

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

**FEDERAL TRADE COMMISSION,**

Petitioner,

v.

**PAUL M. BISARO,**

Respondent.

Misc. No. 10-289 (CKK)(AK)

**MEMORANDUM ORDER**

Pending before this Court are Respondent's Motion for An Order Compelling Petitioner the Federal Trade Commission to Respond to Respondent's Discovery Requests and for Leave to Supplement the Record, and Memorandum in Support ("Mot. to Compel") [16], Petitioner's Opposition to Respondent's Motion to Compel ("FTC Opp'n") [20], and Respondent's Reply Brief in Support of Motion to Compel ("Reply") [23]. On June 24, 2010, this Court held a hearing on the matter. For the reasons set forth below, Respondent's Motion to Compel Discovery is granted in part and denied in part.

**I. BACKGROUND**

Respondent, Paul M. Bisaro ("Mr. Bisaro"), is the President and CEO of Watson Pharmaceuticals, Inc. ("Watson"). (Resp. Opp'n to FTC Pet. for an Order Enforcing Subpoena [13] ("Resp. 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.*)

**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<sup>1</sup>” are either invalid or not infringed by the generic drug. *Id.* The first generic company to mount a challenge to an innovator 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

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<sup>1</sup> 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.”

particular drug.<sup>2</sup> The FTC firmly believes that these “reverse payment” settlements are “unfair methods of competition” in violation of Section 5 of the FTC Act.<sup>3</sup> 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, Inc. (“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 Resolution”). (Pet. Ex. 2.) Four pharmaceutical companies had challenged Cephalon’s original patent for Provigil (the ‘516 patent) on the same day, 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 eventually sued the generic challengers for patent infringement and eventually settled with the four first filers and Watson.

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<sup>2</sup> *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>.

<sup>3</sup> *See, e.g.*, Leibowitz, *supra* fn.2, at 4.

(*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.<sup>4</sup>

On December 19, 2007, Cephalon listed a new patent for Provigil (the ‘346 patent) in the Orange Book. (Pet. Ex. 1 ¶ 9.) Although Watson’s ANDA for a generic version of Provigil was already pending, Watson filed a supplement ANDA and a Paragraph IV certification as to the newly listed patent, *see* 21 C.F.R. § 314.95(a), (d), which was filed on the same day the ‘346 patent was listed in the Orange Book. (*Id.*; Sunshine Decl. ¶ 15.) Although Watson had been late in filing their 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.) However, whether they held any marketing exclusivity depended on facts unknown to Watson – including, whether the four original first filers for the ‘516 patent had relinquished their exclusivity and whether

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<sup>4</sup> Additionally, Watson was subject to an investigation that led to a lawsuit regarding AndroGel – a brand-name testosterone gel used in hormone replacement therapy for men. (Resp. Opp’n at 6.) In January 2009, the FTC sued Watson and three other defendants in connection with settlements of patent litigation related to AndroGel. (*Id.*) The FTC originally brought the case within the Ninth Circuit. However, the district court transferred the case to the Eleventh Circuit, and the District Court for the Northern District of Georgia granted Watson’s motion to dismiss in February 2010 with respect to the FTC’s claims against Watson. (*Id.*) *See In re AndroGel Litig. (No. II)*, No. 09-2084, 2010 WL 668291, at \*5-\*7 (N.D. Ga. Feb. 22, 2010).

Watson was the lone first filer on the '346 patent. (Resp. Opp'n at 9.)

On March 4, 2009, Markus Meier, Assistant Director of the FTC Bureau of Competition Health Care Division, telephoned Steven Sunshine, counsel for Watson, and indicated that Mr. Meier had been in contact with the FDA. (Sunshine Decl. ¶ 16.) 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 regarding the '346 patent in order to clear the way for generic competition to Provigil. (*Id.*) Messrs. Meier and Sunshine spoke again by telephone on March 10 and March 13, 2009. (*Id.* ¶ 17.) Mr. Sunshine alleges that, during these telephone conversations, Mr. Meier again pushed 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.)

Within a week, Watson received a phone call from Apotex, another generic pharmaceutical company, 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.) David Buchen, Watson's Senior Vice President and General Counsel, was primarily responsible for deciding whether to pursue the deal. (Opp. Ex. D at 67.) While Mr. Buchen was considering Watson's options, Mr. Meier indicated to Mr. Sunshine 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, 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.) The

investigation revealed that the FTC was primarily interested in whether Watson had reached agreement with Cephalon to withhold relinquishment of any marketing exclusivity associated with the '346 patent. (Opp. Ex. E ¶ 6.) Watson answered the CIDs, and Mr. Buchen's testimony was taken. (*See Resp. Opp'n* 10-12.)

