UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

REPORT AND RECOMMENDATION[1]

Pending before the Court are Petition of Federal Trade Commission for An Order Enforcing Subpoena *Ad Testificandum* ("Pet.") [3], Memorandum of Points and Authorities in Support of Petition of Federal Trade Commission for an Order Enforcing Subpoena *Ad Testificandum* ("Mem. in Supp.") [4], Respondent's Opposition to Petition of Federal Trade Commission for an Order Enforcing Administrative Subpoena *Ad Testificandum* ("Opp'n") [13], Petitioner's Reply Memorandum in Support of Petition for an Order Enforcing Administrative Subpoena *Ad Testificandum* ("Reply") [20], Petitioner FTC's Motion to Enforce the Subpoena *Ad Testificandum* Forthwith, and Memorandum in Support ("Mot. to Enforce") [32], and Supplemental Brief of Respondent Paul M. Bisaro ("Supp. Br.") [34]. Having heard oral argument and reviewed the submissions of the parties and the relevant case law, the Court issues the following Report and Recommendation.

[1] This case was referred by U.S. District Judge Colleen Kollar-Kotelly to the undersigned for a report and recommendation pursuant to Local Rule 72.3. (*See* Minute Order dated 06/30/2010; *see also* Order Referring Case [17] dated 05/26/2010.)

I. BACKGROUND

Respondent, Paul M. Bisaro ("Mr. Bisaro"), is the President and CEO of Watson Pharmaceuticals, Inc. ("Watson"). (Opp'n at 4.) Watson is engaged in the development, manufacturing, marketing, and distribution of generic pharmaceuticals. (*Id.*) 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. (*Id.*) Specifically, pursuant to a 2006 FTC investigation involving Cephalon, Inc. ("Cephalon"), Watson, and several other pharmaceutical companies, the FTC issued Mr. Bisaro a subpoena *ad testificandum*, which is the subject of the dispute currently before this Court.

A. Reverse Payment Settlements

"Reverse-payment" settlements are settlements of patent infringement litigation brought pursuant to the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984), involving settlement payments from the patent holder (usually a branded pharmaceutical company) to the alleged infringer (typically a generic pharmaceutical company). *See*, *e.g.*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1073-74 (11th Cir. 2005). The Hatch-Waxman Act grants generic companies standing to mount a validity challenge to a patent before the patent's expiration. 21 U.S.C. § 355(j). This is done through an Abbreviated New Drug Application ("ANDA") and a "Paragraph IV" certification to the FDA alleging that the patents of the innovator drug listed in the "Orange Book[2]" are either invalid or not infringed by the generic drug. *Id.* The first generic company to mount a challenge to an innovator

[2] When an new drug application is first approved, the FDA lists all patents covered by that new drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," better known as the "Orange Book."

drug receives 180 days of marketing exclusivity once its generic version is approved, during which no other generic companies can enter the market. *Id.* § 355(j)(5)(B)(iv).

If a settlement between a patent holder and a generic challenger involves payment to the generic challenger to delay entry of its generic drug, this has the effect of creating a bottleneck that blocks any other generic pharmaceutical company from entering the market for that particular drug.[3] The FTC firmly believes that these "reverse payment" settlements are "unfair methods of competition" in violation of Section 5 of the FTC Act.[4] However, three Circuit Courts and several lower courts have found such settlements to be legal where the anticompetitive effects of the settlement remain within the patent's terms – *e.g.*, for the length of the original patent. *See, e.g.*, *Schering-Plough*, 402 F.3d at 1076; *In re Ciprofloxacin Hydrochloride Antitrust Litig*., 544 F.3d 1323, 1333 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009); *In re Tamoxifen Citrate Antitrust Litig*., 466 F.3d 187, 212-213 (2d Cir. 2006).

