited or limited Watson's ability to relinquish marketing exclusivity.

- **The Question Whether Watson Has Entered Into an Agreement Limiting its Ability to Relinquish Marketing Exclusivity Remains Unanswered**

As shown above, the question whether Watson has entered into an agreement that would limit its ability to relinquish marketing exclusivity remains unanswered. Respondent, nonetheless, represents that this "critical question has now been answered eight times, including in sworn testimony and statement." Opp.17; *see also* Opp. 21. In actuality, six of the eight responses are merely unsworn representations by counsel.[5] These representations are not substitutes for the sworn testimony of a live witness. *Cf. Petition of Hoechst Marion Roussel, Inc. to Quash*, FTC File No. 981-0368, 128 F.T.C. 798, 802 (1999) ("[T]he Commission, as it carries out its mandate to enforce the antitrust laws, must conduct its investigation as it sees fit, and plainly cannot simply accept a target's word that nothing fruitful will come out of an investigational hearing.").

Furthermore, contrary to Respondent's assertions, neither Watson's CID responses nor Mr. Buchen's investigational hearing testimony contain a definitive disavowal of an agreement regarding marketing exclusivity. Respondent does not identify which CID responses purportedly disavowed the existence of such an agreement. He merely cites his counsel's bald representation that those responses contain such a statement. *See* Opp. Exh. E ¶ 11 (Raptis Decl.). In actuality, as shown above, neither Watson's CID responses nor the Buchen transcript disavow the existence of an agreement. Indeed, in responding to the CIDs, Watson acknowledged that its settlement agreement with Cephalon "may relate" to its ability to relinquish. Supp. Pet. Ex. 2.

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[5] *See* Opp. Exh. E ¶ 6 (Watson counsel Raptis Decl.); Opp. Exh. L. at 10-11 (Respondent's Petition to Quash before Commission); Opp. Exh. L at 9-11 (Respondent's Petition to Quash before Commission); Opp. Exh. N. at 2 (Watson counsel's Nov. 27, 2009 request for review before Commission); Opp. Exh. Q (Watson counsel's April 13, 2010 Letter to FTC counsel); Sunshine Decl. ¶ 28.

While Respondent now contends that this response was provided only "out of an abundance of caution," Opp. 19, the Commission is not required to accept that rationale in lieu of live testimony.

Other reasons Respondent posits for why his testimony is unnecessary likewise miss the mark.[6] As the Commission explained in denying the Respondent's petition for full review, "While Watson has provided the Commission information relating to the '346 Patent, [Respondent] has not shown that his testimony will shed no light on matters that fall within the scope of the Commission's investigatory concerns. As a key executive of Watson, [Respondent's] testimony may well be useful in elaborating on the information or explaining relevant circumstances." Pet. Ex. 7 at 6.

B. The Testimony of Mr. Bisaro is Not Barred by the So-Called "Apex" Doctrine

Mr. Bisaro also contends that, given his position as a high level corporate executive, the instant subpoena "unreasonably seeks [his] testimony." Opp. 21-24.

First, we are not aware of any case, and Respondent cites none, applying the so-called "apex doctrine" in administrative investigations.[7] Second, even in more narrowly focused civil

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[6] For example, the assertion that Mr. Bisaro purportedly has no relevant documents and might not have been employed at Watson at the time it reached a settlement with Cephalon, *see* Opp. 18, is not dispositive. Even if Respondent is correct, neither condition precludes the possibility that Mr. Bisaro – given his discussions with Mr. Buchen or others and his status as CEO – may have relevant and non-privileged information regarding the possibility of an agreement regarding relinquishment. Finally, even if some testimony by Mr. Bisaro may be protected by the attorney-client privilege, the proper course is for Mr. Bisaro to appear at his investigational hearing and allow his counsel to assert any applicable privileges on the record in response to specific questions.

[7] Notwithstanding the absence of precedent, Respondent argues that restrictions on apex discovery under the Federal Rules of Civil Procedure should apply, reasoning that, as noted in *United States v. Powell*, 379 U.S. 48, 85 S. Ct. 248 (1964), certain limitations on administrative discovery have analogous restrictions in the Federal Rules. Opp. 22. *Powell*, of course, makes

discovery, the doctrine has very limited application, and does not bar litigants from obtaining the testimony of high-ranking corporate executives where they have personal knowledge of relevant events that is not obtainable elsewhere.[8] *See, e.g., Six West Retail Acquisition, Inc. v. Sony Theatre Mgmt. Corp.*, 203 F.R.D. 98, 102 (S.D.N.Y. 2001); *Travelers Rental Co., Inc. v. Ford Motor Co.*, 116 F.R.D. 140, 142 (D. Mass. 1987) (rejecting claim that depositions of corporate executives were noticed solely to harass). Even where a high ranking executive denies having personal knowledge of relevant issues, a litigant is entitled to his sworn testimony to test the scope of his knowledge. *Six West*, 203 F.R.D. at 102 (citation omitted).[9] In fact, Mr. Bisaro has never denied that he has personal knowledge about the key issues in this investigation.

Lastly, Respondent claims that – even if he had discoverable information – an interrogatory or affidavit could replace an investigational hearing. Opp. 24. It is clear, however, that such written discovery is not a suitable alternative to a hearing, especially given Watson's previous incomplete and evasive responses to the Commission's CIDs. In sum, issuance of the

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no mention of the apex doctrine. In any event, as shown below, the disputed subpoena was issued for a proper purpose and was not harassment.

[8] In further support of his contention that he is protected by the "apex doctrine," Respondent contends that only Mr. Buchen discussed the matter with Apotex, and any nonprivileged information related to him by Mr. Buchen about those discussions were discoverable at Mr. Buchen's investigational hearing. Accordingly, he asserts, the Commission cannot show that the requested information is not obtainable elsewhere. Opp. 23. Mr. Bisaro, however, plainly has personal knowledge of the discussions he had with Mr. Buchen regarding and his thoughts about those discussions. Furthermore, particularly given his senior position at the company, it is certainly possible that he may be able to testify about other matters relating to relinquishment of marketing exclusivity that he obtained though sources other than Mr. Buchen and which would be discoverable only in his investigative hearing.

[9] For this reason, this case is distinguishable from cases cited by Respondent, *e.g., Thomas v. IBM*, 48 F.3d 478, 483 (10th Cir. 1995), that barred depositions of high ranking executives who lacked personal knowledge of key facts and where no effort was made to obtain the same information elsewhere.

subpoena on Respondent is reasonable and is not barred by the apex doctrine.

C. Discovery Should be Denied

Respondent contends that the Commission issued the instant subpoena for an improper purpose and that he needs discovery to inquire into the Commission's true purpose in issuing the subpoena. Opp. 25-30; Motion for Order Compelling FTC to Respond to Respondent's Discovery Requests and for Leave to Supplement the Record. Respondent's assertions of impropriety are premised on supposition and bald assertions that do not support his contention that the Commission, or its staff, has engaged in improper conduct. His efforts to evade his responsibility to assist the Commission by providing testimony under oath should not be rewarded by allowing him to impede and interrupt an ongoing law enforcement investigation with his own inquiry into the Commission's purpose in seeking his testimony.

1. The investigation is authorized under the Commission's 2006 Resolution

In opposing the Commission's enforcement petition, Respondent argues – apparently for the first time – that the subpoena was improperly issued because the instant inquiry focuses on conduct regarding Watson that occurred after the Commission issued its August 30, 2006, investigatory resolution. Opp. 24-25. Because Respondent did not raise this argument in its petition to quash before the Commission, he is barred from raising it for the first time here.[10]

In any event, the Commission's compulsory process resolutions apply to all continuing conduct reasonably arising within the scope of the terms of the resolution even if such activities

[10] *See FTC v. O'Connell*, 828 F. Supp. 165, 168 (E.D. N.Y. 1993); *EEOC v. City of Milwaukee*, 919 F. Supp. 1247 (E.D. Wis. 1996); *FTC v. Invention Submission Corp.*, 1991 WL 47104, 1991-1 Trade Cas. (CCH) ¶ 69,338 at 65,351 n.12 (D.D.C. 1991), *aff'd*, 965 F.2d 1086 (D.C. Cir. 1992).

occur after the date of the resolution. Moreover, the current investigation centers on whether the Settlement Agreement between Watson and Cephalon on August 7, 2006 forbids or restricts Watson from relinquishing any marketing exclusivity regarding modafinil. Given that the Settlement Agreement was entered into before the Commission issued its Resolution (and, in fact, was a reason the Commission initiated the investigation to begin with), Respondent's argument fails.

2. Respondent's assertions of impropriety are baseless

Respondent next contends that the Commission issued the present subpoena to "harass" Respondent and Watson for the "improper attempt to engineer its preferred outcome in the modafinil market." Opp. 26. Nothing in Respondent's opposition approaches the sort of "improper purpose" or "bad faith" that would justify invalidating the administrative subpoena, or permitting even the limited discovery sought by Respondent.[11]

Respondent's "evidence" of such improper purpose consists of an allegation that Markus Meier, an Assistant Director in the FTC's Bureau of Competition, suggested that Watson consider relinquishing any marketing exclusivity it might have associated with the '346 patent to another generic manufacturer, Apotex. Opp. 27-28. Such an statement, even if true, does not demonstrate that the Commission acted with an improper purpose in issuing the instant subpoena. As the Commission explained in denying Respondent's petition to quash, it is not at all unusual in an investigation for Commission staff to "explore or suggest certain actions that might negate any anticompetitive concerns identified." Pet. Exh. 7 at 8. Indeed, Watson's

[11] These principles are fully consistent with the presumption of administrative regularity and good faith to which the Commission, in exercising its congressionally mandated responsibilities, is entitled. *See, e.g.*, *FCC v. Schreiber*, 381 U.S. 279, 290, 85 S. Ct. 1459, 1467 (1965); *Invention Submission Corp.*, 965 F.2d 1086, 1091 (D.C. Cir. 1992).

agreement to relinquish any marketing exclusivity it may have with respect to the '346 patent would have shown irrebuttably that it was not party to a potentially unlawful agreement with a rival manufacturer of generic pharmaceuticals. It therefore would have obviated the need for the Commission's investigative staff to pursue an investigation. Thus, although Respondent asks the Court to read menace into Mr. Meier's supposed statement that, in the absence of such relinquishment, the Commission's investigation would likely continue, *see e.g.*, Opp. 27-28 ("the FTC 'Front Office" would open an investigation if Watson did not pursue the Apotex deal"), at most the statement says the obvious: *if* the Commission's competitive concerns are resolved, there will be nothing to investigate; if they are not resolved definitively, further investigation is likely warranted based on existing facts raising such concerns. No improper purpose is demonstrated by such a statement.

