EXHIBIT C

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.	)	

DECLARATION OF SARALISA C. BRAU

Pursuant to 28 U.S.C. § 1746, Saralisa C. Brau declares as follows:

1. I am a Deputy Assistant Director in the Health Care Division within the Bureau of Competition of the U.S. Federal Trade Commission ("FTC" or "Commission"). I have day-to-day supervisory responsibility over the Commission's modafinil investigation.

2. I submit this declaration in support of the Commission's Motion for Leave to Supplement the Record and to Enforce the Subpoena *Ad Testificandum* Forthwith. The facts set forth herein are based on my personal knowledge or information made known to me in the course of my official duties.

3. The Commission opened the modafinil investigation in 2006 to determine if Cephalon, Inc. ("Cephalon"), Watson Pharmaceuticals, Inc. ("Watson"), and certain other generic companies had entered into unlawful agreements to delay the introduction of generic versions of Provigil, Cephalon's branded modafinil product. The initial phase of the modafinil investigation focused on the generic companies' challenges to Cephalon's U.S. Resissued Patent

No. 37,516 ("the '516 patent") and Cephalon's 2005-2006 settlements of the '516 patent litigation, under which Watson and the other generic companies agreed they would not market generic modafinil until 2012. The initial phase of the Commission's modafinil investigation culminated in the filing of a federal court complaint against Cephalon (but not Watson or the other generics) in February 2008, which is currently being litigated in the Eastern District of Pennsylvania. *See FTC v. Cephalon, Inc.*, No. 2:08:-cv-2141-MSG, 2010 U.S. Dist. LEXIS 29905 (E.D. Pa. Mar. 29, 2010) (denying motion to dismiss). After filing the complaint, the Commission's modafinil investigation remained open, albeit inactive.

4. The most recent phase of the modafinil investigation began when, in January 2009, Commission staff first learned that Cephalon had filed a new patent in the Food and Drug Administration's ("FDA's") Orange Book covering Provigil, U.S. Patent No. 7,297,346 ("the '346 Patent"), and that Watson – on the same day – had filed a Paragraph IV certification against the '346 Patent claiming that the patent was either invalid or not infringed by Watson's generic product. Based on my understanding of applicable statutes and regulations, these events created the possibility that Watson might be a "first filer" with regard to the '346 Patent. As "first filers," generic companies are eligible for 180 days of marketing exclusivity at such time that the FDA grants final approval to their generic drug applications. That Watson might have potential marketing exclusivity arising from the '346 patent raised questions about whether Watson's agreement not to market generic modafinil until 2012 might act as an additional impediment to generic modafinil entry by other generic companies. In light of these new facts, FTC staff resumed the modafinil investigation.

5. Between March 2 and May 5, 2009, Markus H. Meier, the Assistant Director of the Health Care Division, and I initiated several telephone calls to Watson's counsel, Steven C. Sunshine of Skadden, Arps, Slate, Meagher & Flom LLP, to discuss the latest developments in the modafinil investigation. Those conversations, and what did and did not occur as a result of those conversations, raised troubling questions about whether Watson had entered into a potentially *per se* unlawful agreement with Cephalon not to relinquish any modafinil marketing exclusivity it might have. Beginning in May 2009, the Commission issued additional compulsory process, including the subpoena *ad testificandum* to Mr. Bisaro, to resolve those questions.

The Evidentiary Basis for the Investigation

6. The evidentiary basis for staff's concerns about an unlawful agreement between Watson and Cephalon not to relinquish Watson's potential exclusivity rights centered on two issues. First, in Section 2.1 of the 2006 Settlement and License Agreement between Cephalon and Watson's business development partner, Carlsbad Technologies, Inc., ("the Settlement Agreement"), Watson had agreed not to "make, use, offer to sell, or sell, *or actively induce or assist any other entity* to make, use, offer to sell, or sell any Generic Modafinil Product within the Territory . . . ."[1] To the extent that Watson's agreement not to "actively induce or assist any other entity," precluded it from relinquishing any exclusivity rights it might have, this provision could violate the antitrust laws as an agreement among potential competitors to block other

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[1] Settlement Agreement § 2.1 (emphasis added). Although to the Commission's knowledge the parties have not disclosed publicly the complete terms of the Settlement Agreement, Cephalon included a redacted version (containing the language quoted above) as Exhibit 10.1 to its 10-Q, filed with the SEC on November 8, 2006.

generic competitors from entering the market. *See In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 907-08 (6th Cir. 2003) (condemning an agreement between a brand and generic company not to relinquish exclusivity rights as a *per se* violation of the antitrust laws). This provision of the Settlement Agreement had not been a focus of the initial phase of the investigation because Watson was not a first filer with regard to the '516 patent, and was therefore not eligible for marketing exclusivity. That changed, however, after FTC staff learned, in January 2009, that Watson was a first filer with potential exclusivity rights arising from the later-listed '346 patent.

