**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| FEDERAL TRADE COMMISSION,<br><br>Petitioner,<br><br>v.<br><br>PAUL M. BISARO,<br><br>Respondent. | Misc. Action No. 10–289 (CKK) (AK) |

**MEMORANDUM OPINION**
(December 2, 2010)

Petitioner, the Federal Trade Commission, has filed this action for the purpose of obtaining an order compelling Respondent Paul Bisaro to comply in full with a subpoena *ad testificandum* issued to him on July 22, 2009 in aid of a law enforcement investigation being conducted by the Federal Trade Commission ("FTC"). This Court referred the matter to Magistrate Judge Alan Kay, who issued a Report & Recommendation recommending that the FTC's petition be granted. *See* Report & Recommendation ("R&R") (Aug. 17, 2010), Docket No. [35]. Respondent timely objected to Magistrate Judge Kay's Report & Recommendation, and the parties have fully briefed Respondent's objections. Pursuant to Local Civil Rule 72.3(c), this Court makes a *de novo* determination regarding Respondent's objections. For the reasons explained below, the Court shall overrule Respondent's objections to the Report & Recommendation and GRANT the FTC's [3] Petition for an Order Enforcing Administrative Subpoena *Ad Testificandum*.

## I. BACKGROUND

Respondent Paul Bisaro is the President and CEO of Watson Pharmaceuticals, Inc.

("Watson"), a company engaged in the development and distribution of generic pharmaceuticals. This dispute arises from the FTC's attempts to investigate and stop so-called "reverse payment" settlements between brand-name pharmaceutical companies and their generic counterparts. "Reverse payment" settlements are the result of patent infringement litigation between brand-name pharmaceuticals and generic companies who seek to enter the market with a generic versions of brand-name drugs prior to the expiration of their patent terms pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the "Hatch-Waxman Act," Pub. L. No. 98-417, 98 Stat. 1585 (1984).

The Hatch-Waxman Act enables generic drugmakers to obtain expedited approval for generic drugs and challenge the validity of brand-name drug patents by submitting an Abbreviated New Drug Application ("ANDA") with the Food & Drug Administration. *See* 21 U.S.C. § 355(j). As part of the ANDA, the applicant must submit a so-called "Paragraph IV" certification attesting that brand-name patent on which the generic drug is based is either invalid or will not be infringed by the generic drug. *See id.* § 355(j)(2)(A)(vii)(IV). The ANDA is approved immediately unless, within 45 days, the brand-name patent holder files an infringement lawsuit against the applicant, in which case approval is delayed for a period of 30 months (unless the patent expires or the patent litigation is resolved sooner). *Id.* § 355(j)(5)(B)(iii). The first generic drugmaker who files a successful ANDA receives a 180-day period of marketing exclusivity for the drug. *Id.* § 355(j)(5)(B)(iv). A "reverse payment" settlement occurs when the brand-name drugmaker pays the generic drugmaker to delay its entry into the market, effectively extending the monopoly period for the brand-name drug. The FTC believes that such payments are "unfair methods of competition" in violation of Section 5 of the Federal Trade Commission

Act, 15 U.S.C. § 45. However, most federal courts examining the issue have determined that such agreements are not unlawful so long they do not expand the scope or duration of the monopoly granted by the patent. *See, e.g.*, *In re Ciproflaxin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009).

*A. The FTC's Modafinil Investigation*

In 2006, the FTC began an investigation into settlement agreements reached between Cephalon, Inc. ("Cephalon") and five generic drugmakers, including Watson, relating to generic versions of modafinil, a narcolepsy drug that Cephalon sells under the brand-name Provigil. *See* Pet. Ex. 2 (Resolution Authorizing Use of Compulsory Process in a Nonpublic Investigation, File No. 0610182 (Aug. 30, 2006)). These generic companies had filed ANDAs challenging Cephalon's patent for Provigil (the '546 patent), and the four companies other than Watson had all filed on the same day before Watson, making them potentially eligible for first-filer marketing exclusivity. *See* Pet. Ex. 1 (Decl. of James Rhilinger, Esq.) ¶ 6. Cephalon sued all of the generic companies for patent infringement, ultimately settling these suits in 2005 and 2006. *Id.* ¶ 7. Cephalon reached a settlement with Watson and its development partner, Carlsbad Technology, Inc. ("Carlsbad"), on August 6, 2006 (the "2006 Settlement Agreement"). *Id.* ¶ 7. Under the terms of these agreements, Watson and the other companies agreed not to market generic Provigil until 2012. *Id.* The FTC filed a lawsuit against Cephalon on February 13, 2008, alleging that its agreement with the four "first filers" was unlawfully anticompetitive. *See FTC v. Cephalon, Inc.*, Civil Action No. 2:08-cv-02141-MSG (E.D. Pa. filed Feb. 13, 2008).

