IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

PETITIONER FTC'S MOTION FOR LEAVE TO SUPPLEMENT THE RECORD AND TO ENFORCE THE SUBPOENA *AD TESTIFICANDUM* FORTHWITH, AND MEMORANDUM IN SUPPORT

On July 13, 2010, this Court entered a Memorandum and Order finding that Respondent had made a "colorable claim" that the Federal Trade Commission ("FTC" or "Commission") had engaged in misconduct by seeking Respondent's oral sworn testimony in a law enforcement investigation issued pursuant to a resolution approved by the full Commission. Contrary to Respondent's assertions, the Commission's actions were carried out for legitimate law enforcement purposes in furtherance of the public interest – and, in one critical instance, with the consent of Respondent's counsel. Accordingly, we submit this Motion to Supplement the Record in order to provide the Court with a more complete factual background, and to ensure that this evidence is available on the public record and not just to Respondent. The Commission also moves this Court to enforce its Subpoena *Ad Testificandum* forthwith, as there is no remaining cause for delay.

For the reasons set forth below, we seek to supplement the record with (i) answers to Respondent's two interrogatories sworn to by Markus H. Meier, chief of the Health Care Division ("Interrog. Resp." attached as Exhibit A,); (ii) a Declaration by Richard A. Feinstein, Director of the Commission's Bureau of Competition and former chief of the Bureau's Health Care Division ("Feinstein Decl." attached as Exhibit B); and (iii) a Declaration by Saralisa C. Brau, Deputy Assistant Director of the Bureau's Health Care Division and the person responsible for day-to-day management of the investigation into potential anticompetitive conduct of Watson Pharmaceuticals, Inc. ("Watson") ("Brau Decl." attached as Exhibit C). Because the factual record amply demonstrates that the requirements for judicial enforcement have been satisfied, and for the reasons set forth in more detail below, the FTC also respectfully moves this Court to take all steps necessary to further the enforcement of the July 22, 2009, subpoena *ad testificandum* forthwith.

PRELIMINARY STATEMENT

The FTC acted appropriately at all times during the course of this investigation. Further, Respondent has made no objective "showing" of misconduct, and the "extraordinary circumstances" that might justify discovery within the context of summary subpoena enforcement proceedings are not present here. *Federal Trade Commission v. Carter*, 636 F.2d 781, 789 (D.C. Cir. 1980). The Commission takes this opportunity to provide the Court with the full story. The proposed submissions – the FTC's Responses to Interrogatories, the Feinstein Declaration, and the Brau Declaration – demonstrate that: the law enforcement investigation giving rise to the subpoena at issue has been conducted in a proper and lawful manner that is fully consistent with the ordinary course of Commission practice; that the Commission did not try to broker any deal

between Watson and Apotex; that Watson's interactions with Apotex are directly relevant to determine whether Watson is bound by an agreement not to relinquish any potential exclusivity rights; that there were no improper disclosures of confidential information made at any time during the course of the investigation; and, finally, that Respondent has impeded an ongoing Commission investigation, potentially causing harm to the public interest.

As detailed below, and elaborated in the papers already on file with this Court, the requirements for judicial enforcement of the subpoena at issue have been fully satisfied. The FTC therefore respectfully requests that this Court, with a complete record now in hand, expeditiously resolve this matter pursuant to Local Civil Rule 72.3 so that the subpoena can be enforced at the earliest possible date. Respondent should be ordered to fulfill his legal obligation to cooperate with the lawful Commission investigation by sitting for an investigational hearing.

STATEMENT OF FACTS

The investigation giving rise to the subpoena in question, like all formal Commission investigations involving the use of compulsory process, required majority vote of the Commission. Feinstein Decl. at ¶ 3; 16 CFR § 2.7(a). On August 30, 2006, the Commission unanimously issued a Resolution authorizing the use of compulsory process in the present investigation.[1] The initial focus of the staff's investigation concerned a patent settlement agreement entered into between Cephalon, Inc. ("Cephalon") and various generic companies involving Cephalon's '516 patent. Interrog. Resp. at 3; Brau Decl. at ¶ 3; *see also* Dkt. No. 4 (Mem. of P. & A. in Supp. of Pet. of F.T.C. for an Order Enforcing Subpoena *Ad Testificandum*) at 4-5.

[1] Resolution Authorizing Use of Compulsory Process in a NonPublic Investigation, File No. 0610182 (August 30, 2006). Pet. Exh. 2 (Dkt. No. 3 at 10).

