IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

PETITIONER'S MOTION FOR LEAVE TO FILE SURREPLY
IN OPPOSITION TO MOTION TO COMPEL

Petitioner Federal Trade Commission ("Commission" or "FTC") respectfully seeks leave of the Court to file the attached Surreply in order to correct several misstatements and distortions of the factual record made for the first time in Respondent's Reply Brief in Support of Motion to Compel ("Reply") [Doc. No. 23] that essentially amount to the assertion of new "facts." These misstatements include false representations that the Commission "conceded" several facts. The Court should grant the Commission's motion in order to allow the Commission to address and correct these misstatements.

The decision to grant or deny leave to file a surreply is committed to the sound discretion of the court. *American Forest & Paper Ass'n, Inc., v. U.S. Environ. Protection Agency*, No. 93-cv-0694 (RMU), 1996 WL 509601, *3 (D.D.C. 1996) (granting leave). Granting leave to file a surreply is appropriate when a reply leaves "a party ... 'unable to contest matters presented to the court for the first time.'" *Ben-Kotel v. Howard Univ.*, 319 F.3d 532, 536 (D.C. Cir. 2003) (citation omitted); *Alexander v. FBI*, 186 F.R.D. 71, 74 (D.D.C. 1998) (granting leave). A surreply may be necessary whether the new matter is factual or raises new legal arguments. It is

is particularly appropriate in order to address and correct inaccuracies in a reply memorandum. *See American Forest & Paper*, 1996 WL 506601 at *3. The Commission's proposed Surreply (copy appended hereto as Attachment 1) easily satisfies this standard.

Argument

Respondent's Reply includes several misstatements, including allegations that the Commission conceded a number of facts. In particular, Respondent claims that the Commission conceded that it improperly shared confidential information from the Food and Drug Administration with Watson Pharmaceuticals, Inc. ("Watson") and Apotex, that it improperly shared confidential information from Watson with Apotex, and improperly pressured Watson to relinquish any potential exclusivity it might possess for marketing modafinil. Reply at 3-4. These statements are categorically false: the Commission has never conceded such facts and categorically denies that it has ever engaged in any improper conduct in this matter. Further, Respondent points to no evidence to support such extravagant allegations.

Respondent may not support his contention that there are "extraordinary circumstances" that warrant discovery in a summary subpoena enforcement proceeding by citing supposition and innuendo that are derived from self-serving statements of counsel. These so-called "facts" so gravely distort the record that they essentially amount to the creation of new – but entirely incorrect – "facts." The Commission's Surreply is necessary in order to address and correct these errors. *See Ben-Kotel*, 319 F.3d at 536; *Alexander*, 186 F.R.D. at 74; *American Forest & Paper*, 1996 WL 506601 at *3.

Conclusion

For the foregoing reasons, the Commission respectfully requests that this Court issue an order granting the Commission leave to file its proposed Surreply.

Respectfully submitted,

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Dated: June 10, 2010

Statement of Compliance with L.Cv.R. 7(m)

Pursuant to L.Cv.R. 7(m), on June 9, 2010, the undersigned Petitioner's counsel conferred by telephone with Julia K. York, counsel for Respondent, regarding Petitioner's Motion for Leave to File Surreply in Opposition to Motion to Compel. Ms. York stated that Respondent opposes the motion.

Dated: June 10, 2010

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CERTIFICATE OF SERVICE

I hereby certify that on June 10, 2010, a true and correct copy of the foregoing Petitioner's Motion for Leave to File Surreply in Opposition to Motion to Compel was filed electronically in the United States District Court for the District of Columbia using the CM/ECF system.

Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing.

Dated: June 10, 2010

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

FEDERAL TRADE COMMISSION'S SURREPLY IN OPPOSITION TO MOTION TO COMPEL

Respondent, Paul M. Bisaro, has submitted a Reply that alleges, for the first time, that the Commission has conceded certain allegations previously made by Respondent.[1] This is false; the Commission has never conceded the truth of the allegations made by Respondent. Indeed, Respondent has not pointed to any factual basis for his claims of impropriety. The Commission categorically denies that it engaged in any improper conduct in this matter. Respondent misstates the record before the Court. Respondent treats innuendo as established "fact," when in reality Respondent's Reply relies on the unsupported assertions of counsel to suggest that the FTC either improperly shared confidential information or pressured Respondent's employer, Watson Pharmaceuticals, Inc. ("Watson"), to enter into a transaction with a third party. The Commission has argued that Respondent's allegations were irrelevant to the issue before the court – namely whether Mr. Bisaro should comply with the Commission's

[1] *See* Respondent's Reply Brief in Support of Motion to Compel ("Reply") [Doc. No. 23].

subpoena – but the Commission never conceded the truth of those allegations. Respondent's distortion of the factual record is so severe and pervasive that it amounts to an assertion of new "facts." The Commission is therefore compelled to submit this Surreply to respond to these misstatements.[2]

Specifically, Respondent asserts as a conceded "fact" the proposition that the Commission improperly shared confidential Food and Drug Administration ("FDA") information with Watson and a third party, Apotex (*e.g.*, Reply at 3, 5), but the Commission has not conceded this point; instead, the Commission denies it, and Respondent points to no evidence to support his assertion. Additionally, Respondent has not even identified any confidential information the Commission purportedly shared; instead, the only authority Respondent puts forward for this purported "fact" is his own counsel's self-serving statement that "Mr. Meier indicated that he discussed the regulatory status [of Watson] with the FDA." *See* Respondent's Opposition ("Resp. Opp.") [Doc. No. 13] at 26-27 (citing Declaration of Steven C. Sunshine [Dec. No. 13-1] ¶¶ 16, 18); *cf.* Resp. Opp. at 26 ("The FTC confirmed to Watson's counsel that it had been in touch with the FDA."). There is nothing in the factual record, however, that Mr. Meier ever conveyed any confidential information that he may have learned from the FDA.