Respondent's allegations of improper disclosure of confidential information (*see* Opp. 26-27) are likewise unavailing. Even if true, they would not justify impeding an investigation into whether Watson or others have engaged in "unfair methods of competition" in violation of the FTC Act. Such collateral matters are not raised properly in defense of a summary subpoena enforcement proceeding. *See Carter*, 636 F.2d at 789 ("information relating to alleged administrative improprieties is irrelevant to [a subpoena enforcement] proceeding"); *CFTC v. Harker*, 615 F. Supp. 420, 425 (D.D.C. 1985) ("[s]uch a 'leak' [of confidential information], if it took place at all, is not the sort of 'extraordinary circumstance' justifying discovery" in a subpoena enforcement action).[12] Furthermore, even if it were possible for Respondent to demonstrate somehow that a single FTC staff attorney acted improperly, that would not justify

[12] Rather, the proper time for raising such issues is in a subsequent enforcement action – if any – that may result from the Commission's investigation.

Respondent's efforts to evade his responsibility to appear and testify under oath. Even if proven, such conduct would not limit the Commission's ability to carry out its congressionally mandated responsibilities to monitor the marketplace and determine whether companies are engaging in "unfair methods of competition" in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45(a). *See Carter*, 636 F.2d at 789 ("enforcement of the subpoena is called for so long as proper purposes exist as well").[13]

Finally, none of the other actions of Commission staff that Respondent complains about or contends reflect an "ulterior motive" even colorably suggest that the Commission acted with an improper purpose in issuing the instant subpoena. *See* Opp. 28.[14]

3. Because the Commission acted properly, the "extraordinary circumstances" that are necessary to conduct discovery in a summary subpoena enforcement proceeding are not present

For the reasons stated above, Respondent's request to conduct discovery must be denied. As the Court of Appeals for this Circuit has declared, discovery is improper in summary subpoena enforcement proceedings except in "extraordinary circumstances." *Invention Submission Corp.*, 965 F.2d at 1091; *see Carter*, 636 F.2d at 789; *FEC v. Committee to Elect Lyndon La Rouche*, 613 F.2d 849, 862 (D.C. Cir. 1979) (it is "well settled that the burden of showing an improper purpose is on the subpoenaed party"). Thus, "district courts must be

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[13] Thus, the ambiguous and equivocal statements of individual members of an agency's staff are never a proper basis for concluding that the agency has acted in bad faith in issuing process. *Resolution Trust Corp. v. Frates*, 61 F.3d 962, 965 (D.C. Cir. 1995).

[14] For example, the Commission reasonably rejected Respondent's offer of an affidavit in place of investigatory hearing based on its previous experience with Respondent's incomplete and evasive responses to the agency's CIDs. Similarly, Commission staff acted in good faith when it served by hand the non-public version of the petition, supporting legal memorandum, and supporting exhibits on the same day the Show Cause Order issued, as required by the Order. *See* Commission's Proof of Service, Docket No. 7 (May 14, 2010).

cautious in granting [such] discovery, lest they transform subpoena enforcement proceedings into exhaustive inquisitions into the practices of the regulatory agencies." *Frates*, 61 F.3d at 965 (quoting *SEC v. Dresser Industries, Inc.*, 628 F.2d 1368, 1388 (D.C. Cir. 1980) (*en banc*)).[15]

Indeed, while recalcitrant subpoena recipients sometimes seek discovery, courts consistently reject their efforts to inquire into an agency's motives or otherwise permit discovery unless truly extraordinary circumstances exist. *See, e.g.*, *Frates*, 61 F.3d at 965; *Invention Submission Corp.*, 965 F.2d at 1091-92; *United States v. Aero Mayflower Transit Co.*, 831 F.2d 1142, 1145-47 (D.C. Cir. 1987); *Carter*, 636 F.2d at 789 (D.C. Cir. 1980); *Dresser Industries*, 628 F.2d at 1388-89; *Harker*, 615 F. Supp. at 423-25. The circumstances of the instant investigation stand in contrast to those present in cases cited by Respondent where some discovery into the agency's good faith has been allowed.[16]

As for Respondent's contention that the discovery he seeks is only "limited" in scope, no authority supports even limited discovery where, as here, the recipient of process has not sustained his burden to demonstrate "extraordinary circumstances" to justify an inquiry into the agency's good faith.

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[15] In *Frates*, the D.C. Circuit held that the district court properly denied discovery because, although a statement by the RTC's staff "could be read to support [respondent's] allegation" of improper purpose, "it could also be read to mean that the RTC was still searching for further evidence * * * so that it might determine whether the evidence of liability was strong enough or the resulting damages large enough to justify filing a complaint." 61 F.3d at 965.

[16] This matter bears no similarity, for example, to *United States v. Fensterwald*, 553 F.2d 231, 232 (D.C. Cir. 1977) in which the IRS selected for a "special" audit a lawyer who had led an investigation of alleged illegal activities by the IRS, and whose representation of various prominent figures in politically controversial cases may have led to an "extraordinary interest" in this taxpayer by some people in the Executive Branch. . Nor does it remotely resemble *SEC v. Wheeling-Pittsburgh Steel Corp.*, 648 F.2d 118 (3rd Cir. 1981), in which ample facts indicated that the SEC had targeted respondent for investigation at the behest of a powerful Senator, without exercising its own independent judgment concerning the merits of the action.

Because Respondent has not shown that "extraordinary circumstances" exist, no discovery is warranted. This Court should issue an order to enforce the administrative subpoena because Mr. Bisaro's testimony is highly relevant to the critical question whether Watson entered into a potentially anticompetitive agreement that restricted its ability to relinquish any exclusivity it might possess to market generic Provigil.

CONCLUSION

For the foregoing reasons, this Court should direct Mr. Bisaro to comply in full with the July 22, 2009, subpoena *ad testificandum* and deny his motion for an order compelling discovery.

Respectfully submitted,

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Dated: May 27, 2010

CERTIFICATE OF SERVICE

I hereby certify that on May 27, 2010, a true and correct copy of the foregoing Petitioner's Reply Memorandum in Support of Petition for an Order Enforcing an Administrative Subpoena *Ad Testificandum* and Opposition to Respondent's Motion to Compel, supporting exhibits, and proposed Order, were filed electronically in the United States District Court for the District of Columbia using the CM/ECM 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/ Michael D. Bergman
Michael Bergman
Attorney for Petitioner
Federal Trade Commission

Supplemental Petition Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION Petitioner, v. **PAUL M. BISARO,** Respondent.	)	Misc. Action No. 10-289 (CKK)

SUPPLEMENTAL DECLARATION OF JAMES RHILINGER, ESQ.

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

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

2. I submit this supplemental declaration in support of the Commission's Petition for an Order Enforcing Administrative Subpoena *Ad Testificandum* ("Petition"). I have read the Petition, the Commission's Reply Memorandum in Support of Petition, and the exhibits referenced in the Reply Memorandum (those exhibits are hereinafter referred to as "Supp. Pet. Exh."). I verify that Supp. Pet. Exh. 2 (this declaration is Supp. Pet. Exh. 1) through Supp. Pet. Exh. 5 are true and correct copies of the original documents contained in the Commission's files.

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

3. On May 19, 2009, the Commission issued narrowly targeted CIDs to Watson and its development partner, Carlsbad, to determine, *inter alia*, whether Watson is a party to any agreement that limits its ability to relinquish any marketing exclusivity rights it may have with respect to modafinil. *See* Supp. Pet. Exh. 2. On June 10, 2009, Watson responded to the Commission's CIDs, to which Watson only provided partial responses. Supp. Pet. Exh. 2. Accordingly, by letter dated June 11, 2009, Commission staff communicated with Watson's counsel, identified information Watson had failed to provide, and requested that Watson supplement its initial responses. Supp. Pet. Exh 3. Watson's counsel, by letter dated June 17, 2009, denied that the initial responses were deficient and again failed to provide the requested information, in part, on the basis of attorney-client privilege. Supp. Pet. Exh. 4.

4. On June 25, 2009, pursuant to a subpoena *ad testificandum,* David A. Buchen, Watson's Senior Vice President, General Counsel, and Secretary, appeared and testified at an investigational hearing. His testimony was recorded and subsequently transcribed. Supp. Pet. Exh. 5. Mr. Buchen did not fully respond to the Commission's questions, including those inquiring whether Watson had entered into any agreements that would prohibit or otherwise limit its ability to relinquish any marketing exclusivity rights for modafinil. *Id.* Mr. Buchen identified Mr. Bisaro as the only person at Watson with whom he had spoken regarding relevant discussions with a third party about a possible deal for generic Provigil. *Id.*

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

Executed on: May 27, 2010

James Rhilinger, Esq.

Supplemental Petition Exhibit 2

WATSON PHARMACEUTICALS, INC.

Responses to Civil Investigative Demand, File No. 061 – 0182

Responses to Specifications 1 – 8

Dated: June 10, 2009

Maria A. Raptis, Esq.
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HIGHLY CONFIDENTIAL

Responses to Specifications 1 – 8

Watson Pharmaceuticals, Inc. ("Watson" or the "Company") submits the following responses to the Civil Investigative Demand ("CID") issued by the Federal Trade Commission ("FTC") on May 19. 2009 pursuant to Section 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1.

Information is provided to the extent it is in Watson's possession, custody or control or can reasonably be produced on the basis of data maintained in the ordinary course of the Company's business. To the extent that information is not provided, Watson does not maintain, track or possess the requested information in the ordinary course of its business. Please note that Watson reserves the right to supplement, clarify or correct these responses, and to provide further responses to these Specifications and the CID, as necessary.

Furthermore, Watson objects to the CID to the extent it calls for the production of documents protected from disclosure by any applicable doctrine of privilege or immunity from disclosure, including without limitation documents developed for or in anticipation of litigation, documents that constitute or reflect an attorney's work-product, or contain attorney-client communications, and documents or information protected from disclosure by a protective order, or any other privilege granted by state and/or federal statutory or common law. These privileges or immunities may belong to Watson alone, or may be held in common with another entity pursuant to a common interest or joint defense privilege. To the extent that any such document is inadvertently produced, the inadvertent production is not to be construed as a waiver of any applicable privilege, and such document and all copies thereof shall be returned to Watson's counsel.

Specification 3

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

(a) The name and address of the parties to the agreement;
(b) The date of the agreement;
(c) The portion(s) of the agreement that prohibit or limit Watson or Carlsbad's ability to relinquish;
(d) The name, title, and division of any employee, officer, or director of Watson and the other company involved in the discussions;
(e) The name and address of the current employer of any Watson employee, officer, or director involved in the discussions, but no longer employed by Watson; and
(f) The agreement(s) and/or subject matter with respect to which the individual was involved in decision making.

Response to Specification 3

Watson objects to this Specification to the extent it requests information protected from disclosure by any applicable doctrine of privilege or immunity from disclosure, including without limitation documents developed for or in anticipation of litigation, documents that constitute or reflect an attorney's work-product, or contain attorney-client communications, and documents or information protected from disclosure by a protective order, or any other privilege granted by state and/or federal statutory or common law.