On December 19, 2007, Cephalon listed a new patent for Provigil (the '346 patent), and Watson and Carlsbad filed a supplemental ANDA and Paragraph IV certification as to the newly

listed patent on the same day. *See* Resp't's Opp'n, Decl. of Steven C. Sunshine ("Sunshine Decl.") ¶¶ 14-15.

*B. The FTC Reopens Its Investigation*

Although the listing of a new patent by Cephalon was a matter of public record, the FTC staff who had conducted the modafinil investigation did not learn of it until January 2009. *See* FTC's Interrog. Resp. at 3. When the FTC learned that Watson had filed a supplemental ANDA and Paragraph IV certification with respect to the new patent, the FTC realized that it was possible that Watson could have first-filer marketing exclusivity and potentially block other companies from entering the market for generic modafinil. *See id.* at 3-4. The FTC had discussions with FDA staff in January and February 2009 regarding the implications of the '346 patent and how Watson's potential first-filer status might affect the market for generic modafinil. *Id.* at 4-5.

As part of its investigation, the FTC also contacted Apotex, Inc. ("Apotex"), a pharmaceutical company that had filed an ANDA for modafinil and was selling generic modafinil in Canada. *See* FTC's Interrog. Resp. at 7. From February 2 through March 3, 2009, FTC staff had approximately four conversations with Apotex's Vice President, who is a published expert in the field of generic drug patent and FDA law. *Id.* at 7-8. The discussions focused on the following issues: (1) Cephalon's listing of the '346 patent; (2) whether Apotex had submitted to the FDA an amended ANDA containing a Paragraph IV certification as to the '346 patent; (3) Apotex's analysis of whether any first filer(s) eligible for marketing exclusivity on the later-listed '346 patent would block Apotex's ability to launch generic Provigil; (4) what it would take Apotex to launch a generic version of Provigil in the United States, assuming it was

interested in doing so; and (5) how a generic company could know the date on which a brand-name patent holder would list a later-issued patent with the FDA so that it could try to become a first-filer by submitting an amended ANDA on the same day. *See id.* at 9.

Beginning on March 2, 2009, Markus H. Meier and Saralisa Brau, Assistant Director and Deputy Assistant Director in the FTC's Health Care Division of the FTC, respectively, contacted counsel for Watson, Steven C. Sunshine, to discuss the FTC's modafinil investigation. *See* FTC's Interrog. Resp. at 9. According to Mr. Sunshine, Mr. Meier suggested that Watson should consider relinquishing any first-filer exclusivity rights associated with its supplemental ANDA for the '346 patent, and he posited several hypothetical scenarios under which Watson could profit from relinquishment. Sunshine Decl. ¶ 16. The FTC believed at this time that relinquishment could be a more profitable option for Watson than waiting to launch its generic modafinil product under the terms of the 2006 Settlement Agreement. *See* Decl. of Saralisa C. Brau ("Brau Decl.") ¶ 7. According to Mr. Sunshine, Mr. Meier telephoned him on March 13, 2009 and reiterated that Watson should consider relinquishing its marketing exclusivity and stated that failure to relinquish would likely cause the FTC "Front Office" to reopen the modafinil investigation. Sunshine Decl. ¶ 17. Mr. Meier also told Mr. Sunshine that he was in contact with a third-party generic company and inquired whether Watson would be open to communicating with them. *Id.* ¶ 18. Mr. Sunshine indicated that Watson would be interested and identified Watson's General Counsel, David Buchen, as the appropriate contact person. FTC's Interrog. Resp. at 9. The FTC then contacted Apotex's Vice President to inform him of Watson's interest and gave him Mr. Buchen's contact information. *Id.* at 10. Apotex subsequently contacted Watson to discuss a possible agreement whereby Watson would

relinquish its exclusivity to bring generic modafinil to market. Sunshine Decl. ¶ 18.