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procedure followed in the ordinary course of Commission investigations. Feinstein Decl. at ¶ 10. At no time did staff improperly disclose any confidential information to the FDA, nor did staff improperly discuss any confidential FDA information with Watson or others. Interrog. Resp. at 5, 11; Feinstein Decl. at ¶¶ 2, 14.

More specifically, issuance of the '346 patent represented a novel situation to staff, Interrog. Resp. at 4, and a potentially new impediment to generic entry in the modafinil market. To the extent generic manufacturers obtained first-filer rights on this patent, and had entered into unlawful agreements with respect to those rights, it might allow them to block entry by other companies seeking to enter with a low-cost generic version of modafinil, causing further anticompetitive harm to consumers. Interrog. Resp. at 4; Brau Decl. at ¶ 4. That harm might be avoided if a generic company decided to relinquish any claim of exclusivity rights it might have on the '346 patent. But the FTC staff were concerned that Watson had lost the ability to do that. Indeed, Section 2.1 of the 2006 Settlement Agreement between Watson and Cephalon could be read to prohibit Watson from relinquishing any new exclusivity rights it might have obtained based on any filing with respect to the '346 patent. *See* Brau Decl. at ¶ 6.

In March 2009, Mr. Meier, the chief of the Commission's Health Care Division in its Bureau of Competition, contacted counsel for Watson, to probe whether Watson was willing to relinquish any exclusivity rights it might have. Interrog. Resp. at 9; Brau Decl. at ¶ 8. The basis for this inquiry was staff's belief that relinquishment could provide Watson with a potential business opportunity and, at the same time, potentially save consumers of Provigil millions of dollars a year by facilitating entry of generic modafinil. Brau Decl. at ¶ 7. If Watson was not interested in relinquishing, *i.e.*, was foregoing a potentially profitable opportunity against its

Despite the opportunity presented to it, Watson declined to negotiate a deal to relinquish any exclusivity it may have, thereby leaving open the possibility that it had entered into an illegal agreement with Cephalon. The Commission continued to investigate whether Watson had agreed with Cephalon not to relinquish. Brau Decl. at ¶ 12

In short, notwithstanding efforts by the staff to determine whether such an agreement existed, Watson has, to this date, refused to give the Commission staff an unequivocal answer to one simple question: has Watson agreed with Cephalon not to relinquish any exclusivity rights that it might hold with respect to generic modafinil? Feinstein Decl. at ¶ 12; Brau Decl. at ¶¶ 14-19; *see also* Pet'rs Reply Mem. in Supp. of Pet. for an Order Enforcing Admin. Subpoena *Ad Testificandum* and Opp'n to Respondent's Mot. to Compel, at 2-7 [Dkt. No. 21]. The Commission seeks the sworn testimony of Mr. Bisaro for a proper purpose – to determine

[4] As the full Commission expressly noted in its Letter Opinion denying Petitioner's Motion to Quash the subpoena:

> Courts have expressed great skepticism of agreements in which a generic manufacturer who is eligible for the 180-day exclusivity agrees with the branded manufacturer not to relinquish or waive that exclusivity. *See, e.g. In re Ciprofloxacin*, 544 F.3d 1323, 1339 (Fed. Cir. 2008) (agreeing that "the only legitimate allegation by the plaintiffs was that the 180-day exclusivity period had been manipulated.");

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finding by the Court potentially damages the public's confidence in the work the agency does. It is therefore important that the Commission have the opportunity to complete the record in this case to make clear that the Commission has properly conducted itself in all respects in this matter.

Notably, in partially granting Respondent limited discovery in this matter, the Court has directed the Commission to answer two interrogatories and has allowed Respondent ten days after receiving the answers to supplement the record. The Court's Order does not provide the Commission with an opportunity to respond. Unless the Commission is given an opportunity to supplement the record now, this means that the only evidentiary materials before the Court when it ultimately decides this matter may be those provided by the party that has the greatest interest in undermining the Commission's integrity. Fundamental notions of fairness and due process dictate that the Court be fully informed when making its decision. The Court should therefore grant the Commission's motion to supplement the record.