Expressly reserving and without waiving this objection, attached to this Specification as Exhibit 3-1 is a copy of the Settlement and License Agreement dated August 2, 2006 by and among Cephalon, Inc. ("Cephalon") Watson Pharmaceuticals, Inc. ("Watson") and Carlsbad Technology, Inc. ("Carlsbad"). This agreement may relate to Watson or Carlsbad's ability to relinquish eligibility to claim 180-day Marketing Exclusivity for Generic Provigil. Any relevant limitations or restrictions are contained therein. Please refer to Watson's response to the CID issued by the Federal Trade Commission on May 18, 2007 for information regarding the individuals involved in the discussions and decision-making pertaining to the Settlement and License Agreement.

There is no other agreement between Watson and any party pertaining to the ability to relinquish eligibility to claim 180-day Marketing Exclusivity for Generic Provigil.

Specification 4

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

(a) The name and address of the company;
(b) The date of the discussions;
(c) The name, title, and division of any employee, officer, or director of Watson and the other company involved in the discussions;
(d) The name and address of the current employer of any Watson employee, officer, or director involved in the discussions, but no longer employed by Watson;
(e) The substance of the discussions; and
(f) Whether Watson entered into an agreement as a result of the discussions, and the reasons for Watson's decision.

Response to Specification 4

Watson objects to this Specification to the extent it requests information protected from disclosure by any applicable doctrine of privilege or immunity from disclosure, including without limitation documents developed for or in anticipation of litigation, documents that constitute or reflect an attorney's work-product, or contain attorney-client communications, and documents or information protected from disclosure by a protective order, or any other privilege granted by state and/or federal statutory or common law.

Expressly reserving and without waiving this objection, Watson has had contacts relating to the '346 patent consisting of communications with its patent counsel, Frommer Lawrence & Haug LLP, and with its development partner, Carlsbad, regarding the filing of: (i) a supplement to Carlsbad's ANDA containing a Paragraph IV certification relating to the '346 patent, and the submission of the appropriate notice to Cephalon informing them of the supplement. These communications are reflected in Watson's response to Specification 6 of this CID.

In addition, Watson provides the following response:

(a) Apotex, Inc., 150 Signet Drive, Toronto, Ontario M9L 1T9 Canada
(b) Approximately March 18, 2009 – May 25, 2009
(c) David Buchen, Senior Vice President, General Counsel & Secretary, Watson Pharmaceuticals, Inc. and Shashank Upadhye, Vice President, Global Intellectual Property, Apotex, Inc.
(d) N/A
(e) Proposal by Apotex that Watson relinquish eligibility to claim 180-day

Marketing Exclusivity in exchange for a royalty on sales; specific terms were not discussed

(f) No agreement or decision has been reached

Please see also Watson's response to Specification 5 of this CID.

Supplemental Petition Exhibit 3

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

Bureau of Competition
Health Care Division

Saralisa C. Brau
Deputy Assistant Director

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

June 11, 2009

By Electronic Mail

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

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

Dear Maria:

I write concerning deficiencies in Watson and Carlsbad's June 10, 2009 response to the Commission's May 19, 2009 Civil Investigative Demands (CIDs), and to request that Watson and Carlsbad supplement their responses by June 17, 2009.[1]

The Commission's original CIDs specified a production date of June 3, 2009. On June 2, 2009, I sent you a letter memorializing the FTC's agreement to your request to extend the CID production date to June 10, 2009. We received your production yesterday, and note the following deficiencies:

SPECIFICATION 3(c)

- Specification 3(c) requires Watson to identify **"the portion(s) of [each] agreement that prohibit or limit Watson or Carlsbad's ability to relinquish"** its eligibility to claim 180-day marketing exclusivity.

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

- Watson's response provides that the "***Settlement and License Agreement dated August 2, 2006 by and among [Cephalon, Watson, and Carlsbad] . . . may relate to Watson or Carlsbad's ability to relinquish eligibility for exclusivity. Any relevant limitations or restrictions are contained therein***."

- Watson's response fails to identify the specific "portion(s)" of Settlement and License Agreement that "may relate" to its ability to relinquish, and is therefore deficient.

SPECIFICATION 4(f)

- Specification 4 requires Watson to "identify each company with which Watson had contact relating to: the '346 patent; Watson or Carlsbad's First Filer status for Generic Provigil; eligibility to claim 180-day Marketing Exclusivity for Generic Provigil; or the relinquishment thereof." Section 4(f) further requires Watson to identify for each such company "**whether Watson entered into an agreement as a result of the discussions, the reasons for Watson's decisions.**"

- Watson's response to Specification 4 identified contacts with Apotex (among others). Its response to Specification 4(f) provided that "***no agreement or decision has been reached***" as a result of its discussion with Apotex.

- Watson's response to Specification 4(f) fails to identify "the reasons for Watson's decision" not to reach an agreement or decision with Apotex, and is therefore deficient.

SPECIFICATION 5

- Specification 5 requires Watson and Carlsbad to **"identify whether [each] had any communications with Cephalon relating to the '346 patent; Watson or Carlsbad's First Filer status for Generic Provigil; eligibility to claim 180-day Marketing Exclusivity for Generic Provigil; or the relinquishment thereof."**

- Watson and Carlsbad's response to Specification 5 reads in relevant part that each party "***did not have any communications with Cephalon relating to Watson or Carlsbad's First Filer Status for Generic Provigil; eligibility to claim 180-day Marketing Exclusivity for Generic Provigil; or the relinquishment thereof . . .***"

- Watson and Carlsbad's responses to Specification 5 fail to identify whether Watson or Carlsbad had any communications with Cephalon relating to the '346 patent, and is therefore deficient.

Please supplement Watson and Carlsbad's CID responses to the above-referenced Specifications to provide the required information by June 17, 2009. Please feel free to call me with any questions at (202) 246-3792.

Sincerely,

Saralisa C. Brau

Supplemental Petition Exhibit 4

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

TEL: (212) 735-3000
FAX: (212) 735-2000
www.skadden.com

CONFIDENTIAL

June 17, 2009

Saralisa C. Brau, Esq.
Federal Trade Commission
601 New Jersey Avenue, N.W.
Room 7225
Washington, D.C. 20001

Re: FTC File No. 0610182

Dear Saralisa:

I write on behalf of Watson Pharmaceuticals, Inc. ("Watson") in response to your June 11, 2009 letter regarding Watson's response to the Civil Investigative Demand ("CID") issued by the Federal Trade Commission ("FTC") on May 19, 2009. Your letter states that Watson failed to identify information responsive to portions of Specifications 3, 4 and 5 of the CID, and demands that Watson supplement its response. For the reasons discussed below, your assertion that Watson's response was deficient is incorrect and Watson stands by its response.

SPECIFICATION 3(c)

Specification 3 requires Watson to identify any agreement potentially prohibiting or limiting its ability to relinquish marketing exclusivity related to the '346 Patent. In its response, Watson identified the Settlement and License Agreement dated August 2, 2006 (the "Agreement"), which the FTC has had in its possession since August 21, 2006, as potentially relating to its ability to relinquish

marketing exclusivity in connection with the '346 Patent.[1] Your letter states that Watson's response is nonetheless deficient because it "fails to identify" the specific portions of the Agreement that may be relevant.

The FTC has been in possession of the Agreement for almost three years and has had ample opportunity to study its provisions and determine whether and to what extent they may be relevant to this issue. The Agreement speaks for itself. To the extent you believe this Specification is calling for Watson's analysis of the legal implications of the Agreement, and how the Agreement may relate to FDA marketing exclusivity, that analysis is protected from disclosure by the attorney-client privilege and work product doctrines.

SPECIFICATION 4(f)

Specification 4 requires Watson to identify any contacts with third parties relating to the '346 patent or marketing exclusivity for generic Provigil. Subsection 4(f) demands that Watson identify "[w]hether Watson entered into an agreement as a result of the discussions, and the reasons for Watson's decision." Watson's response to Specification 4 discloses certain preliminary communications with Apotex, Inc., and states clearly that no agreement has been reached, and also that ***"[n]o decision . . . has been reached"*** with respect to these discussions.

Your letter now essentially demands that Watson provide the reasons for Watson's decision not to reach a decision – a matter arguably outside the scope of the information requested in Specification 4. Nevertheless, the decision whether to relinquish marketing exclusivity and enter into a license with another company is inextricably intertwined with legal matters; Watson's internal deliberations regarding this matter implicate legal advice and are protected from disclosure by the attorney-client privilege.

SPECIFICATION 5

Finally, Specification 5 requires Watson to identify any contacts with Cephalon relating to the '346 patent or marketing exclusivity for generic Provigil. Watson's response states that "Watson and Carlsbad did submit a notice to Cephalon informing them of Carlsbad's supplemental ANDA filing and Paragraph IV certification." For the sake of clarity, the contacts listed in Watson's response are

---

[1] Watson originally submitted the Agreement as part of its Section 1112(a) filing pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

the only contacts responsive to the FTC's demand that Watson identify any contacts relating to the '346 patent.

We hope the above clears up any misunderstandings about Watson's response to the CID. Should you have any questions, please call me at (212) 735-2425.

Very truly yours,

Maria A. Raptis /JS

Maria A. Raptis

cc: Bradley Albert, Esq.

Supplemental Petition Exhibit 5

IN THE MATTER OF CEPHALON, INC.

FTC File No. 0610182

Los Angeles, California

Thursday, June 25, 2009

Testimony of DAVID BUCHEN, taken in the above-referenced INVESTIGATIONAL HEARING, by counsel for the FEDERAL TRADE COMMISSION, taken at 300 South Grand Avenue, Suite 2850, Los Angeles, California, beginning at 10:08 a.m. and ending at 12:06 p.m., on Thursday, June 25, 2009, before Tracey Kuhlin, Certified Shorthand Reporter No. 7735.

APPEARANCES:

ON BEHALF OF THE FEDERAL TRADE COMMISSION:
FEDERAL TRADE COMMISSION
BY: MARKUS MEIER, ESQ.
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ON BEHALF OF CEPHALON, INC.:
SKADDEN, ARPS, SLATE, MEAGHER & FLOM, LLP
BY: STEVEN C. SUNSHINE, ESQ.
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INDEX

THURSDAY, JUNE 25, 2009, LOS ANGELES, CALIFORNIA
10:08 a.m.
--
DAVID BUCHEN,
having been first administered an oath,
was examined and testified as follows:

EXAMINATION

BY MR. MEIER:

Q. Mr. Buchen, would you please state your name.

A. David Buchen, B-u-c-h-e-n.

Q. Mr. Buchen, as you know, my name is Markus Meier. I'm an attorney with the Federal Trade Commission. I'm going to be asking you questions today giving rise to our investigation of Watson with respect to the settlement with Cephalon involving the '516 patent for the product Provigil.

I know that you've taken depositions before, and I also know that you've been subject to a couple FTC investigation hearings, so I think you understand the way this process works; is that correct?

