UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION,

Petitioner,

v.

PAUL M. BISARO,

Respondent.

Misc. Action No. 10–289 (CKK) (AK)

("Watson"), a company engaged in the development and distribution of generic pharmaceuticals.

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

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

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.

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

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 ourt el

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

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

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 learne