B. Modafinil Investigation

In 2006, the FTC initiated an investigation into the anticompetitive nature of several settlement agreements between Cephalon, a brand name pharmaceutical company, and several generic pharmaceutical companies (including Watson), concerning the marketing of a generic version of Cephalon's brand-name version of modafinil – Provigil. *See* FTC Resolution Authorizing Use of Compulsory Process in a Nonpublic Investigation (Aug. 30, 2006) ("2006

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

[4] *See, e.g.*, Leibowitz, *supra* fn.2, at 4.

Resolution"). (Pet. Ex. 2.) The purpose of the investigation was to determine whether Cephalon, Watson, and other pharmaceutical companies had engaged in "any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act . . . by entering into agreements regarding modafinil products." (*Id.*) Four pharmaceutical companies had challenged Cephalon's original patent for Provigil (the '516 patent) on the same day the patent was listed in the Orange Book, making all four companies "first filers" under the Hatch-Waxman statutory scheme. (Pet. Ex. 1 ¶ 6.) Watson, however, challenged the '516 patent much later. (*Id.*) Cephalon sued the generic challengers for patent infringement and eventually settled with the four first filers and Watson. (*Id.* ¶ 7.)

With regard to Watson, the FTC focused its investigation on the settlement agreement between Cephalon and Watson that was entered on August 2, 2006, after Cephalon had settled with the first four generic challengers. (Sunshine Decl. ¶ 8-9.) The FTC has since brought an action against Cephalon alleging that its settlement agreements with the four "first filers" prevented generic competition to Provigil in violation of Section 5 of the FTC Act, 15 U.S.C. § 45. *FTC v. Cephalon, Inc.*, No. 08-2141 (E.D. Pa. filed Feb. 13, 2008). None of the generic challengers were named in the complaint.

On December 19, 2007, Cephalon listed a new patent for Provigil (the '346 patent) in the Orange Book. (Pet. Ex. 1 ¶ 9.) Watson filed a supplemental ANDA and a Paragraph IV certification as to the newly listed patent on the same day the '346 patent was listed in the Orange Book. (*Id.*; Sunshine Decl. ¶ 15.) Although Watson had been late in filing its ANDA challenging the original Provigil patent – the '516 patent – it was now possible that Watson was the "first filer" for the '346 patent. (Pet. Ex. 1 ¶ 9.)

The investigation authorized by the 2006 Resolution lay dormant until January 2009 when

the FTC discovered the filing of the '346 patent and Watson's supplemental ANDA. (Interrog. Resp. at 3-4; Brau Decl. ¶ 4.) The discovery of a second Provigil patent and the filing of Watson's supplemental ANDA created a series of questions regarding the impact these events might have on the competitive conditions in the generic modafinil market. The questions included: whether this second patent could be used to block generic entry; whether Watson now held any marketing exclusivity for generic modafinil; and whether Watson had agreed with Cephalon not to relinquish or pursue those rights in exchange for a payment from Cephalon (Opp'n at 9; Interrog. Resp. at 4; Brau Decl. at ¶ 4.)

In the course of investigating whether Watson now had marketing exclusivity and whether its earlier agreement with Cephalon prevented it from relinquishing that exclusivity, the FTC contacted the FDA and Apotex, Inc. ("Apotex") – a competing generic pharmaceutical company – to gather information on the '346 patent and its possible effects on the generic modafinil market. (Interrog. Resp. at 4, 7.) The FTC alleges that consulting with Apotex was an "obvious choice" considering that it had filed an ANDA that was currently being blocked by Cephalon's earlier modafinil settlements, that it was already selling generic modafinil in Canada, and that its Vice President was a "published expert in the field." (Interrog. Resp. at 7.)