The FTC claims that it did not "broker a deal" between Watson and Apotex and that it played no further role in the discussions between the two companies. *See* FTC's Interrog. Resp. at 10. However, the FTC did periodically follow up with Apotex to inquire about the status of the discussions with Watson. *Id.* On May 6, 2009, Apotex told the FTC that discussions with Watson had stalled and that Watson did not appear to be interested in pursuing a deal. *Id.*; Brau Decl. ¶ 10. The FTC became concerned that the reason Watson was not pursuing a potentially profitable business deal was because its 2006 Settlement Agreement with Cephalon restricted Watson's right to relinquish, and FTC believes that such an agreement would be unlawful. *See* Brau Decl. ¶¶ 5-7, 11. On May 19, 2009, the FTC issued civil investigative demands ("CID") to Watson and Carlsbad and a subpoena *ad testificandum* to David Buchen. Sunshine Decl. ¶ 19. The CIDs sought 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 generic Provigil. Brau Decl. ¶ 12; Pet. Ex. 4(F) (CID issued to Watson on May 19, 2009). Watson provided responses to the CID, and David Buchen appeared before the FTC in an investigational hearing held on June 25, 2009.

The FTC issued a subpoena *ad testificandum* to Respondent on May 22, 2009, but it later withdrew that subpoena and issued a new one on July 22, 2009. *See* Pet. Ex. 3 (Subpoena *Ad Testificandum* issued to Paul Bisaro on July 22, 2009). Respondent filed a petition to quash the subpoena, and on April 2, 2010, the FTC issued an order denying the petition and ordering Respondent to appear for an investigational hearing on April 15, 2010. *See* Pet. Ex. 7 (FTC Order of April 2, 2010). On April 27, 2010, the FTC filed with this Court its Petition for an

Order Enforcing Administrative Subpoena *Ad Testificandum*. On May 22, 2010, Respondent filed his opposition to the Petition, along with a motion to compel discovery from the FTC regarding the purpose for issuing the subpoena. *See* Docket Nos. [13], [16]. This Court subsequently referred the Petition to Magistrate Judge Alan Kay for a report and recommendation.

*C. Magistrate Judge Kay's Report & Recommendation*

Before he could address the merits of the FTC's Petition, Magistrate Judge Kay had to resolve Respondent's motion to compel the FTC to produce discovery relating to its purpose for issuing the subpoena. On July 13, 2010, Magistrate Judge Kay issued a [31] Memorandum Order granting-in-part and denying-in-part the motion to compel, rejecting Respondent's request to depose Mr. Meier but compelling the FTC to answer Respondent's First Set of Interrogatories. Magistrate Judge Kay acknowledged that discovery in a subpoena enforcement proceeding is only warranted in extraordinary circumstances, but he determined that based on the facts in the record, Respondent had made a colorable claim that the FTC exceeded its authority by using its investigative power to pressure Watson into a business deal that the FTC considers desirable. *See* [31] Mem. Order at 7-9. Following this discovery, both parties supplemented the record.

On August 17, 2010, Magistrate Judge Kay issued his Report & Recommendation based on the supplemented record. Magistrate Judge Kay found that the information the FTC seeks from Respondent is relevant and not unreasonably duplicative of what it already possesses. Magistrate Judge Kay also concluded that Respondent's status as the CEO and President of Watson does not immunize him from being deposed. Furthermore, he found that although Respondent had previously made a colorable showing that the FTC had acted outside its

authority, the supplemented record did not establish that the FTC had conducted its investigation for an improper purpose, issued the subpoena to harass Respondent, or shared confidential information about Watson with unauthorized parties. Accordingly, Magistrate Judge Kay recommended that this Court grant the FTC's Petition.