A. Yes.

Q. So I don't think I need to go through a lot

of explanation on that, but let me ask you this one question. Is there anything that may affect your ability to give truthful and complete testimony today?

A. No.

Q. Is it correct that you are currently the senior vice president, general counsel and secretary of Watson Pharmaceuticals, Incorporated?

A. Yes.

Q. And you've held these positions since November 2002?

A. Correct.

Q. And you've been with Watson since February 1998?

A. November 1998.

Q. I'm sorry. You've been with Watson since November 1998?

A. Yes.

Q. And you're a lawyer?

A. I am.

Q. And a member of the California Bar?

A. Yes.

Q. Is it correct that you have experience negotiating agreements on behalf of Watson?

A. Yes.

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Q. Have you ever been involved in negotiating patent settlement agreements on behalf of Watson?
A. Yes.
Q. Do you know how many?
A. No.
Q. Can you give me an approximate number?
A. No.
Q. Can you remember any of the ones that you've been involved in?
A. Probably less than 25.
Q. More than 15?
A. More than 10.
Q. And which ones, specifically, do you recall having been involved in negotiating?
A. I had some involvement with negotiating the Androgel settlement; I had some involvement in Cardizem LA; I had some involvement with the settlement that we're here to discuss today, Provigil; I had some involvement with Wellbutrin. Those come to mind.
Q. With respect to your role in negotiating patent settlement agreements on behalf of Watson, is there a typical role that you play, or does it vary from settlement to settlement?
A. It varies.

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Q. How would you describe the role you had in the 2006 patent settlement with Cephalon concerning Provigil?
A. I had oversight responsibilities, and I had ultimate responsibility for the form of the settlement.
Q. Can you describe in a little more detail what your oversight responsibilities were?
A. In the early phases, Amy Hulina was working on trying to settle the case, and she would consult with me as necessary. I'm her direct supervisor.
Q. Do you recall roughly approximately how many times you had interactions with Amy Hulina regarding the 2006 patent settlement?
A. No.
Q. Were there certain aspects to the 2006 patent settlement with Cephalon where Amy Hulina knew she would need to consult with you?
A. I can't recall how -- or which items she consulted with me on. She would keep me generally informed of how the negotiation was going.
Q. Do you recall whether there were any items specific to the 2006 patent settlement with Cephalon concerning Provigil that she did consult with you on?

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A. I recall from the last deposition I gave in this matter that there were -- that there was discussion concerning the terms of the settlement agreement as it relates to being in the same position as other filers.
Q. What does that mean, "same position as other filers"?
A. That we didn't want to have a settlement agreement that was going to put us at a competitive disadvantage to other filers.
Q. Was that an important business strategy for Watson, to be in no worse position than any of the other filers?
A. To the extent we were able, based upon our status, yes.
Q. Do you know, sitting here today, whether Watson was successful in negotiating a settlement with Cephalon in which it was no worse off than the other filers?
A. On the particular matter that I'm recalling, which is the breadth of the license with respect to the patented suit, I believe we were successful.
Q. How about with respect to other general terms in the settlement?

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A. I don't have a recollection of the other terms of the settlement. That was the one I was thinking about.
Q. With respect to other terms in the settlement, was it also a business strategy of Watson to be in a position no worse off than the other generic filers?
A. Our business strategy is to always get the best settlement we can.
Q. In addition to your oversight responsibilities with Amy Hulina, you had indicated that you had ultimate responsibility for the settlement, the 2006 patent settlement with Cephalon concerning Provigil.
What do you mean by the "ultimate responsibility"?
A. Amy reports to me; therefore, as the senior member of the department, all matters within the legal department ultimately end up being my responsibility.
Q. You didn't actually sign the 2006 patent settlement with Cephalon, did you?
A. I don't believe so, no.
Q. Do you know why?
A. No.

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Q. And with respect to some of these other patent settlements that you've been involved in negotiating, do you sometimes sign the patent settlement documents?
A. I can't recall. As I sit here today, I don't know.
Q. In your capacity as a senior vice president of Watson Pharmaceuticals, Incorporated, is it correct you have a number of vice presidents who you supervise --
A. Yes.
Q. -- and oversee?
A. Yes.
Q. And this includes the vice president of internal audit?
A. Yes.
Q. Vice president of government affairs?
A. Yes.
Q. And the vice president that's involved as patent counsel?
A. Correct.
Q. Are there any other vice presidents you have oversight responsibility of?
A. Yes. I have oversight responsibility for a vice president and assistant general counsel and

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compliance officer.
Q. Is that one person?
A. Yes.
Q. Are there any other vice presidents you oversee?
A. No.
Q. Is it correct, as a senior vice president, you have authority to bind the company in contracts?
A. Yes.
Q. And is it also correct that all senior vice presidents, even those who aren't lawyers, have authority to bind Watson in contracts?
A. Yes.
Q. Are there any other responsibilities you have as a senior vice president that I haven't asked about?
A. I don't understand the question.
Q. Well, I understand, as a senior vice president, you supervise a number of vice presidents, and you also have authority to bind the company in contracts. And my question is, when you are wearing the hat as a senior vice president, are there other responsibilities formally that you have as a senior vice president?
A. Do you mean distinct from my

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responsibilities as the general counsel or as the secretary of the company?
Q. That's correct; I do mean that.
A. I don't think I segregate my responsibilities in that manner.
Q. Well, let's take a look at some of the responsibilities you have as secretary.
Is it correct, as secretary, you attend Watson board meetings?
A. Yes.
Q. You are responsible for keeping the board minutes of the Watson board?
A. Yes.
Q. And this is the Watson board of directors; correct?
A. Correct.
Q. And is the Watson board of directors the highest organ within the company?
A. It's the board of directors that --
Q. Board of directors has the ultimate authority over the decisions of the company; is that correct?
A. Board of directors does not manage the day-to-day operations of the company. The board of directors is an oversight body that oversees the

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strategies and business plans of the company as in any other public company.
Q. And as secretary, is it correct that you attend committee meetings of the board of directors?
A. Yes.
Q. And this includes the audit committee?
A. Yes.
Q. The compensation committee?
A. Yes.
Q. The nominating and corporate governance committee?
A. Yes.
Q. The regulatory compliance committee?
A. Yes.
Q. Are there any other committees of the board?
A. No.
Q. Do you actually attend the meetings of these various committees?
A. I do.
Q. Is it correct that the audit committee oversees the company's financial reporting responsibilities?
A. Yes.
Q. Is it fair to say that, on a daily basis,

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you do a lot of different things within the company?
A. Yes.
Q. Is it fair to say that not all the things you do on a daily basis require being a lawyer?
A. Yes.
Q. Many things you do at work on a daily basis could be done by someone who isn't a lawyer; is that correct?
A. That's correct.
Q. And is it fair to say that you are not just involved in the legal strategy for Watson, but you also get involved in business strategy?
A. That's correct.
Q. And you report to Watson's CEO?
A. I do.
Q. And the current CEO is a man named Paul Bisaro?
A. That's right.
Q. Have you ever been involved in negotiating agreements with any other pharmaceutical company that included terms under which you would relinquish the 180-Day Marketing Exclusivity on behalf of Watson?
A. Yes.
Q. Do you know how many times you've done

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that?
A. Once, to my recollection.
Q. And what product was that?
A. Metroprolol, M-e-t-r-o-p-r-o-l-o-l.
Q. That's the generic name; right?
A. That's the generic name for Toprol, T-o-p-r-o-l.
Q. And the brand of product is actually Toprol XL?
A. Yes.
Q. So you were involved in negotiating an agreement in which one of the terms was the requirement to relinquish the 180-Day Marketing Exclusivity for Toprol XL?
A. Yes.
Q. Were you involved in the decision to relinquish the 180-Day Marketing Exclusivity for a product called Androgel?
A. I was involved in the settlement of Androgel. As a consequence of the settlement, we forfeited our 180 days of exclusivity. That was not an agreement specifically to relinquish the exclusivity to another generic company. That's what I thought you were asking about.
Q. Okay. That's a fair distinction. Thank

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you.
With respect to forfeiting the exclusivity to Androgel, was that a decision that Watson made unilaterally?
A. I don't recall.
Q. Was the decision to forfeit exclusivity for Androgel made together with any other company?
A. I don't recall.
Q. Do you know why Watson chose to forfeit exclusivity for Androgel?
MR. SUNSHINE: Just be careful. If you can answer that from a business perspective, that's fine, but to the extent it involves legal analysis, I would instruct you not to answer that.
THE WITNESS: I think it involves legal analysis.
BY MR. MEIER:
Q. I would like to be clear. I'm definitely not trying to ask you anything today that would impinge upon a legitimate claim of privilege, and that will be true for every question I ask.
So without getting into anything that might be subject to a legitimate claim of privilege, do you have any other understanding of why Watson chose to forfeit exclusivity for Androgel?

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A. I can't answer that question without invading the privilege.
MR. MEIER: For the record, could I have a statement of what precise privileges would be claimed for that?
Are we talking about attorney-client? Attorney work product?
MR. SUNSHINE: We're talking about both attorney-client privilege and work-product doctrines.
MR. MEIER: Is there also a common interest privilege claim in there?
MR. SUNSHINE: Common interest, I think, is not a privilege. Common interest is just a question who owns the privilege. So I'm asserting this privilege on behalf of Watson.
BY MR. MEIER:
Q. And I understand you're going to refuse to answer my question on the basis of the privilege?
A. Yes, I will follow my counsel's instruction.
MR. SUNSHINE: And we can stipulate that for the rest of the deposition.
MR. MEIER: Fair enough. It'll save having to ask about that, then.

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Q. With respect to negotiating an agreement to relinquish the 180-Day Marketing Exclusivity for Toprol XL, do you recall why Watson chose to do that?
A. Watson was in a position where it would effectively lose its exclusivity prior to the date we thought we would be able to take advantage of it with our own ANDA.
Q. Can you explain more about that?
A. My recollection is that Watson had exclusivity on patents that were subject to expiration that would have rendered the value of our exclusivity zero if we didn't extract value out of the exclusivity prior to the patent expiree. We didn't know whether we would be able to launch our own product prior to the date of expiration of those patents.
Q. Who did Watson actually agree with to relinquish the 180-day exclusivity for Toprol?
A. Sandoz.
Q. That's another generic company?
A. Yes.
Q. When Watson relinquished --
MR. SUNSHINE: I just want to clarify the record. There is an agreement; as you know, it's

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been reported to the FTC, but the relinquishment, I believe, as legal matter, is a unilateral relinquishment. I just don't want to create any confusion.
MR. MEIER: Okay. Okay.
Q. You agreed with Sandoz that you would do it, but you unilaterally actually filed with the FDA?
A. Yes. We didn't selectively waive. We unilaterally relinquished our exclusivity.
We also had an agreement with Sandoz that provided us with a royalty on their sales.
Q. Can you take me through the business analysis and steps that Watson considered in deciding to relinquish the exclusivity with respect to Toprol? How did that decision get made?
A. I think I just explained it. The business analysis was, we hold an exclusivity. When do we think the exclusivity will expire? Do we think we'll be able to get approval and launch our own product prior to that date? And, if not, is there a way to monatize the asset prior to the time that it loses its value.
Q. I believe you indicated that in return for agreeing to relinquish the 180 days, Sandoz paid you

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some royalties?
A. Yes.
Q. And that was royalties on the sale of Toprol?
A. That's my recollection.
Q. What was the effect of Watson relinquishing the 180 days on Toprol for Sandoz? What was the advantage to Sandoz?
A. Sandoz was able to launch its product. It would have otherwise been blocked by our exclusivity.
Q. Do you know how much money Watson made as a result of agreeing with Sandoz to relinquish the 180-Day Marketing Exclusivity?
A. No.
MR. MEIER: Could I have this marked for the record as Exhibit 1, Buchen Exhibit 1.
(Buchen Exhibit 1 was marked for identification.)
BY MR. MEIER:
Q. Could you take a look at what's been marked as Buchen Exhibit 1. It may look familiar to you once you've had a chance to look at it.
While you're looking at it, I'll read into the record what it appears to be.