On March 4, 2009, Markus Meier, Assistant Director of the FTC Bureau of Competition Health Care Division, telephoned Steven Sunshine, counsel for Watson, to probe whether Watson was willing to relinquish any exclusivity rights it might now have. (Sunshine Decl. ¶ 16; Interrog. Resp. 9; Brau Decl. ¶ 8.) According to Mr. Sunshine, Mr. Meier suggested that it might be in Watson's financial interest to relinquish or "waive" any exclusivity associated with its supplemental ANDA for the '346 patent in order to clear the way for generic competition of Provigil. (Sunshine Decl. ¶ 16; *see also* Brau Decl. ¶ 7.) Meier and Sunshine spoke again by telephone on March 10

and March 13, 2009. (Sunshine Decl. ¶ 17.) Mr. Sunshine alleges that during these telephone conversations Mr. Meier again importuned Watson to relinquish its marketing exclusivity. (*Id.*) Mr. Meier also asked Mr. Sunshine whether Watson would be interested in receiving a call from a generic pharmaceutical company that was prepared to launch a generic Provigil product. (*Id.* ¶ 18.) Before the call ended, Mr. Sunshine gave Mr. Meier permission to put another generic modafinil maker into contact with Watson. (Interrog. Resp. at 9.) The FTC thereafter contacted Apotex and indicated that if it was interested in pursuing a deal to jointly market modafinil, it should contact David Buchen, Watson's Senior Vice President and General Counsel. (Interrog. Resp. at 9-10.)

Within a week, Mr. Buchen received a phone call from Apotex seeking to negotiate a deal wherein Watson would give up its purported first filer rights to the '346 patent and jointly market a generic version of Provigil with Apotex. (Sunshine Decl. ¶ 18.) While Mr. Buchen was considering Watson's options, Mr. Meier spoke to Mr. Sunshine and indicated that failure to waive its first filer rights soon would likely cause the FTC "Front Office" to initiate an investigation against Watson. (Sunshine Decl. ¶ 17.) Shortly thereafter, but prior to Watson's decision *vel non* to deal with Apotex, the FTC issued civil investigative demands ("CIDs") to Watson and a subpoena *ad testificandum* to Mr. Buchen. (Sunshine Decl. ¶ 19; Opp. Ex. D at 33, 40, 67.) Watson answered the CIDs, and Mr. Buchen's testimony was taken. (*See* Resp. Opp'n 10-12.)

During that time, Apotex's President and COO, Jack Kay, tried to speak with Mr. Bisaro directly about this matter, but Mr. Bisaro refused. (Sunshine Decl. ¶ 23.) On July 15, 2009, Mr. Kay forwarded Mr. Bisaro an internal Apotex email indicating that Mr. Buchen had told Apotex that Watson would not discuss a business deal while the FTC was investigating it. (Opp. Ex. H.) The email also indicates that Apotex had several conversations with the FTC regarding Watson and its refusal to deal with Apotex. (*Id.*) The email states:

> "Watson refuses to talk to us about a deal to relinquish exclusivity so that we can market modafinil (US). Watson is oddly saying that it cannot talk to us due to FTC investigation relating to modafinil (US). Yet FTC is investigating because Watson refuses to talk to us . . . In my call with the FTC enforcement this morning, I indicated and [the FTC] confirmed that Watson is just mum about deal making. The reason for silence truly evades us and the FTC."

(*Id.*)

The FTC withdrew its original subpoena of Mr. Bisaro, but issued a new one on July 23, 2009. (Opp. Ex. K.) On July 30, 2009, Mr. Bisaro moved to quash the subpoena. (Opp. Ex. L.) The FTC denied this motion on November 13, 2009. (Opp. Ex. M at 1-2.) Mr. Bisaro requested review by the full Commission, but on April 2, 2010, the FTC denied full Commission review. (Opp. Ex. N; Pet. Ex. 7.) After Watson's counsel indicated Mr. Bisaro's unwillingness to appear for the deposition, the FTC petitioned this Court to enforce the subpoena *ad testificandum* against Mr. Bisaro on April 23, 2010. (Pet. at 1.) An order to show cause was issued (Order [6] dated 5/12/10), and Mr. Bisaro responded and also moved to compel limited discovery as to whether the FTC was acting with an improper purpose in issuing the subpoena. (Opp'n; Mot. to Compel [16].)