During this 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. for Order Enforcing Admin. Subpoena [3].) 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. (Resp. Opp'n [13]; Mot. to Compel [16].)

## II. LEGAL STANDARD

Although a subpoena enforcement proceeding is typically a summary procedure, it is nevertheless within the court's discretion to order discovery. *United States v. Aero Mayflower Transit Co.*, 831 F.2d 1142, 1146-47 (D.C. Cir. 1987). The D.C. Circuit has repeatedly held that discovery may be available in some subpoena enforcement proceedings where extraordinary circumstances indicate that further information is necessary for the courts to discharge their duty. *Id.*; see *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1089 (D.C. Cir. 1992); *SEC v. Dresser Indus., Inc.*, 628 F.2d 1368, 1388 (D.C. Cir. 1980). The burden lies on the subpoenaed party to show these extraordinary circumstances exist. *FEC v. Committee to Elect Lyndon La Rouche*, 613 F.2d 849, 862 (D.C. Cir. 1979). Where a subpoena recipient raises colorable allegations of an improper purpose and seeks to prove those allegations, the enforcement court should afford the subpoena recipient some opportunity to substantiate those allegations. *Id.*

However, courts "must be cautious in granting such discovery rights, lest they transform subpoena enforcement proceedings into exhaustive inquisitions into the practices of regulatory agencies." *Aero Mayflower*, 831 F.3d at 1147 (quoting *Dresser*, 628 F.2d at 1388). The D.C. Circuit has only found one instance where extraordinary circumstances existed to warrant discovery. See *United States v. Fensterwald*, 553 F.2d 231, 232 (D.C. Cir. 1977) (finding limited discovery into IRS audit selection procedure appropriate where lawyer who headed a committee

investigating the IRS was then selected for special audit).<sup>5</sup> Any discovery that is allowed should be limited to the minimum necessary in the interest of justice. *See Dresser Indus.*, 628 F.2d at 1388.

### III. DISCUSSION

While Mr. Bisaro challenges the subpoena on several grounds, the only challenge relevant to his motion to compel limited discovery is the allegation that the subpoena was issued for an improper purpose. (Mot. to Compel at 5-8.) Mr. Bisaro alleges that the reason the FTC issued the subpoena was to put pressure on Watson to enter into a 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. (Resp. Opp’n at 26.) Mr. Bisaro also alleges that the subpoena was issued to harass Watson for refusing to enter into the deal with Apotex. (*Id.*)

The facts indicate that any FTC investigation against Watson lay dormant until 2009 when Mr. Meier and other FTC officials attempted to get Watson and Apotex to negotiate a deal whereby Watson would relinquish its exclusivity rights to the ‘346 patent and jointly market a generic version of modafinil with Apotex. (Sunshine Decl. ¶¶ 16-22; Hr’g Tr. dated 6/24/10 at 10-11, 15, 36, 38-39.) It was only after Watson refused the purported deal that the FTC renewed its previous investigation authorized by the 2006 Resolution. (Sunshine Decl. ¶¶ 17-20.) In fact, the FTC states 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 10-11.) Mr. Bisaro

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<sup>5</sup> Courts outside this circuit have similarly permitted discovery in enforcement proceedings where “substantial allegations that agencies were abusing the judicial process” existed. *SEC v. Wheeling-Pittsburgh Steel Corp.*, 648 F.2d 118, 128 (3d Cir. 1981); *see also EEOC v. Bashas’, Inc.*, No. 09-209, 2009 WL 3241763, \*10-14 (D. Ariz. Sept. 30, 2009), *order clarified*, 2009 WL 5206632 (D. Ariz. Dec. 24, 2009).

also produces an email from Apotex's President that indicates the FTC had been sharing information with Apotex about Watson – potentially confidential information. (Opp. Ex. H.) The FTC admits that it spoke with Apotex about the purported deal, but denies that it divulged any confidential information. (Hr'g Tr. dated 6/24/10 at 25.)

Mr. Bisaro alleges that these facts present extraordinary circumstances that take him out of the category of the ordinary respondent and should compel the Court to deny the FTC's petition to enforce the subpoena or, at the very least, convince the Court to allow him limited discovery. (Resp. Opp'n at 30.) Thus, the question is whether these facts are indeed extraordinary enough to overcome the tough burden carried by the respondent in what is ordinarily a simple summary enforcement proceeding.