On August 31, 2010, Respondent filed his Objections to the Report & Recommendation, presenting three arguments as to why the Petition should be denied: (1) an agency cannot establish a *prima facie* case for enforcement of a subpoena when the only information the agency seeks is already within its possession; (2) a court may not enforce an administrative subpoena that is issued for the improper purpose of pressuring a company to relinquish statutory rights just because there is a facially proper purpose for the subpoena; and (3) enforcement of the subpoena would amount to an abuse of process because (a) the subpoena was issued to pressure Watson to relinquish its rights in order to partner with Apotex to bring generic modafinil to market and (b) the FTC improperly shared confidential information relating to Watson with third parties to further its attempt to broker a business deal beyond its statutory mission. The FTC filed a memorandum in response, and Respondent filed a reply.

## II. LEGAL STANDARD

Like many federal agencies, the Federal Trade Commission has authority to issue subpoenas to compel the testimony of witnesses in the course of an investigation. *See* 15 U.S.C. § 49 ("[T]he Commission shall have power to require by subpoena the attendance and testimony of witnesses and the production of all such documentary evidence relating to any matter under investigation."). "It is well established that a district court must enforce a federal agency's investigative subpoena if the information sought is reasonably relevant—or, put differently, not

plainly incompetent or irrelevant to any lawful purpose of the [agency]—and not unduly burdensome to produce." *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1089 (D.C. Cir. 1992) (internal citations and quotation marks omitted). An agency's own appraisal of relevancy must be accepted so long as it is not "obviously wrong." *Id.* at 1089; *see also FTC v. Texaco, Inc.*, 555 F.2d 862, 874 (D.C. Cir 1977) (en banc) ("[T]he relevance of the agency's subpoena requests may be measured only against the general purposes of its investigation.").

The Supreme Court has found the FTC's investigatory function to be comparable to that of the grand jury, which "can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not." *United States v. Morton Salt Co.*, 338 U.S. 632, 642 (1950); *see also FTC v. Carter*, 636 F.2d 781, 786 (D.C. Cir. 1980) ("[T]he Commission is not limited by 'forecasts of probable result of the investigation,' nor is the district court 'free to speculate about the possible charges that might be included in a future complaint.'" (quoting *FTC v. Texaco*, 555 F.2d at 874-76)). A district court may "impose reasonable conditions and restrictions with respect to the production of the subpoenaed material if the demand is unduly burdensome." *Texaco*, 555 F.2d at 881. However, "[b]roadness alone is not sufficient justification to refuse enforcement of a subpoena." *Id.* at 882. "[C]ourts have refused to modify investigative subpoenas unless compliance threatens to unduly disrupt or seriously hinder normal operations of a business." *Id.* at 881.

The Supreme Court has recognized, however, that when administrative agencies seek the aid of the courts in enforcing investigative powers, courts should not permit their process to be abused. In *United States v. Powell*, 379 U.S. 59 (1964), a case involving an administrative summons issued by the Internal Revenue Service, the Court explained that "[s]uch an abuse

would take place if the summons had been issued for an improper purpose, such as to harass the taxpayer or put pressure on him to settle a collateral dispute, or for any other purpose reflecting on the good faith of the particular investigation." 379 U.S. at 58. The Court explained that the burden of showing an abuse of process is on the party challenging the agency's process. *Id.* The *Powell* Court analogized the IRS's authority to that of the FTC, and the federal courts have recognized that the "improper purpose" defense applies to investigatory subpoenas issued by other federal agencies. *See, e.g.*, *Fed. Election Comm'n v. Comm. to Elect Lyndon La Rouche*, 613 F.2d 849, 862 (D.C. Cir. 1979) (reciting the standard with respect to subpoenas issued by the Federal Election Commission).

Respondent argues that *Powell* requires an agency to establish "that the information sought is not already within [its] possession." *Powell*, 379 U.S. at 57-58. However, this requirement is best understood as originating from § 7605(b) of the Internal Revenue Code, which explicitly protects a taxpayer from being subjected to "unnecessary examination or investigations." *See* 26 U.S.C. § 7605(b). Therefore, it is doubtful that *Powell* puts the burden of proof on any agency other than the IRS to establish that the information sought is not already within its possession. Nevertheless, if it is clear that the agency already possesses the information it seeks, the Court may find the agency is abusing its process by acting in bad faith or with an improper purpose.