On July 13, 2010, the undersigned issued an order granting in part Mr. Bisaro's motion for limited discovery. In the order, the undersigned found that Mr. Bisaro had made a "colorable claim that the FTC may have exceeded its authority by using its investigative power to pressure Watson to enter into a business deal that the FTC considers desirable." (Mem. Order [31] at 10.) The undersigned also found that, based on the evidence submitted by Mr. Bisaro, there was a likelihood that the FTC had improperly shared confidential information about Watson with Apotex, and it was in "the Court's best interest to further examine this matter to ensure that enforcement of the subpoena would not amount to an abuse of process." (*Id.* at 11.) Thus, the undersigned granted Mr. Bisaro's motion to compel the FTC to answer the two interrogatories propounded to it. (*Id.*)

However, the undersigned declined to compel the deposition of Mr. Meier. (*Id.*)

Pursuant to this Court's order, the FTC answered the interrogatories and both parties supplemented the record. The FTC argues that it acted with a proper purpose in issuing Mr. Bisaro's subpoena and submits the interrogatory answers and two declarations to support its assertions. (*See* Mot. to Enforce.) The FTC further urges this Court to enforce the subpoena forthwith now that the record is complete and no improper purpose can be shown (*Id.*) Mr. Bisaro, however, maintains that the petition should be denied on several grounds, the least of which is that the subpoena was issued for an improper purpose. (*See* Supp. Br.) Mr. Bisaro also submits a sworn declaration of Mr. Buchen that the 2006 settlement with Cephalon does not prevent relinquishment. (Buchen Decl. [34-1].)

II. LEGAL STANDARD

A proceeding to enforce an administrative subpoena, because of the important governmental interest in the expeditious investigation of possible unlawful activity, is summary in nature and the scope of issues that may be addressed in such a proceeding will be limited accordingly. *See United States v. Powell*, 379 U. S. 48, 57-58 (1964); *United States v. Morton Salt Co.*, 338 U. S. 632, 652-53 (1949). The focus of the enforcement proceedings generally will be on whether the inquiry is within the statutory authority of the agency, the demand not too indefinite, and the information sought reasonably relevant to the inquiry. *Morton Salt*, 338 U.S. at 652.

Even if the agency makes out a prima facie case for enforcement, a court can nonetheless decline to enforce the subpoena if the recipient of the agency process shows that enforcement would amount to an abuse of the court's process. *Powell*, 379 U.S. at 58. For example, "if the summons had been issued for an improper purpose, such as to harass the [subpoenaed party] or to put pressure on him to settle a collateral dispute, or for any other purpose reflecting on the good faith of the

particular investigation." *Id.* The burden is on the recipient of the agency process to prove that enforcement would amount to an abuse of the court's process. *Id.* However, these circumstances are rarely found, and, despite allegations of an improper purpose, courts will often enforce an agency subpoena so long as a proper purpose *also* exists. *FTC v. Carter*, 636 F.3d 781, 789 (citing *Donaldson v. United States*, 400 U.S. 517, 534-35 (1971)).

III. DISCUSSION

Mr. Bisaro challenges the subpoena on several grounds. First, Mr. Bisaro alleges that the subpoena is unreasonable because the FTC is already in possession of the information it demands, which he alleges the FTC acquired through the CIDs and the testimony of Mr. Buchen. (Opp'n at 16-21.) The FTC, however, alleges that one critical question remains unanswered and that it seeks Mr. Bisaro's testimony for this purpose. (Mot. to Enforce at 7-8.) In particular, the FTC says that Watson has failed to "provide the Commission with a clear and unequivocal answer to the question of whether [Watson] has agreed with Cephalon not to relinquish any exclusivity rights to generic modafinil." (*Id.* at 8.) While Mr. Bisaro argues that this question has been answered multiple times (Supp. Br. at 2 n.1), he now provides the sworn declaration of Mr. Buchen stating unequivocally that the earlier settlement with Cephalon in no way "prevents Watson from relinquishing any exclusivity rights it may have related to generic modafinil, nor in any way limits Watson's ability to relinquish such rights." (Buchen Decl. ¶ 6.) Mr. Buchen also confirms that there is "no other agreement between Watson and Cephalon that prevents Watson from relinquishing any exclusivity rights it may have related to generic modafinil or in any way limits its ability to relinquish such rights." (*Id.*)