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The first two pages appear to be a letter from Skadden, Arps law firm, dated June 10, 2009, the second page signed by attorney Maria A. Raptis; and attached to it appears to be a number of pages of a Watson Pharmaceuticals, Incorporated Response to Civil Investigative Demand, File No. 061-0182, also dated June 10, 2009.
At this point, I'm only going to ask you about the response to specification No. 8, which is essentially some of what we've been talking about here for the last few minutes.
A. I see it.
Q. Do you see in the response there's a discussion of Toprol XL?
A. Yes.
Q. And do you see item C there where it says "Approximately $47.5 million"? Do you see that?
A. I do.
Q. And if you look at the top of the page, the actual specification itself, item C, says, "The revenues or profits Watson made as a result of relinquishment."
Do you see that?
A. Yes.
Q. Does this help refresh your recollection as

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to what Watson made as a result of agreeing with Sandoz to relinquish the 180-Day Marketing Exclusivity for Toprol?
A. Yes.
Q. And sitting here today, do you have any independent recollection as to whether $47.5 million sounds about right?
A. It sounds about right.
Q. Does Watson still make money on royalties related to Toprol XL, generic Toprol, today?
A. No, not to my recollection. I think we could, but we are not because Sandoz ran into manufacturing problems and hasn't been selling the product.
Q. After discussion of Toprol, you see it says, "On behalf of Andrx, Watson provides the following responses"?
A. Yes.
Q. And it lists the products Prilosec, Wellbutrin and Monopril in the next page?
A. Yes.
Q. Other than what's here, were you involved in any way with any agreements involving the agreement to relinquish 180-Day Marketing Exclusivity for those three products -- Prilosec,

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Wellbutrin or Monopril?
A. If I understand your question, are you asking whether I was involved with the relinquishment for these products?
Q. That's what I meant to say, although you said it better than I did.
A. I was not involved. This is prior to the time Andrx was a subsidiary of Watson.
Q. Okay. Thank you.
Still looking at Buchen Exhibit No. 1, specification No. 8, let's go back to the entry there, the answers for Androgel.
Do you see that?
A. I do.
Q. And you see item D says, "Settlement of the Androgel patent litigation"?
A. Yes.
Q. And if you look up at the instruction, the instruction asks for -- D said, "The reasons for Watson's decision to relinquish."
Do you see that?
A. Yes.
Q. How was Watson's decision to relinquish the 180-Day Marketing Exclusivity for Androgel related to the settlement of the Androgel patent litigation?

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MR. SUNSHINE: I'm going to instruct Mr. Buchen not to answer that question.
BY MR. MEIER:
Q. Independent of any information you have as a result of discussions that may be protected by legitimate claim of privilege, do you have any understanding of that?
A. My recollection is part of the settlement.
Q. Could you explain part of -- how was it a part of the settlement? What way?
MR. SUNSHINE: Again -- and I don't mean to be difficult, but obviously we're in litigation with the FTC over this. That provision is incorporated in the settlement agreement. Obviously, the FTC has the settlement agreement. The settlement agreement speaks for itself.
If you have a question that goes beyond what is the settlement agreement, say, that you think is a business question, go ahead and try to ask it. But if you are going to get into the analysis of why it's there, that's where we're going to draw the line.
BY MR. MEIER:
Q. Well, I'll take Mr. Sunshine's invitation and ask you whether you understand a business reason

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other than the legal strategy.
A. I think I answered that before. I can't respond without getting into areas of privilege.
Q. Are you familiar with a pharmaceutical company called Carlsbad?
A. Yes.
Q. And is it correct that Watson has a development and supply agreement with Carlsbad with respect to the development of a generic Provigil product?
A. Yes.
Q. Is it correct that Carlsbad actually filed the Abbreviated New Drug Application for generic Provigil?
A. Yes.
Q. And as a result of Carlsbad filing the ANDA for Provigil, it was sued by Cephalon?
A. Yes.
Q. Is it also correct that Watson bears the cost of any litigation resulting from the filing of the generic Provigil ANDA by Carlsbad?
A. Yes.
Q. Is it also correct that, under the agreement with Carlsbad, Watson controls the litigation and incurs the litigation expenses?

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A. Yes.
Q. Under the agreement with Carlsbad, Watson also has the right to determine whether to litigate or whether to settle?
A. Yes.
Q. Did there come a time when you heard about a patent that's referred to as the '346 patent that Cephalon had filed for Provigil with the FDA?
A. Yes.
Q. How did Watson find out about the listing of the '346 patent?
A. We found out about the listing of the '346 patent when it was listed.
Q. Did Watson have any conversations with Carlsbad regarding making certification to the '346 patent?
A. Not that I'm aware of.
Q. As between Watson and Carlsbad, whose decision was it to file a supplemental ANDA for the '346 patent?
A. That would have been Watson's decision.
Q. Why did Watson choose to file certification to the '346 patent?
A. It would be a regulatory requirement for us to certify to the patent in order to obtain approval

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of the ANDA.
Q. Do you know, as between Watson and Carlsbad, who actually made the filing?
A. Watson would have provided the certification or the notice letter, and Carlsbad would have provided the certification to the FDA as the ANDA holder.
Q. If I understand it correctly, the distinction you are making is that Carlsbad would have filed the certification with the FDA?
A. Yes.
Q. And Watson filed the notice letter to Cephalon?
A. Watson, through outside counsel, would have provided notice to Cephalon, if I'm remembering correctly.
Q. Did Watson do any financial analysis of the benefits of filing a supplementary paragraph 4 certification for the ANDA with respect to the '346 patent?
A. Not that I'm aware of.
Q. Did Watson know it was the first to file on the '346 patent when it made its certification to the FDA?
A. We knew we filed on the first day the

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patent had listed. As I sit here, I still don't know whether we're the only ones who filed on the first day.
Q. Sitting here today, what is your understanding of any advantage or benefit that Watson might have with respect to getting first filer status on the '346 patent when Watson did not have first-to-file status with regard to the '516 patent?
A. Because we were late on the '516 patent -- and maybe I should preface it by asking you to agree, when I talk about what we did, I'm referring to Carlsbad and Watson.
Q. Yes.
A. Okay. We were late on the '516 patent, so we would be prevented from launching until 180 days after the first wave of filers who all were tied for first on the '516 patent.
If we were able to be the only first filer on the '346 patent, we would then, effectively, be blocking those four first filers as a result of our first-to-file status on the later-listed patent. And therefore, as my understanding of the FDA regulations, we would have shared exclusivity, and we would then be in the position where we would be

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able to launch the product on the same day as the other four first filers, rather than waiting six months.
Q. Prior to Cephalon actually listing the '346 patent in the FDA Orange Book -- and that's capital "O," capital "B" -- start that again then.
Prior to Cephalon actually listing the '346 patent in the FDA Orange Book, did Watson have any communications with Cephalon about the plans to list the '346 patent?
A. No, not that I'm aware of.
Q. Other than the notice Watson submitted to Cephalon informing Cephalon of the supplemental ANDA with the paragraph 4 certification on the '346 patent, did Watson have any communications with Cephalon about filing a supplemental ANDA?
A. Not that I'm aware of.
Q. Has Watson had any communications with Cephalon about getting first-filer status for the '346 patent?
A. No.
Q. Has Watson had communications with anyone else about the listing of the '346 patent?
A. Yes.
Q. Okay. Who else has Watson had

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communications with about the listing of the '346 patent?
A. Apotex.
Q. Other than Apotex, has Watson had any communications with anyone else about its filing on the '346 patent?
A. Yes.
Q. Who else?
A. Federal Trade Commission.
Q. Anybody else come to mind?
A. Skadden, Arps.
Q. Anybody else?
A. Frommer, Lawrence & Houg.
Q. Anybody else?
A. Not that I can think of.
Q. Do you know whether Watson has had any other communications -- I'm sorry.
Do you know whether Watson has had communications with other pharmaceutical companies other than Apotex or Carlsbad about its certification on the '346 patent?
A. We have not, to my knowledge, had any communications with other pharmaceutical companies.
Q. You've indicated that Watson has had some communications with Apotex regarding the filing on

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the '346 patent; correct?
A. Yes.
Q. Do you know who those communications were with?
A. I believe all of the communications were with me.
Q. And who from Apotex?
A. Shashank Upadhye.
MR. MEIER: We'll give you that spelling on a break.
THE REPORTER: Thank you.
MR. MEIER: It's a tough one.
Q. Anybody else at Apotex?
A. No.
Q. Do you recall roughly when those communications took place?
A. Yes.
Q. Can you give me roughly the time frame?
A. Roughly March through early May, late April.
Q. Of what year?
A. 2009.
Q. Do you remember what form these communications took place? I mean in person? Telephone? E-mail or other means?

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A. They were telephonic and through e-mail.
Q. Did you ever meet with Mr. Upadhye?
A. No.
Q. But you had conversations on the telephone with him?
A. Yes.
Q. Do you recall roughly how many telephone conversations?
A. Less than five.
Q. Other than telephone conversations and e-mails, did you have any other form of communication with Mr. Upadhye regarding a potential business deal for generic Provigil?
A. No.
Q. During the discussions with Apotex concerning a potential business deal for generic Provigil, did you discuss the possibility of relinquishing any eligibility Watson may have for a 180-Day Marketing Exclusivity for Provigil?
A. Yes.
Q. What do you recall about those conversations?
A. Shashank contacted me and said the purpose of the call was to discuss whether Watson was interested in potentially agreeing to selectively

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waive or relinquish its exclusivity on the '346 patent.
Q. Do you recall what your response was to that invitation from Apotex?
A. I said we would be willing to listen and hear what Apotex had to say.
Q. Did there ever come a time when there were any specific proposals made by either Watson or Apotex regarding a business deal?
A. I don't understand what you mean by "specific proposals."
Q. I mean something more than just conceptually; more than just the concept of "would you be interested in waiving"?
A. In terms of how the arrangement would be structured, what the economics would be, there were no such discussions. We never got to that point.
Q. Why didn't you get to that point?
A. Watson was evaluating the entire situation and whether or not it would make sense to enter into a transaction of the general nature that Apotex had proposed, and we were still conducting that evaluation when we received the investigative demand from the Federal Trade Commission, and at that point all of our discussions with Apotex stopped.