II. The Record, As Fairly Supplemented, Is Sufficient to Order Enforcement of the Subpoena *Ad Testificandum* Forthwith

The standards for judicial enforcement of administrative investigative process have long been settled in this Circuit. "[T]he court's role in a proceeding to enforce an administrative subpoena is a strictly limited one." *FTC v. Texaco, Inc.*, 555 F.2d 862, 871-72 (D.C. Cir. 1977) (*en banc*) (*citing Endicott Johnson Corp. v. Perkins*, 317 U.S. 501, 509 (1943); *accord, Oklahoma Press Publ'g Co. v. Walling*, 327 U.S. 186, 209 (1946); *United States v. Morton Salt Co.*, 338 U.S. 632, 643 (1950)). A district court must enforce agency process so long as the information sought is not "unduly burdensome" to produce (*Texaco*, 555 F.2d at 881), and is "reasonably relevant" (*id.* at 872-73 n.23 (quoting *Morton Salt*, 338 U.S. at 652), or, putting it

differently, "not plainly incompetent or irrelevant to any lawful purpose" of the agency. *Texaco*, 555 F.2d at 872 (quoting *Endicott Johnson*, 317 U.S. at 509). In making this determination, the agency's own appraisal of relevancy must be accepted so long as it is not "'obviously wrong.'" *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1089 (D.C. Cir. 1992) (citing *Carter*, 636 F.2d at 787-88 (quoting *Texaco*, 555 F.2d at 877 n.32)).

Respondent has previously argued that the "most important[]"of its reasons against enforcement of the subpoena is that enforcement would result in an abuse of this Court's process because "the FTC exceeded its statutory law-enforcement mission by seeking to broker a business deal between Watson and Apotex ... improperly using its privileged access to confidential information in the process, and apparently providing Watson's confidential information to Apotex." Resp'ts Mem. in Opp'n, Dkt. No. 12, at 3. As Respondent has also acknowledged, in his Motion to Compel, this argument turns on a factual question. Dkt. No. 16, at 3. The Court now has the evidence in hand necessary to resolve this factual question. There is no record support that the FTC has exceeded its authority or otherwise acted improperly – beyond the insinuations contained within the declaration of Respondent's counsel. And there is now ample evidence to the contrary.

With the Commission's submissions now before the Court, the record demonstrates that

The agency timely began to investigate any potential anticompetitive effects resulting from the filing of the '346 patent as soon as it first learned of the filing of the patent, *before* any conversations with Watson's counsel. Interrog. Resp. at 3; Brau Decl. at ¶ 4. There was, and continues to be, good reason for the agency to seek this information. *See Modern Home Institute, Inc. v. Hartford Acc. & Indem. Co.*

manufacturer, Cephalon, limits Watson's ability to relinquish any exclusivity rights it may have with respect to marketing of the drug modafinil.

The Commission has shown that an investigational hearing of Respondent is necessary, because, to date, none of the sworn testimony contains a definitive disavowal of the existence of an agreement between Watson and Cepahlon that would prevent Watson from relinquishing exclusivity. Respondent has failed to rebut the Commission's showing that the investigative hearing is necessary. Moreover, Respondent does not dispute that Watson has repeatedly failed to answer, under oath, critical questions about the settlement agreement; it does not dispute that Respondent knows relevant facts to the investigation; and it does not assert that the investigational hearing would be unduly burdensome.

In furtherance of the interests of judicial economy and the public interest, and for the reasons previously articulated to this Court, the FTC respectfully requests that the Court recommend that Mr. Bisaro be directed to comply in full with the subpoena *ad testificandum*.

CONCLUSION

For the foregoing reasons, the Commission respectfully requests that this Court grant its Motion for Leave to Supplement the Record and Petition to Enforce the Subpoena Forthwith.

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Statement of Compliance

Pursuant to L.Cv. R. 7(m), on July 20, 2010, Petitioner's counsel conferred with counsel for Respondent regarding Petitioner's Motion for Leave to Supplement the Record, and counsel for Respondent opposes the motion. There is no obligation, under the local rules, to confer with respect to Petitioner's dispositive motion to Enforce the Subpoena *Ad Testificandum* Forthwith.

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CERTIFICATE OF SERVICE

I hereby certify that on July 22, 2010, a true and correct copy of the foregoing Motion for Leave to Supplement the Record and to Enforce the Subpoena *Ad Testificandum* Forthwith, together with: Exhibit A: FTC's Responses to First Set of Interrogatories of Respondent Paul M. Bisaro sworn to by Markus H. Meier; Exhibit B: Declaration of Richard A. Feinstein; Exhibit C: Declaration of Saralisa C. Brau; and a Proposed Order, were filed electronically in the United State District Court for the District of Columbia using the CM/ECF system.

Notice of this filing will be sent by email to all parties by operation of the Court's