While the FTC alleges that getting an answer to this critical question was the main impetus for subpoenaing Mr. Bisaro, it does state that it seeks other "critical facts relevant to the

Commission's investigation." (Mot. to Enforce at 7.) 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. As the CEO, "Mr. Bisaro is the only Watson executive besides [Mr. Buchen] who is likely to have [relevant] knowledge." (*Id.*) Mr. Buchen admits that he spoke with Mr. Bisaro on a number of occasions to discuss this investigation and the issue of relinquishment. (Buchen Decl. ¶ 11.) The FTC has no way of knowing what relevant information Mr. Bisaro has, and the only way to find out is through his testimony. Moreover, there can be no question that Mr. Bisaro's testimony could be relevant to the FTC's investigation, and this Court must accept the Commission's own appraisal of relevancy so long as it is not "obviously wrong." *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1089 (D.C. Cir. 1992). The undersigned finds that the information the FTC seeks from Mr. Bisaro is relevant and not unreasonably duplicative.

Second, Mr. Bisaro alleges that the subpoena should not be enforced because it unreasonably seeks testimony from the apex of Watson's organization, and that it is improper to depose a high-ranking or "apex" employee unless the requesting party has reason to believe that he has personal knowledge or relevant information that cannot be obtained through other means. (Opp'n at 21.) *See, e.g.*, *Six West Retail Acquisition, Inc. v. Sony Theatre Mgmt. Corp.*, 203 F.R.D. 98, 102 (S.D.N.Y. 2001) (holding that it might be appropriate to preclude deposition of a highly placed executive when the information the subpoena seeks is "unreasonably cumulative or duplicative"). As the FTC noted, this doctrine has very limited application, and Mr. Bisaro fails to cite a single case where it was applied in administrative investigations. (Reply at 7-8.) The fact that Mr. Bisaro is the CEO and President of Watson does not immunize him from being deposed when it is believed that he may have knowledge of relevant information that cannot be obtained elsewhere, s*ee id.*, and

the undersigned has already found that the information the FTC seeks from Mr. Bisaro is relevant and not unreasonably duplicative (*see supra* at 10-11). Thus, Mr. Bisaro's argument on this ground fails.

Mr. Bisaro also argues that the 2006 Resolution authorizing the investigation is retrospective and cannot be used to investigate activity that occurred after it was issued because the language of the resolution indicates that the scope of investigation is "to determine whether [the named parties] *have engaged* in any unfair methods of competition." (Opp'n at 24-25.) This argument is without merit. It is logical that the resolution applies to all continuing conduct reasonably arising within the scope of the resolution's terms, and Mr. Bisaro does not cite any authority to the contrary.

Finally, Mr. Bisaro alleges that the reason the FTC issued the subpoena was to put pressure on Watson to agree to the business deal the FTC was attempting to broker between Watson and Apotex to get Watson to relinquish its statutory "first filer" rights to the '346 Provigil patent. (Opp'n at 25-29.) Mr. Bisaro also alleges that the subpoena was issued to harass Watson for refusing to agree to the deal with Apotex. (*Id.*)

Mr. Bisaro presents declarations taken under penalty of perjury by Watson's attorneys – Mr. Sunshine and Julia York – setting forth facts showing the FTC was pressuring Watson to relinquish any exclusivity rights it had with respect to the '346 patent, and threatening to start an investigation if Watson did not soon relinquish those rights. (*See* Sunshine Decl. [13-1]; York Decl. [13-2]). In fact, the FTC admits that if Watson had just agreed to relinquish any marketing exclusivity with respect to the '346 patent, it never would have pursued this investigation. (Reply at 11.) Mr. Bisaro also presents an email from Apotex's President that indicates the FTC had been sharing potentially confidential information about Watson with Apotex. (Opp. Ex. H.)