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Q. Do you believe that, but for the FTC's investigation of this, Watson may have continued to have discussions with Apotex about possibly doing a business deal for generic Provigil?
A. Yes.
Q. You indicated that Watson was evaluating whether it made sense. Can you describe for me some of the steps Watson took to evaluate that from a business standpoint of whether it would make sense to do a deal with Apotex?
A. We would consider the likely market scenario, in the event of our relinquishment, versus the likely market scenario in the event we did not relinquish.
Q. Did Watson actually do an analysis of the likely market scenario with relinquishment versus the likely market scenario without relinquishment?
A. No.
Q. Can you tell me how far did Watson actually do an analysis of likely market scenarios, what steps were actually taken?
A. It was preliminary.
Q. Who was involved in those preliminary steps to look at likely market scenarios?
A. I was primarily involved.

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Q. You say you were primarily involved. Who was involved?
A. I was really the one doing the analysis, and when I say "analysis," I use the term loosely. There was no formal analysis done. It was more consideration of the relevant market entrance; what the status of their applications were, and how it would play out if we were to relinquish.
There was also -- I had some discussions about it with Shashank, and he shared his thoughts.
Q. Did you ever reduce any of that thinking to writing?
A. No.
Q. Did you make any notes?
A. I made notes of one conversation. The initial conversation I had with Shashank, but I don't believe these matters came up during that conversation.
Q. If I understand correctly, then -- and please correct me if I'm wrong -- this preliminary analysis you did occurred mostly in your head?
A. Yes; I would say entirely in my head.
Q. And this was based on your many years' experience as an executive in the pharmaceutical business?

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A. Yes.
Q. At any time, with respect to going through this preliminary analysis, did you ask anybody at Watson to do any kind of research for you looking into the status of other potential generic companies; things like that?
A. No. I was able to do that myself. It's very simple. You go onto the FDA Web site and you look and see who has tentative approval.
Q. And is that what you did?
A. Yes.
Q. Beyond looking at the FDA Web site to do tentative approval, did you do any other research on your own?
A. I had some conversations with Shashank that I just mentioned, but I don't recall any other independent research.
Q. So other than those conversations with Shashank and going onto the FDA Web site, do you recall doing any other kind of work with respect to informing yourself about likely market scenarios?
A. I don't recall doing any other work. This was really not a high priority.
I viewed this as a small-market potential transaction, and there were a lot of other things

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going on in the company that were more important.
Q. Did you have any conversations with Watson's CEO, Paul Bisaro, about your communications with Apotex regarding a possible business deal for generic Provigil?
A. I informed Mr. Bisaro of the call I had received from Apotex.
Q. This would be the initial call that you got from Apotex?
A. I don't recall if it was the initial call or the second call. Somewhere in there.
Q. Did you have any other conversations or communications with Mr. Bisaro about a possible business deal with Apotex regarding generic Provigil?
A. Yes.
Q. Can you tell me about those?
A. I informed Mr. Bisaro when we received the investigative demand.
MR. SUNSHINE: I just want to make sure -- you're talking about when the conversations occurred, and that's fine; I just want to be very careful.
MR. MEIER: That's fine.
Q. And you should keep that in mind and, of

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course, you're a lawyer, so you understand this well.

And again, I'm asking about business strategy questions and things that aren't necessarily related to your legal counsel.

MR. SUNSHINE: Can we have a standing instruction with respect to his conversations with Bisaro?

MR. MEIER: And please, you know, you will feel free to remind your witness of that, and I'll feel free to remind you that that's not what I'm looking to ask about.

MR. SUNSHINE: Okay.

THE WITNESS: I understand.

BY MR. MEIER:

Q. Roughly how many conversations or communications of any kind did you have with Mr. Bisaro regarding the possible deal with Apotex?

A. I don't recall specifically. Again, I'd say it's fewer than five.

Q. Other than your communications with Mr. Bisaro about a possible business deal with Apotex regarding generic Provigil, did you have conversations with or communications with anybody else at Watson about that?

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A. I don't recall any other conversations.

Q. Do you recall any other communications?

A. No.

Q. During the period that you were talking with Apotex -- which I think you indicated was roughly March to May of 2009 --

A. Yes.

Q. -- as you were considering likely market scenarios in your head, did you ever do any kind of financial analysis in your head about the possibility of what it would be like to do a deal with Apotex to relinquish now versus holding onto the exclusivity to 2012?

A. No, because we never got to terms with Apotex; so it would not have been meaningful to do any sort of financial analysis.

Q. But for the FTC's investigation, do you think you might have come closer to having discussions with Apotex about terms?

MR. SUNSHINE: I'm sorry. I think that question was confusing. Would you mind restating that?

MR. MEIER: Why don't we read it back, and then I'll hear it, and see if I can make it better.

(Record read.)

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BY MR. MEIER:

Q. Do you understand the question?

A. I think I understand the question.

Q. Okay.

A. I don't know the answer. I think we would have continued talking to Apotex but for the FTC investigation.

Q. Why did Watson decide not to pursue a business deal with Apotex to relinquish any exclusivity Watson might have for the '346 patent?

A. We never made that decision.

Q. Has Watson had any prior experience doing business with Apotex?

A. No.

Q. Did Watson ever have any communications with Carlsbad about Apotex's approach to Watson about possibly doing a business deal involving generic Provigil?

A. No.

Q. Why not?

A. Watson would control that decision.

Q. Did Watson ever have any communications with Cephalon about a potential deal with Apotex to relinquish any exclusivity Watson might have for the '346 patent?

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A. There was a conversation among our outside counsel; there was never any conversation between anybody inside Watson and anybody at Cephalon.

Q. Other than your outside counsel and Apotex, did Watson ever have any communications with anyone else about a possible deal with Apotex?

A. Other than the FTC, no.

Q. Has anyone at Watson ever done any analysis on how much money Watson potentially could make by relinquishing its 180-day exclusivity for the '346 patent and then entering upon its own?

A. No.

Q. Has Watson ever considered entering into an arrangement with another pharmaceutical company to relinquish any 180-Day Market Exclusivity it might have related to the '346 patent?

A. No.

Q. Has Watson had any communications with any other pharmaceutical company regarding the relinquishment of any 180-Day Marketing Exclusivity it might have related to the '346 patent?

A. No.

MR. MEIER: We've been going for about an hour. Do you want to take a break?

(Brief recess.)

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BY MR. MEIER:
Q. Has Watson entered into any agreement that restricts, in any way, Watson's ability to relinquish its eligibility to claim 180-Day Marketing Exclusivity for generic Provigil?
MR. SUNSHINE: I would just instruct you to answer that, if you can, without disclosing any of your internal legal analysis or any privilege or advice that you may have either thought yourself or received from others.
THE WITNESS: The factors that we were considering when we were deciding whether to do a deal with Apotex did not have anything to do with any agreements that may or may not relate to the '346 patent.
From a business standpoint, I think that's the best way I can answer your question.
BY MR. MEIER:
Q. Can you pull out Exhibit 1 again, and can we look at specification No. 3, and could you take a moment to read that to yourself, the questions and then the answers.
A. Okay.
Q. Did you have any role in helping to draft the responses to the CID that is contained in

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Exhibit No. 1?
A. Yes.
Q. Were you involved in drafting the response to specification No. 3?
A. Yes.
Q. Sitting here today, do you believe that the settlement agreement that Watson has with Cephalon regarding Provigil that was entered in August of 2006 in any way prohibits, blocks, prevents, compromises or limits Watson's ability to relinquish the eligibility claim to 180-Day Market Exclusivity for generic Provigil?
MR. SUNSHINE: I want to give the same instruction we gave before, but to the extent you can answer that from a business perspective --
THE WITNESS: I think, from a business perspective, I can understand how it would relate to the waiver, and maybe I can -- do you want me to explain?
BY MR. MEIER:
Q. Yes.
A. Apotex approached Watson and asked us if we would be interested in entering into a transaction to forfeit our exclusivity.
I believe, prior to that, the FTC contacted

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our counsel, outside counsel, and told our outside counsel that the Federal Trade Commission was interested in Watson forfeiting its exclusivity, and that they wanted to know whether Apotex could contact Watson.
And, as a consequence of Apotex asking us to do a deal, and the Federal Trade Commission telling us that there was a possible investigation about the transaction, the investigation was launched, and the investigation is ongoing, and I'm being deposed, and we're being indemnified by Cephalon under this agreement.
So that's how they relate.
Q. I would like to go back to my question as to whether -- I'm asking whether, sitting here today, you have an understanding that the 2006 agreement with Cephalon, settling the Provigil litigation, prohibits, blocks, presents or limits in any way, prevents or limits in any way Watson's ability to relinquish the 180-day marketing exclusivity claim for generic Provigil.
MR. SUNSHINE: Let me just stop you right there. You are asking for a lawyer's analysis of a legal agreement. You have the agreement. You have his discussion of the business considerations in his

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calculus, but I'm going to instruct him not to provide you with his legal analysis.
BY MR. MEIER:
Q. I'm going to ask a couple more questions about this.
A moment ago, you were explaining about an understanding you have about what the FTC said to your counsel.
A. Yes.
Q. Was that based on a conversation you had with your counsel?
A. It's based on a conversation that my counsel had with the FTC, which he reported to me.
Q. So your answer is based on conversations you had with your outside counsel?
A. It's conversation my outside counsel reported to me about a conversation he had with the FTC.
Q. You didn't have -- at that point, you didn't have direct conversations with anybody from the FTC; correct?
A. That's correct.
Q. And the outside counsel who had those communications with you is Steve Sunshine?
A. Yes.