[2] Respondent's motion to compel discovery was filed in the context of an FTC petition to enforce an administrative subpoena requiring Mr. Bisaro's testimony because Watson has refused to answer a central question in the Commission's investigation — namely, whether Watson's settlement agreement with a rival manufacturer, Cephalon, Inc. ("Cephalon") limits Watson's ability to relinquish any exclusivity rights it may have with respect to marketing of the drug modafinil. In his Reply, Respondent fails to rebut the Commission's showing that his investigative hearing is necessary, does not dispute that Watson has repeatedly failed to answer under oath important questions about the settlement agreement, does not dispute that he knows relevant facts to the investigation, and does not assert that the investigational hearing would be unduly burdensome.

In nearly identical fashion, Respondent baldly states as conceded "fact" that the Commission shared with Apotex confidential information it received from Watson. *E.g.*, Reply at 3. Once again, the Commission has not conceded this point; it denies it, and Respondent points to no evidence to support it. Further, he again fails to identify any confidential information that was shared. Indeed, the only "authority" he has ever cited for this purported "fact," *see* Resp. Opp. [Doc. No. 13] at 27 (*citing* Opp. Decl. Exh. H [Doc. No. 13-10]), is an email excerpt that merely indicated that FTC staff had been in touch with Apotex. The excerpt provided does not show that the FTC improperly shared any confidential information.

Likewise, the Commission never conceded that it "pressured" Watson into entering into a business transaction with Apotex to market modafinil. *E.g.*, Reply at 3-4. The only evidence Respondent has ever adduced on this point, *see* Sunshine Decl. [Doc. No. 13-1] ¶¶ 16-18; Opp. Exh. H [Doc. No. 13-10], merely indicates efforts to have Watson consider relinquishment of any potential exclusivity related to its supplemental ANDA for modafinil – a result that would moot any preexisting anticompetitive concerns that the Commission had. Watson, of course, was free to ignore such a suggestion and to allow the investigation to proceed.[3]

Throughout these proceedings Respondent has repeatedly failed to support his repeated assertions of "facts" with sworn declarations or other admissible evidence demonstrating that confidential information was shared improperly or that the Commission improperly pressured Watson to enter into a transaction involving modafinil. Instead, to support his allegations of agency impropriety, he has relied on innuendo and insinuation. *See, e.g.*, Resp. Opp. at 13

[3] The Commission has certainly never taken the position – as Respondent now asserts – that the only way Watson can prove that no agreement exists is to enter an agreement with Apotex. *See* Reply at 6. If no agreement exists, Watson could simply answer the Commission's questions on the subject.

("Staff was apparently sharing . . ."), Resp. Opp. at 26 (Respondent "has reason to believe" confidential information was shared based on the fact that the FTC said it spoke to the FDA); Resp. Opp. at 27 ("it appears that the FTC may have violated confidentiality obligations . . . This possible wrongful sharing of information is suggested by . . .").

The Commission had argued previously that allegations of improper disclosure and undue pressure were irrelevant to whether Mr. Bisaro has to comply with the Commission's subpoena.[4] For example, the Commission stated that "even if" Mr. Meier suggested to Watson's counsel that it relinquish any marketing exclusivity it might have for modafinil, any such conduct would be entirely permissible as Watson's relinquishment to Apotex necessarily would have obviated any anticompetitive concerns. FTC Opp. at 10-11. Likewise, the Commission stated that "even if" there were an improper disclosure of confidential information, the proper forum in which to address it is not a summary subpoena enforcement proceeding, but rather an FTC enforcement action, if one is ever filed. FTC Opp. at 11. These statements, however, do not amount to any sort of factual "concession" by the Commission. It therefore was entirely improper for Respondent to newly assert in his Reply that the Commission conceded his manufactured "facts" in opposing the motion to compel.[5]

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[4] *See* Reply Memorandum in Support of Petition for an Order Enforcing Administrative Subpoena *Ad Testificandum* and Opposition to Respondent's Motion to Compel ("FTC Opp.") [Doc. No. 21].

[5] Respondent also misrepresents that it had raised before the Commission its argument that the supposed retrospective-only language of the 2006 Resolution precludes investigating conduct allegedly occurring after the Resolution was issued, including Watson's conduct regarding relinquishment. *See* Reply at 9-10. In fact, Respondent made a different argument before the Commission based on the Resolution: that because the Commission had filed a civil action against Cephalon (without also challenging the conduct of the generic manufacturers), the Resolution could not be "resurrected" for a subsequent investigation against Watson. *See, e.g*, York Decl. Ex. L at 15 n. 73 [Doc. 13-14]. Respondent did *not* base this argument on the

Respondent's unsupported allegations of agency misconduct should not be allowed to obfuscate the relevant issue at hand – that Watson has consistently refused to answer a central question in the Commission's investigation. In attempting to supplement the factual record through misstatement and distortion, Respondent fails utterly to establish the "extraordinary circumstances" that are necessary to warrant discovery in a summary subpoena enforcement proceeding, or to rebut the Commission's showing that the subpoena seeking Mr. Bisaro's testimony should be enforced.

Respectfully submitted,

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supposed retrospective-only language in the Resolution.

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[Proposed] ORDER

Upon consideration of Petitioner's Motion for Leave to File Surreply in Opposition to Respondent's Motion to Compel, and the record herein, it is hereby

ORDERED that Petitioner's motion is **GRANTED** .

ISSUED this _____ day of _____, 2010.

ORDERED:

_____
Hon. Alan Kay
United States Magistrate Judge

Parties to be served:

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