In its July 13, 2010, order granting in part Mr. Bisaro's motion to compel limited discovery, the undersigned found that Mr. Bisaro made a colorable showing that the FTC was acting outside its authority in issuing the subpoena. (Mem. Order at 10.) Before the undersigned could recommend that the trial court enforce the subpoena, it allowed a limited inquiry to determine whether the FTC was in fact sharing confidential information about Watson with unauthorized third parties. (*Id.* at 11.) Both the FTC and Mr. Bisaro have since supplemented the record pursuant to the undersigned's July 13, 2010 Memorandum Order and July 28, 2010 Minute Order.

The facts before this Court now do not establish a direct attempt by the FTC to misuse the Court's process for it has not been shown that the subpoena itself was issued to harass Mr. Bisaro or that the investigation has been conducted for an improper purpose. Nor do the facts establish that the FTC shared confidential information about Watson with unauthorized third parties. While Mr. Bisaro initially made a colorable showing that the FTC shared confidential information with Apotex, he has subsequently failed to prove those allegations. The record reflects that the FTC was in contact with Apotex (*see* Interrog. Resp. at 9-11), but there is nothing beyond slight inferences and strong accusations to show that the FTC divulged confidential information (*see* Supp. Br. 4-6). This is not enough to overcome the heavy burden a respondent has in subpoena enforcement proceedings. *See Powell*, 379 U.S. at 255.

Once the FTC discovered that a subsequent Provigil patent – the '346 patent – and Watson's supplemental ANDA had been filed, it was reasonable for the FTC to be concerned that the new patent and Watson's potential exclusivity rights could be used to further delay generic entry into the modafinil market. Once these questions were raised, it was also reasonable for the FTC to reactivate the investigation authorized by the 2006 resolution to seek information via compulsory process from Watson and its CEO, Mr. Bisaro.

To be sure, the undersigned disagrees with the way the FTC conducted this aspect of its investigation – in particular, the FTC's attempts "to use its investigative power to pressure a company to waive statutory rights it had legitimately acquired or to enter into a business deal with a competitor." (Mem. Order at 10.) However, enforcement of a subpoena is called for as long as a proper purpose does exist. *FTC v. Carter*, 636 F.2d 781, 789 (D.C. Cir. 1980) (citing *Donaldson v. United States*, 400 U.S. 517, 534-35 (1971)). Here, the undersigned has found there was a proper purpose for subpoenaing Mr. Bisaro. Although the undersigned finds the FTC's approach questionable,[5] it is not appropriate in this case for the Court to "transform subpoena enforcement proceedings into exhaustive inquisitions into the practices of regulatory agencies." *SEC v. Dresser Indus., Inc.*, 628 F.2d 1368, 1388 (D.C. Cir. 1980). The undersigned believes that this is a task more appropriately left to the legislature.

IV. RECOMMENDATION

For the foregoing reasons, and in accordance therewith, the undersigned recommends that the Petition of Federal Trade Commission for an Order Enforcing Administrative Subpoena *Ad Testificandum* be **granted.**

V. REVIEW BY THE DISTRICT COURT

The parties are hereby advised that under the provisions of Local Rule 72.3(b) of the United States District Court for the District of Columbia, any party who objects to the Report and Recommendation must file a written objection thereto with the Clerk of this Court within 14 days of the party's receipt of this Report and Recommendation. The written objections must specifically

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[5] In particular, the undersigned found it questionable for the FTC to use "its investigative power to pressure Watson to enter into a business deal that the FTC considers desirable." (Mem. Order at 10.)

identify the portion of the report and/or recommendation to which objection is made, and the basis for such objections. The parties are further advised that failure to file timely objections to the findings and recommendations set forth in this report may waive their right of appeal from an order of the District Court that adopts such findings and recommendation. *See Thomas v. Arn*, 474 U.S. 140 (1985).

Dated: August 17, 2010

/s/
ALAN KAY
UNITED STATES MAGISTRATE JUDGE