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Q. The same Steve Sunshine who is sitting here today?
A. The very same.
MR. SUNSHINE: There is another one.
THE WITNESS: He's a partner at Bryan Cave.
BY MR. MEIER:
Q. Let's take a look at the Buchen Exhibit No. 1, response to specification No. 3, the second full paragraph.
A. I see it.
Q. I'll just start to read it.
It says, "Expressly reserving, and without waiving, this objection, attached to the specification as Exhibit 3-1 is a copy of the settlement and license agreement dated August 2, 2006 by and amongst Cephalon, Incorporated, Cephalon, Watson Pharmaceuticals, Incorporated, Watson and Carlsbad Technology, Incorporated, Carlsbad. This agreement may relate to Watson or Carlsbad's ability to relinquish eligibility to claim 180-Day Marketing Exclusivity for generic Provigil."
Do you see that?
A. I do.
Q. Do you know what provision or provisions in

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the agreement may relate to Watson's or Carlsbad's ability to relinquish eligibility to claim 180-Day Marketing Exclusivity for generic Provigil?
MR. SUNSHINE: Can I have a clarification before I object. Are you asking him for a legal analysis of --
MR. MEIER: No. I'm asking him if he understands what part of the agreement might relate to it.
THE WITNESS: The indemnification provision might relate to the investigation.
BY MR. MEIER:
Q. In addition to the indemnification provision, any other provisions?
MR. SUNSHINE: Again, I think at this point you're asking a lawyer for his analysis of the -- of a legal agreement. I don't think you are entitled to get that in a deposition context.
MR. MEIER: I'm trying to understand this answer better because it's really quite vaguely drafted, and that's my objective.
Q. You have given us a partial answer here; you've given us a suggestive answer here.
If I take literally Mr. Sunshine's objection, then I don't think you should have even

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given us this answer. I don't see how you could have given us this answer without waiving some attorney thinking.
So I'm trying to understand what this -- what does this answer actually mean?
MR. SUNSHINE: Well, let me stop there because I think you are making some statements there that we don't agree with.
You have a copy of the settlement agreement; you're entitled to have a copy of the settlement agreement. It's something else to say how is that legally analyzed.
MR. MEIER: That's fair enough, but -- you can make your record; I'm making my record.
Q. The next sentence says, "Any relevant limitations or restrictions are contained therein."
Do you see that?
A. I see that.
Q. Are there any specific provisions within that agreement that are relevant to the questions that we've asked in specification 3 of the CID?
MR. SUNSHINE: Same instruction.
BY MR. MEIER:
Q. And I take it you are going to follow your lawyer's instructions not to answer if he instructs

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you not to answer?
A. Yes.
Q. In response to my previous question before you refused to answer my question, you indicated that the indemnification provision of the 2006 agreement with Cephalon may relate to Watson or Carlsbad's ability to relinquish eligibility to claim 180-Day Marketing Exclusivity for generic Provigil; correct?
A. Yes.
Q. Can you explain how the indemnification provision may relate to Watson or Carlsbad's ability to relinquish eligibility to claim 180-Day Marketing Exclusivity?
MR. SUNSHINE: Be careful in disclosing only what's publicly known.
THE WITNESS: I think it may relate because that's the basis of your investigation, and our entitlement to have Cephalon pay our legal fees in connection with this investigation is a consequence of that agreement.
MR. MEIER: Can you read back that answer, please.
(Record read.)
BY MR. MEIER:

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Q. I generally don't understand that answer.
Is there any way you can explain that better? I really -- I don't even know how to break it down, because I don't understand it.
A. I'll try.
MR. SUNSHINE: I won't object to the form of that question.
THE WITNESS: The Federal Trade Commission is investigating our decision, or lack of decision, to waive our exclusivity on the '346 patent. We're entitled to indemnification by Cephalon in connection with this investigation
The 2006 settlement agreement is the document which entitles us to indemnification and requires Cephalon to pay our legal fees in connection with this investigation.
That's the best I can do.
BY MR. MEIER:
Q. Since I can't remember exactly how I asked these questions before, I'm going to have to ask it one more time.
Does Watson's 2006 settlement agreement with Cephalon prohibit, block, prevent, compromise or limit in any way Watson or Carlsbad's ability to relinquish eligibility to claim 180-day marketing

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exclusivity for generic Provigil?
MR. SUNSHINE: Same instruction.
BY MR. MEIER:
Q. This instruction not to answer -- you are not going to answer that?
A. Yes, and I think you did ask it before.
MR. SUNSHINE: The instruction was not simply "don't answer that."
MR. MEIER: I apologize if I didn't characterize your instruction correctly.
Q. Has Watson had any discussions with Cephalon about whether the August 2006 settlement agreement prevents Watson from relinquishing any 180-day Marketing Exclusivity it might have related to the '346 patent?
A. I have not had any conversation with anyone about that issue.
Q. Do you know if anybody else at Watson has had any conversations with Cephalon about that issue?
A. I don't think anyone within Watson has talked to Cephalon about this at all.
Q. During the negotiations that Watson had with Cephalon leading up to the 2006 settlement agreement, do you know whether there was any

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conversations between Watson and Cephalon about whether such an agreement would include language that would prohibit Watson from relinquishing any 180-day marketing exclusivity claim it might have?
A. Not that I'm aware of.
Q. You indicated not that you are aware of. Is there anybody else in the company that might know that?
A. I don't think so. I think I would be aware of such communication, and I'm not.
Q. I know you've given the FTC some prior testimony about the settlement with Cephalon in the investigational hearing in 2007, so I'm going to try to move through this pretty quickly, but I need to flesh out a few more details.
Why did Watson settle the patent litigation with Cephalon in August 2006?
MR. SUNSHINE: Again, answer that just to the extent you can do it without disclosing any privileged information.
THE WITNESS: I think the fact that we were late and the fact that the other first filers had settled made us realize there was no point in continuing to pursue the litigation and that it was going to get very expensive for us if we did without

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any real benefit.
BY MR. MEIER:
Q. In the August 2007 investigational hearing -- I'd be happy to pull that out if it helps -- you testified that there would be no economic incentives for Watson to continue to litigate.
A. That's generally what I just said, yeah.
Q. Right, exactly.
What was the basis for concluding that Watson had no economic incentive to continue the litigation?
A. Most of the expense associated with challenging the patent was being borne by the first filers.
Watson, as a late filer, had not spent a lot of money or effort on litigation. Once the first filers settled their lawsuits, it would have been Watson that would have had to spend all the time and effort and money challenging the patents, and even if we had prevailed, we still would have been blocked by the first filer's exclusivity.
Q. Was part of the basis for the conclusion that there were the potential to face numerous other generic competitors?

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A. Part of it was that.
Q. Did Watson do any analysis of whether it would have made economic sense had there been fewer generic competitors?
A. I don't know. If I testified to that in my 2007 hearing, then --
Q. No. This is -- the first part was to lead up to that. This was the new part.
A. Sorry to disappoint you.
Q. Just trying to find out; just trying to understand.
A. Sure.
Q. I believe earlier today there was some indication that Watson's business strategy was that it wanted to make sure it would settle on terms that would, as nearly as possible, put Watson in no worse position than other generic applicants.
Do you recall that?
A. I do.
Q. Do you recall whether Watson had access to at least some of the other first filers' settlement agreements when it was negotiating its settlement with Cephalon?
A. Yes.
Q. So Watson knew at least some of the other

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generic settlement agreements with Cephalon?
A. We knew some of the terms of some of the other settlers.
Q. Do you know, sitting here today, whether Watson's business strategy was successful in terms of getting a deal that made it no worse than the other settling generics?
A. I don't know.
Q. Sitting here today, does Watson anticipate making money selling generic Provigil in the future?
A. I don't know that we've conducted that analysis at the senior management levels to make that assessment. It will depend on market conditions at the time we're eligible to launch.
Q. Sitting here today, when is the earliest that you would understand that Watson could launch, assuming nothing else changes between now and into the future?
A. The earliest we could launch, depending on how many, if any, other filers there were on the '346 patent, would be April of 2012.
Q. You indicated Watson hasn't done any projections or financial analyses at the senior management level.
Do you know whether Watson has done any

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projections, financial analyses, at lower levels about whether it expects or anticipates making money selling generic Provigil in the future?
A. I think, as part of the ordinary course, our generic line people do projections for most of our products, and that Provigil generic was one of them.
I'm aware that we produced some forecasts that were generated by what I would call, you know, mid-level, low-level management as part of the ordinary course of business.
Q. Is that a group headed by somebody named Andy Boyer?
A. Yes.
Q. That's the generic sales and marking group?
A. Yes.
Q. Have you ever heard of a product called Nuvigil?
A. Yes.
Q. Do you know what Nuvigil is?
A. It's a follow-on product to Provigil.
Q. Are you aware of whether or not Cephalon has launched Nuvigil in the United States?
A. My understanding is they launched it very recently.

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Q. Do you have any understanding of what Cephalon's strategy is with respect to Nuvigil; how it intends to position it in the market?
A. No.
Q. Have you heard anything about Cephalon's intentions to try to shift as much of the Provigil market to Nuvigil? Have you heard about that?
A. Yes.
Q. What do you understand about that?
A. Shashank mentioned that to me during one of our conversations.
Q. Other than the conversation with Shashank, do you have any awareness of whether Cephalon has an intent to try to shift the Provigil market to Nuvigil?
A. I don't have any specific information about that product.
Q. Is it correct that, using terminology in the generic industry, that Nuvigil is a follow-on product? Is that a term that's typically used?
A. Yeah. I think I actually used that in an answer a minute ago.
Q. Has Watson had any experience where it launched a generic product following the brand's launch of a follow-on product?

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A. Yes.
Q. What was that experience? Can you tell me the product and what was the experience when you launched a generic in the face of a follow-on brand of products?
A. There are several. It's a very common practice among big pharma to go through life-cycle-management activities so they will introduce follow-on products when an earlier product loses patent protection; for example, an immediate-release product will be replaced with a sustained-release product; a sustained-release product will be replaced an extended-release product.
Q. In your experience, what impact does that typically have when you launch your generic product in the face of a follow-on brand of product?
A. It depends on the success of the follow-on product.
Q. Let's assume the follow-on product is reasonably successful, 50 percent market share shift.
What is your experience with launching generic?
A. The generic erodes the remaining 50 percent of the original product.

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Q. Has Watson made any projections or analyses concerning future generic Provigil sales, taking into account the presence of Nuvigil in the market?
A. I think there were some assumptions made in those forecasts that I mentioned a moment ago that were done by Andy Boyer's group, but I don't think anybody within senior management has conducted any analysis of that.
Q. Are you aware that Teva, Barr, Mylan and Ranbaxy were first filers on the '516 patent for Provigil?
A. Yes.
Q. Have you heard anything about whether the four filers on the '516 patent have or will relinquish their first-to-file rights?
A. Yes.
Q. How did you hear that?
A. Shashank told me.
Q. Other than Shashank telling you that, have you heard that in any other forum or in any other way?
A. Can I -- I need to confer with my counsel.
(Recess taken from 11:32 a.m. 11:39 a.m.)
BY MR. MEIER:
Q. Maybe we can -- I don't know if you want to try to answer the question or give an explanation, or do we want to read the question back that prompted the break?

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(Record read.)
THE WITNESS: I heard from my counsel that the FTC said that they had secured agreements to forfeit the exclusivity from the other four first filers.
BY MR. MEIER:
Q. Okay. So other than Shashank and your counsel, have you heard that from any other source?
A. Any other conversations I had about that would be in the context of attorney-client privileged communications for the purpose of giving advice.
Q. Have you had any conversations with Cephalon about whether the four first filers on the '516 patent have or will relinquish their first-to-file rights?
A. No.
Q. Have you had any discussions with Teva about whether it would relinquish its first-to-file rights?
A. No.
Q. Have you had any discussions with Mylan about whether it would relinquish its first-to-file rights?