## III. DISCUSSION

Respondent objects to both the legal standard applied by Magistrate Judge Kay and his conclusion that the FTC issued the subpoena for a proper purpose. Specifically, Respondent argues that (1) there is no basis for enforcing the subpoena because the FTC already has the

information it seeks in its possession; (2) the FTC may not enforce a subpoena that is issued for an improper purpose even if there is also some other legitimate purpose for the subpoena; and (3) the enforcement of the subpoena would be an abuse of process because the record clearly shows that the FTC did not issue the subpoena for a valid purpose and that the FTC improperly shared confidential information about Watson to further an improper purpose. The Court shall address these arguments below, beginning with its contention that the FTC already possesses the information it seeks to obtain through its subpoena.

*A. The FTC's Knowledge Regarding Watson's Agreements About Exclusivity*

Respondent argues that the subpoena should not be enforced because the FTC already has a definitive answer from Watson regarding its agreements with Cephalon about its right to relinquish any exclusivity rights it may have. The FTC disputes this, claiming that the answers given by Watson and Mr. Buchen are inconsistent and incomplete.

The Court need not wade through the parties' discovery exchanges in detail because the FTC is not required to prove that Respondent possesses some unique personal knowledge in order to subpoena his testimony. As the Supreme Court explained in *Morton Salt Co.*, the FTC's investigatory power is analogous to that of the grand jury, and it may take steps to inform itself as to whether there is a probable violation of the law. *See* 338 U.S. at 642-43. As the CEO and President of Watson, Respondent is in a position likely to possess relevant information, and the FTC may properly seek his testimony to determine what he knows and what he does not. Moreover, there is evidence in the record suggesting that Respondent does have personal knowledge about information relevant to the FTC's investigation. The record demonstrates that Respondent was involved in conversations with Mr. Buchen regarding a possible deal with

Apotex. *See* Pet'r's Reply, Suppl. Ex. 5 (Investigational Hr'g Tr.) at 37. Therefore, it is plausible that Respondent possesses information relevant to the relinquishment issue that is the subject of the investigation. If this were a civil action, the FTC would clearly have authority to depose Respondent in order to determine whether or not he knows anything about this issue. The scope of the FTC's investigative powers is no less broad than the scope of discovery permissible under the Federal Rules of Civil Procedure. *Cf. Okla. Press Publ'g Co. v. Walling*, 327 U.S. 186, 216 & n.55 (1946) (comparing a federal agency's investigative function to that of the federal courts in issuing discovery orders).

Nevertheless, Respondent argues that "the only information that the [FTC] itself claims it needs is indisputably already within the agency's possession." Resp't's Objections at 1. The record, however, is not so crystal clear. The FTC is seeking to determine whether Watson chose not to partner with Apotex because it has a potentially unlawful agreement with Cephalon. In Watson's response to the FTC's CID, Watson identified the 2006 Settlement Agreement as an agreement that "may relate" to Watson's ability to relinquish exclusivity, but it failed to identify, as requested by the FTC, "[t]he portion(s) of the agreement that prohibit or limit Watson or Carlsbad's ability to relinquish." *See* Resp't's Opp'n, Ex. R (Watson's Responses to May 22, 2009 CID) at 5. In response to the FTC's follow-up inquiry, Watson supplemented its response by asserting that the 2006 Settlement Agreement speaks for itself and chiding the FTC for failing to investigate the scope of the agreement sooner. *See* Pet'r's Reply, Suppl. Pet. Ex. 4 (June 17, 2009 response letter to FTC) at 2. When Mr. Buchen testified before the FTC, he declined (on advice of legal counsel) to answer questions regarding whether the 2006 Settlement Agreement restricts in any way Watson's right to relinquish. *See* Pet'r's Reply, Suppl. Pet. Ex. 5