The FTC argues that it was still acting within its investigatory power authorized in the 2006 Resolution, and therefore the inquiry should end there. The FTC cites *FTC v. Carter*, 636 F.2d 781, 789 (D.C. Cir. 1980), for the proposition that discovery is improper and “an administrative subpoena must be enforced whenever a valid purpose appears, even if an otherwise improper purpose also appeared.” (FTC Opp'n at 12.) Such an interpretation, however, implies that an agency subpoena could *never* be challenged as an abuse of process, so long as there is some legitimate authorization for its use of compulsory process. This cannot be squared with *United States v. Powell*, 379 U.S. 48 (1964), which holds that it is an abuse of the court's process to enforce a subpoena that was issued for an improper purpose. *Id.* at 58. A court may inquire into the underlying reasons for the investigation as long as the subpoenaed individual can show that the agency's investigation was being conducted in bad faith. *Id.*

This Court finds that the facts before it present a strong possibility that the FTC did share

confidential information with Watson's competitor, that it did attempt to broker a deal between Apotex and Watson that would require Watson to relinquish any statutory "first filer" rights it had acquired, and that it did initiate this investigation to pressure Watson to relinquish these rights and to harass it when it refused. *Powell* holds that it would be an abuse of the court's process to enforce an agency summons that "had been issued for an improper purpose, such as to harass the [recipient] or to put pressure on him to settle a collateral dispute." 379 U.S. at 58. The facts before us suggest that the FTC sought to place Watson between a rock and a hard place, where the only way Watson could clear its name and escape further FTC scrutiny was to give in to the pressure the FTC was placing on Watson to enter into the business deal with Apotex.

Mr. Bisaro has 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. The FTC Act empowers the FTC "to prevent [persons or corporations] . . . from using unfair methods of competition in or affecting commerce." 15 U.S.C. § 45(a)(2). But, it does not appear that there is any statutory or regulatory authority that would empower the FTC 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. The FTC alleges that it initiated the investigation because it suspected that Watson was engaging or had engaged in anticompetitive activities with respect to marketing its generic version of modafinil. However, the only reason it came to this conclusion was because Watson refused the deal that the FTC and Apotex were pressuring it to enter.

Furthermore, if the FTC did divulge Watson's confidential information to Apotex in its

attempt to broker this deal, that would also fall outside its investigative authority. *See* 15 U.S.C. §§ 57b-2(b)(3)(c), 57b-2(c), 57b-2(f)(1) (FTC confidentiality provisions). If these facts can be proven, they would be sufficient to transcend the judicial deference normally given to an agency in these types of enforcement proceedings. *See SEC v. Wheeling-Pittsburgh Steel Corp.*, 648 F.2d 118, 125 (3d Cir. 1981). It is 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.

Mr. Bisaro asks the Court to compel limited discovery so that he may gather further evidence to support his allegations that the FTC was acting outside its authority. Although the standard in administrative enforcement proceedings is a strict one and discovery is rarely granted, this Circuit has repeatedly held that a court *can* order limited discovery when it finds that extraordinary circumstances exist and that discovery is necessary for the court to carry out its duties. *See, e.g., Aero Mayflower*, 831 F.2d at 1146-47. This Court finds that the facts presented here are extraordinary enough to grant very limited discovery.

Mr. Bisaro seeks limited discovery in the form of two interrogatories (Mot. to Compel Ex. A) and a deposition notice to Mr. Meier, the FTC official implicated above (Mot. to Compel Ex. B). This Court finds the limited interrogatories appropriate and notes that this Circuit has endorsed such an approach. *See Fensterweld*, 553 F.2d at 232-33. However, this Court does not believe a deposition of an FTC official would be appropriate, nor has it found any instance where this Circuit has permitted such action in the course of subpoena enforcement proceedings.

**IV. CONCLUSION**

For the foregoing reasons, the Court finds that Respondent's Motion to Compel Discovery should be granted in part and denied in part.

It is this 13th day of July, 2010, hereby

**ORDERED** that Mr. Bisaro's Motion to Compel the deposition appearance of Markus H. Meier, Assistant Director of the FTC Bureau of Competition's Health Care Division is **denied**; it is further

**ORDERED** that the FTC shall answer the First Set of Interrogatories of Respondent Paul M. Bisaro dated May 21, 2010, within 10 days from the date of this order; and it is further

**ORDERED** that Mr. Bisaro will have 10 days from the date it receives the answers to the interrogatories to supplement the record with the Court.

\_\_\_\_\_/s/\_\_\_\_\_  
ALAN KAY  
UNITED STATES MAGISTRATE JUDGE