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A. No.
Q. Have you had any discussion with Ranbaxy about whether it would relinquish its first filer rights?
A. No.
Q. Have you heard one way or the other whether Cephalon has plans to sue or has sued any of the first filers for relinquishing their exclusivity rights?
A. I believe they made public, in pending litigation, that they would not.
Q. Where did you hear that or see that?
A. I think it's in the Pennsylvania litigation. It's in pleadings in the Pennsylvania litigation that Cephalon is taking the position that it would not view forfeiting the first-filer status as any violation of their agreements with those parties.
Q. Do you know whether Cephalon takes that same position vis-a-vis the settlement it has with Watson?
A. I have no -- I've had no conversations with them on that subject.

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Q. Other than any conversation, do you know in public filings or statements Cephalon has made whether it would take the same position vis-a-vis Watson in the settlement agreement that you entered in 2006?
A. I have no information at all on whether or not they would, other than my own speculation based upon what the position was with respect to the other first filers.
Q. Are you aware of the fact that Teva had acquired Barr?
A. I'm well aware of that.
Q. Based on your 10-plus years of experience in the generic industry, would you expect Teva to launch two generic Provigil products when it is legally allowed to enter the market with generic Provigil?
A. I would not.
Q. Are you aware of Ranbaxy's current difficulties before the Food and Drug Administration?
A. General.
Q. What generally do you know about that?
A. Ranbaxy is having problems with the FDA with respect to both good manufacturing practices

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issues and possible assembly product development; laboratory issues.
Q. Do you know whether Ranbaxy's difficulties with the FDA affect Ranbaxy's ability to launch a generic Provigil product in the United States today?
A. No, I don't.
Q. Do you know whether Teva or Mylan are prepared, from a manufacturing and distribution standpoint, to launch generic Provigil today?
A. No.
Q. Do you know what it would take for Teva or Mylan to be prepared to do so?
A. As a matter of my general pharmaceutical knowledge?
Q. Yes.
A. Yes.
Q. Okay. What would it take for Teva or Mylan to be prepared to do so?
A. I don't know what their level of preparation is today. Are you asking generally what does a pharmaceutical company have to do --
Q. Let me ask it in a better way, then.
If Watson and Carlsbad were legally able to enter the market with generic Provigil today and they decided to do so, what would it take to be

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ready to do so?
A. When you say "legally able," do you mean we had final approval from the FDA?
Q. Final approval, there was no legal impediment of any kind.
A. We would validate the product, and we would launch.
Q. Do you know how long it would take Watson to do that under those circumstances?
A. No.
MR. SUNSHINE: I just wasn't clear what the starting line was and the finish line in that question.
MR. MEIER: If Watson and Carlsbad were legally able to enter the market with generic Provigil today and they decided to do so, how long would it take to actually have product for sale in the marketplace?
THE WITNESS: It varies from product to product, and I don't know -- with respect to modafinil, I don't know whether the manufacturing process has already been validated or whether that's something that would have to be done.
BY MR. MEIER:
Q. When you say "it varies from product to

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product," can you give me an approximate range?
A. No.
Q. Could it be as fast as a month?
A. Some manufacturing campaigns can be done in a matter of days; others, depending upon how many steps, they can take weeks.
Q. Months?
A. Months to manufacture a product?
Q. Yes, from the time you decide you get final approval to the time you are able to get it out in the marketplace.
A. It depends on whether you are having manufacturing issues or validation issues or whether it's a simple product to manufacture. So I can't give you a generalization.
I will say this is not a particularly difficult product to manufacture; based on what I know, it's a pretty simple product to manufacture.
Q. Based on it being a fairly simple product to manufacture, do you have a sense of what kind of a range of time it would take if Watson and Carlsbad were legally able to enter the market with generic Provigil today and decided to do so, how long it would take?
A. No.

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Q. Even within a range?
A. I don't know.
MR. MEIER: We can stop here for a moment.
(Brief interruption.)
BY MR. MEIER:
Q. During some of my questioning earlier, I believe you indicated -- and if I got this wrong, you'll correct me -- that you've had five or fewer communications with Mr. Bisaro about Apotex's interest in doing a business deal with respect to development of a generic Provigil; correct?
A. Yes.
Q. Other than these five or so communications --
MR. SUNSHINE: Less than five, actually.
MR. MEIER: Five or fewer or fewer than five.
Q. Other than these fewer-than-five communications with Mr. Bisaro, do you know whether Mr. Bisaro has had any other involvement in discussions with Cephalon regarding Provigil?
A. To my knowledge, Mr. Bisaro has had no communications with Cephalon regarding generic Provigil and Apotex I should say.
Q. I know this is really wide open, but I'll

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start that way, and if it's too wide, we can find a way to shrink it, but other than your fewer-than-five communications with Mr. Bisaro, do you know whether Mr. Bisaro has had any involvement with the issues we've been discussing today?
A. My understanding is that I'm the only person who has had any dealings with Apotex with respect to this issue, and the only communications Mr. Bisaro has had with respect to this issue are the fewer-than-five communications he's had with me.
I'm trying to respond as best I can.
Q. I know, and I realize the question wasn't a great one, but it was the easiest way to ask that.
Sitting here today and looking at this from a business strategy standpoint, do you believe that Watson is better off holding any exclusivity it may have on the '346 patent for the future than doing a deal with Apotex to relinquish that exclusivity?
A. I can tell you that we had not made any decisions because we never got to business terms, but my inclination -- and I was the one primarily responsible for this -- was that we were probably better off, as a business matter, preserving our exclusivity and waiting to launch the product ourselves rather than giving up our exclusivity for

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the hope of a royalty stream from Apotex.
Q. And why did you believe that?
A. My belief is that, as a business matter, Apotex would have triggered -- by its launch, would have triggered entry by a number of other generic competitors; that it would have been a crowded market, and that the royalty stream we would have gotten would have been small, and I think that, as a generic competitor, we would be in a better position launching our own product and being an active participant in the market with a timely launch, rather than the possibility of a small royalty that would, I believe, help Apotex a lot more than it would help us.
Q. Do you think Watson would be in a better position even in the face of the Nuvigil launch?
A. Yes.
Q. And what basis do you have for believing that?
A. I think -- they are different products, and again, we didn't negotiate with Apotex with respect to what portion we would get, so it's all somewhat speculative, but I think as a general business matter, I would rather launch the generic version of Provigil even if it's into a smaller market, than

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not participate in that market other than as a royalty stream in a crowded market.
Q. And what was your basis for believing that, if you did a deal with Apotex today, you would be launching into a crowded market?
A. My understanding that any launch by Apotex would allow the other first filers to launch, and that it would be a crowded market based on the number of competitors, and I think that, as a general matter, if Apotex had any sort of first-mover advantage, it would have been very limited and short in duration, and that many times, if the other entrants launch within the same quarter, that first-mover duration is eliminated -- sorry, first-mover advantage is eliminated anyway because of the way we conduct business with shelf stock adjustments and price matches that their profits, Apotex's, would have been diminished a lot by the other generic launches.
Q. Did you ever give any consideration to the possibility of doing a deal with Apotex in which you would simply be paid for relinquishing, rather than taking, a royalty stream?
A. No.
MR. MEIER: At this point, I'd offer up --

whether Mr. Sunshine has any questions he wants to ask or whether you want to clarify any of your answers.

MR. SUNSHINE: The only thing that I would request is that we get a copy of the transcript, if possible, next-day delivery in connection with a possible petition to quash the deposition of Mr. Bisaro. We think the testimony will be highly relevant to that petition.

So we would ask -- we're willing to pay the cost to the court reporter to get that transcript.

MR. MEIER: Okay. I'll take it under advisement and then get back to you on that. I know we didn't order it with one-day turn around ourselves.

MR. SUNSHINE: We're happy to pick up the difference in that price, so that shouldn't stop it.

MR. MEIER: I'm done, so we can go off the record. Thank you for your time and that's it.

(Brief interruption.)

MR. MEIER: We've gone back on the record in order to memorialize an understanding that we just reached a few minutes ago with respect to the deadline for a petition and motion to quash and the dates for setting the possible investigational

hearings of Paul Bisaro and Robert Wan, and I'll try to state it, and if I get it right we'll say it's right -- the deadline for petitions for motions to quash is set as June 29.

We've agreed to push that back to Thursday, July 2, close of business.

In that interim time, I will talk with people at the FTC about whether it's even necessary to do an investigational hearing of Mr. Bisaro and Mr. Wan, and we'll try to decide that before July the 2nd.

Additionally, we've agreed to postpone any probable investigational hearing of Mr. Bisaro and Mr. Wan to be set not earlier than sometime after July 6, but we don't have precise dates for either one of those at this time.

MR. SUNSHINE: That's correct.

MR. MEIER: Is this a fair understanding of what we've reached?

MR. SUNSHINE: That is. I think that's correct. I think it's important that we also get a copy of the transcript.

MR. MEIER: Correct. I've also agreed that we'll make the transcript available -- that the court reporter can release and sell a copy of the

transcript to you all from today's investigational hearing of Mr. Buchen, and I believe you've asked for it to be with one-day turnaround or do you still want that?

MR. SUNSHINE: I think with the schedule that we have now that the two-day turnaround is fine, so we would have it on Monday.

THE REPORTER: Yes.

MR. SUNSHINE: That's acceptable to us.

MR. MEIER: And if that's all the business, then we can go ahead and go off the record.

(Deposition concluded at 12:06 p.m.)

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CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary, I will attach on a separate sheet of paper to the original transcript.

_____
Signature of Deponent

I hereby certify that the individual representing himself/herself to be the above-named individual, appeared before me this _____ day of _____, 2009, and executed the above certificate in my presence.

_____
NOTARY PUBLIC IN AND FOR

_____
County Name

MY COMMISSION EXPIRES:

CERTIFICATE OF REPORTER

I, TRACEY KUHLIN, CSR 7735, do hereby certify that the foregoing transcript is a true and correct record of the statements of Counsel; that I am neither counsel for, related to, nor employed by any of the parties to the action; an further, that I am not a relative or employee of any attorney or counsel employed by the partied hereto, nor financially or otherwise interested in the outcome of the action.

_____

TRACEY KUHLIN, CSR No. 7735

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION, Petitioner, v. **PAUL M. BISARO**, Respondent.	Misc. No.: 1:10-mc-00289 (CKK)

[Proposed] ORDER

Upon consideration of Respondent's Motion for an Order Compelling Petitioner the Federal Trade Commission to Respond to Respondent's Discovery Requests, Petitioner's Opposition thereto, the applicable law, and the record herein, it is hereby

ORDERED that Respondent's Motion is **DENIED**.

ISSUED this ___ day of _____, 2010.

_____
United States Magistrate Judge

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