(Investigational Hr'g Tr.) at 50-51. Mr. Buchen also testified that there were non-privileged bases for not pursuing an agreement with Apotex—reasons that had not been disclosed in response to the FTC's earlier inquiries. *See id.* at 33-36. Although Mr. Buchen has now provided the FTC with a less equivocal declaration stating that the 2006 Settlement Agreement does not restrict Watson's right to relinquish, *see* Resp't's Suppl. Br., Decl. of David A. Buchen, the FTC is not required to rely on this declaration as conclusive proof on this issue. The Court agrees with Magistrate Judge Kay that it must defer to the FTC's judgment as to whether further testimony from Respondent will aid its investigation. *See* R&R at 10 ("To the extent that the FTC still believes that Mr. Bisaro may have information relevant to its investigation and not already in the FTC's possession, it is proper for it to take Mr. Bisaro's testimony.").

It is true that courts may modify a subpoena in cases where the request is "unduly burdensome." *See Texaco*, 555 F.2d at 882 ("We emphasize that the question is whether the demand is unduly burdensome or unreasonably broad."). However, the Court is not persuaded that the burden on Respondent in this case is undue. Respondent has argued that the Court should apply the "apex" doctrine to preclude the deposition of a high-ranking official unless the requesting party can demonstrate he has personal knowledge of relevant information that cannot be obtained through other means. *See* Resp't's Objections at 26 n.6 (citing *Thomas v. IBM*, 48 F.3d 478, 483 (10th Cir. 1995)). Magistrate Judge Kay correctly noted that this doctrine has very limited application and that Respondent has failed to identify any cases in which it was applied in an administrative investigation. *See* R&R at 10. Moreover, Respondent has failed to demonstrate that compliance with the subpoena—which merely requires him to testify at a hearing or deposition before the FTC in Washington, D.C.—would be burdensome at all, let

alone unduly so. Therefore, the Court overrules Respondent's objection and adopts Magistrate Judge Kay's conclusion that the FTC may subpoena Respondent to testify despite the fact that Mr. Buchen has already provided a direct answer to the FTC's central question.

*B. The Improper Purpose Defense*

Respondent argues that Magistrate Judge Kay both applied the wrong legal standard and wrongly discounted evidence that the FTC issued the subpoena for an improper purpose. Because this Court must review the record *de novo*, the Court shall not parse the Report & Recommendation to determine the extent to which the alleged errors are legal or factual in nature. Rather, the Court shall discuss the facts in the record and make an independent legal conclusion as to whether the FTC issued the subpoena for an improper purpose.

The FTC contends that the subpoena was issued as part of a legitimate investigation into whether the 2006 Settlement Agreement contained any anticompetitive provisions restricting Watson's ability to relinquish its exclusivity rights. Respondent disputes this, arguing that the real purpose behind the subpoena (and the investigation as a whole) was to coerce Watson to relinquish its exclusivity rights and partner with Apotex to bring generic modafinil to market.[1] Based on Mr. Meier's statements to Mr. Sunshine on the telephone on March 13, 2009, the Court can certainly understand why Respondent believes this to be the case, and Magistrate Judge Kay agreed that the initial record was sufficient to warrant the extraordinary step of allowing limited discovery into the FTC's basis for the investigation. However, the evidence that has been produced by the FTC as a result of that discovery demonstrates that the subpoena was not issued

[1] The Court assumes without deciding that the FTC has no legitimate authority to use its investigatory power for such a purpose.

for the reason that Respondent believes.

The declarations and verified interrogatory answers submitted by FTC officials clearly indicate that the FTC reopened its modafinil investigation in January 2009 once it learned of Watson's supplemental ANDA for the '346 patent—not in response to Watson's subsequent reluctance to enter into an agreement with Apotex. Therefore, the fact that the FTC allegedly threatened to "reopen" its investigation during a March 2009 telephone call does not show that the FTC's investigation was motivated by an improper purpose. Respondent attempts to cast doubt on the agency's declarations by pointing out that the FTC never communicated its concerns about the 2006 Settlement Agreement with Watson until it raised the prospect of a reopened investigation in March 2009. However, "until evidence appears to the contrary, agencies are entitled to a presumption of regularity and good faith." *FTC v. Owens-Corning Fiberglas Corp.*, 626 F.2d 966, 975 (D.C. Cir. 1980). There is no basis in the record for disbelieving the FTC's explanation that it reopened its modafinil investigation in January 2009, before it began talking to Apotex and Watson.

Respondent also points to the fact that the FTC had communications with Apotex prior to contacting Watson about a potential business deal in which the FTC and Apotex discussed, *inter alia*, what it would take Apotex to launch a generic version of Provigil in the United States. *See* FTC's Interrog. Resp. at 9. However, the FTC has explained that the purpose of this discussion was to help the investigatory staff understand the regulatory significance of the '346 patent and how it might affect the market for generic modafinil. *See id.* at 8. Respondent argues that the record shows that the FTC conceived of the potential deal with Apotex and acted as an intermediary to bring the parties together. However, while the FTC facilitated contact between

the two companies, the FTC credibly explains that it did so as a part of its investigative process to determine whether Watson was open to the possibility of relinquishing its exclusivity rights, which the FTC believed was in its economic interest. The FTC disavows any intent to broker a deal, and the record does not clearly show that the FTC took any actions to coerce either party to enter into such an agreement. Respondent relies heavily on the FTC's concession that the modafinil investigation continued as a result of Watson's failure to reach an agreement with Apotex. However, this is hardly surprising, as the purpose of the FTC's investigation was to determine whether Watson had any agreement affecting its exclusivity rights. If Watson had made a deal with Apotex to bring generic Provigil to market in the United States, the FTC's investigation naturally would have terminated because it would know that Watson did not have any such anticompetitive agreement. Therefore, this fact does not support a finding that the subpoena was issued for an improper purpose.

Respondent also argues that the FTC must have issued the subpoena for an improper purpose because it was issued after Watson had already explained to the FTC that its Settlement Agreement with Cephalon did not preclude Watson from relinquishing its exclusivity rights and after Mr. Buchen testified that there were legitimate business reasons for not pursuing a deal with Apotex. However, as explained in the previous section, Watson's responses to the FTC's initial inquiries were somewhat evasive and inconsistent, and the FTC reasonably determined that further investigation was necessary to determine the veracity of Watson's position. Respondent also relies on the fact that the FTC was continuing to communicate with Apotex about the status of a deal with Watson as late as July 15, 2009, the week before the subpoena was issued. However, the timing of that communication is not circumspect in light of the ongoing status of

the FTC's investigation. Respondent points to an email from Apotex's Vice President indicating that the FTC said it was investigating Watson because it refused to talk to Apotex. *See* Resp't's Opp'n, Ex. H (July 15, 2009 email from S. Upadhye). However, that email merely reflects Apotex's understanding that the FTC was trying to determine why Watson was not interested in a potentially profitable business deal—a legitimate subject of investigation given the FTC's concerns about the scope of the 2006 Settlement Agreement.

Lastly, Respondent argues that his clear lack of personal knowledge regarding the Settlement confirms that the FTC issued the subpoena for an improper purpose. As the Court explained above, there is evidence in the record suggesting that Respondent does have personal knowledge about the reasons that Watson chose not to pursue a deal with Apotext, and the FTC is entitled to depose Respondent in order to determine precisely what he knows rather than rely on the statements of others.

The record shows, at best, that an FTC official made an inappropriate comment in the context of a lawful investigation that suggested that the purpose of the FTC's investigation was to coerce Watson to enter into an agreement with Apotex. In fact, Watson may have felt that it was under pressure from the FTC to reach some agreement with Apotex. However, the Court's inquiry is focused on purpose rather than effect, and the record as a whole does not support the conclusion that the FTC initiated the investigation or issued the subpoena for an improper purpose. Even if the Court could conclude that Mr. Meier had an improper purpose in making his comments on the telephone to Watson's counsel, that alone would not establish an abuse of process with respect to the subpoena, which was issued several months later. *See Carter*, 636 F.2d at 789 ("[E]ven if an improper purpose by an agency or member of the staff is shown,

enforcement of the subpoena is called for so long as proper purposes exist as well.").

Respondent attempts to buttress his improper purpose argument by claiming that the record shows that the FTC improperly disclosed confidential information about Watson's first-filer status to Apotex in the course of its investigation. However, the Court agrees with Magistrate Judge Kay's conclusion that "there is nothing beyond slight inferences and strong accusations to show that the FTC divulged confidential information." R&R at 12. Respondent relies primarily on two facts in the record to support its claim: (1) the FTC used hypothetical scenarios in the course of its investigation causing inferences to be drawn by the recipients; and (2) an email from Apotex's Vice President suggests that the FTC confirmed to Apotex that Watson was "mum about deal making," a fact that Respondent claims could only have been learned through its confidential investigation of Watson.

With respect to the use of hypothetical scenarios, Respondent points to the FTC's admission that FTC staff posited hypothetical scenarios to Watson "to determine if Watson could profit from relinquishment of any modafinil marketing exclusivity for which it might be eligible, including scenarios where Watson relinquished any such exclusivity to potential new entrants into the market." *See* FTC's Interrog. Resp. at 9. Respondent argues that because the FTC posed hypothetical questions suggesting that Watson had marketing exclusivity and then put it contact with Apotex for a potentially profitable deal, the only logical inference that could be drawn was that Watson had marketing exclusivity. However, FTC officials have explicitly denied that they disclosed any confidential information in the course of the investigation. *See* FTC's Interrog. Resp. at 5, 11; Decl. of Richard Feinstein ¶¶ 14. As a practical matter, the Court understands that

although the FTC's investigation is nonpublic, the agency cannot solicit information from market participants in a vacuum; hypothetical questions are an investigatory tool that agencies utilize to get answers to questions without explicitly disclosing underlying facts, which may be confidential. *See* Decl. of Richard Feinstein ¶¶ 6-9 (describing the FTC's use of hypothetical questions). The fact that Watson could draw the correct inference from the nature of the FTC's questioning does not establish that the FTC improperly disclosed confidential information.

Respondent also argues that an email in the record from Apotex's Vice President dated July 15, 2009, "leads to the inescapable inference that the FTC was discussing with Apotex information obtained from Watson in its supposedly nonpublic investigation." *See* Objections at 37; Resp't's Opp'n, Ex. H (July 15, 2009 email from S. Upadhye). However, the language in the email is not so clear. The pertinent language reads, "In my call with FTC enforcement this morning, I indicated and he confirmed that Watson is just mum about deal making. The reason for silence truly evades us and FTC." Resp't's Opp'n, Ex. H. It is unclear exactly what inference should be drawn from this statement; it is plausible that the FTC merely told Apotex that Watson had not informed it of any deal and that the FTC does not know why it would not pursue one. Such a statement would not necessarily disclose the existence of an investigation. Respondent makes much of the fact that Mr. Buchen had already informed the FTC of Watson's reasons for discontinuing discussions with Apotex, *see* Resp't's Reply in Supp. of Obj. at 16, but that would seem only to confirm that the FTC did not share information learned during its investigation with Apotex.

Ultimately, the record as a whole does not establish that the FTC disclosed confidential information relating to Watson in the course of its investigation. The evidence relied on by

Respondent is inconclusive and directly rebutted by sworn declarations by agency officials. Accordingly, the Court finds that the FTC did not issue the subpoena *ad testificandum* to Respondent for an improper purpose, and it would not be an abuse of process to issue an order enforcing the subpoena.

## IV. CONCLUSION

Having reviewed the record as a whole *de novo*, the Court finds that the subpoena *ad testificandum* issued to Respondent by Petitioner Federal Trade Commission is relevant to a valid investigation, not unreasonably duplicative, and not issued for an improper purpose. Therefore, the Court overrules Respondent's Objections and adopts Magistrate Judge Kay's [35] Report & Recommendation insofar as it is not inconsistent with this Memorandum Opinion. The Court shall GRANT the FTC's [3] Petition for an Order Enforcing Administrative Subpoena *Ad Testificandum* and issue an order enforcing the subpoena. An appropriate Order accompanies this Memorandum Opinion.

*/s/*
COLLEEN KOLLAR-KOTELLY
United States District Judge