7. Second, Watson appeared disinclined to pursue a potentially profitable business opportunity in which it could relinquish any modafinil exclusivity rights it might have in exchange for substantial compensation. In a telephone conversation with Mr. Sunshine in March 2009, Mr. Meier posited hypothetical scenarios to explore whether Watson might profit from relinquishment of any exclusivity rights it might have. Based on my understanding of the facts at the time, it appeared that relinquishment could be a more profitable option for Watson than waiting to launch its generic modafinil product under the terms of the Settlement Agreement.

8. On March 13, 2009, Mr. Meier asked Mr. Sunshine if Watson would be interested in talking with a third party, Apotex, Inc. ("Apotex") about a potential agreement to relinquish whatever marketing exclusivity rights Watson might have. Mr. Sunshine affirmed that Watson would be interested in talking to Apotex about the possibility of relinquishment, and identified David Buchen, Watson's General Counsel, as the person at Watson that Apotex should contact.

9. If Watson chose to relinquish its potential exclusivity, the FTC's ongoing investigation about whether Watson had agreed with Cephalon *not* to relinquish its exclusivity

would have been resolved, leaving nothing further to investigate. In contrast, if Watson chose not to relinquish its potential exclusivity, the FTC would need to assess whether Watson was acting independently or whether the reason for the decision was attributable to an unlawful agreement with Cephalon not to relinquish.

10. On May 5, 2009, Mr. Meier and I called Mr. Sunshine to determine whether there had been any further developments relating to Watson's potential relinquishment. On May 6, 2009, Mr. Meier and I placed a similar call to Apotex's Vice President of Global Intellectual Property, Shashank Upadhye. Mr. Upadhye told FTC staff that discussions with Watson had stalled and that Watson did not appear to be interested in pursuing a business arrangement with Apotex. Based on these conversations, by early May 2009, it appeared to FTC staff that Watson was not interested in potential relinquishment.

11. Watson's apparent decision to forego a potentially profitable business opportunity relating to relinquishment raised further questions to staff about why Watson was acting in a manner that appeared to be contrary to its own economic interest. These questions, combined with staff's concerns about Section 2.1 of the Settlement Agreement, required further investigation to assess whether the reason for the decision was attributable to an unlawful agreement with Cephalon not to relinquish.

Watson Repeatedly Fails to Answer the FTC's Questions

12. On May 19, 2009, the Commission issued narrowly targeted Civil Investigative Demands ("CIDs") to Watson (the "Watson CID") and its development partner, Carlsbad, to determine, *inter alia*, whether Watson is a party to any agreement that limits its ability to relinquish any marketing exclusivity rights it may have with respect to generic Provigil.

13. Specifically, Specification 3 of the Watson CID required it to identify "each agreement, written or oral, that prohibits, blocks, prevents, compromises, or limits in any way Watson or Carlsbad's ability to relinquish eligibility to claim 180-day Marketing Exclusivity for Generic Provigil," as well as "[t]he portion(s) of the agreement that prohibit or limit Watson's or Carlsbad's ability to relinquish." (Pet'r's Reply Mem. in Supp. of Pet. for an Order Enforcing Administrative Subpoena Ad Testificandum and Opp'n to Resp't's Mot. to Compel, Supplemental Pet. Ex. 2. (Doc. No. 20))

14. In its written response dated June 10, 2009, Watson identified the Settlement Agreement as the only agreement that "may relate" to its ability to relinquish, stating that "[a]ny relevant limitations or restrictions are contained therein." Watson, however, did not identify the relevant portions of the agreement as required by Specification 3 of the CID. (*Id.* at Ex. 2.) On June 11, 2009, Commission staff responded with a letter to Watson's counsel identifying the deficiency of Watson's initial CID response and again requesting that it identify the relevant portion of the Settlement Agreement as required by the CID. (*Id.* at Ex. 3.)

15. In a letter from counsel responding to Commission staff on June 17, 2009, Watson again refused to provide the requested information, stating that "[t]he Agreement speaks for itself," and claiming privilege for "Watson's analysis of . . . how the Agreement may relate to FDA marketing exclusivity." (*Id.* at Ex. 4.)

16. During the June 25, 2009 investigational hearing of David Buchen, Watson's General Counsel, Mr. Buchen identified an indemnification provision of the Settlement Agreement that "might relate to the investigation," but refused to answer when asked about any other provisions. (*Id.* at Ex. 5.) Mr. Buchen also refused to answer when asked whether the

Settlement Agreement limits Watson ability to relinquish any rights to marketing exclusivity it may have with respect to generic Provigil. (*Id.*)

17. The May 19, 2009 Watson CID also sought information relating to Watson's discussions with third parties regarding relinquishment. Specifically, Specification 4 required Watson to identify "each company with which Watson had contact relating to: ". . . eligibility to claim 180-day Marketing Exclusivity for Generic Provigil; or the relinquishment thereof," and "[w]hether Watson entered into an agreement as a result of these discussions, and the reasons for Watson's decision." (*Id.* at Ex. 2.)

18. On June 10, 2009, Watson identified Apotex in its written response as a firm with which it had discussed relinquishment, stating that "[n]o agreement or decision has been reached." Watson, however, did not provide the reasons as required by Specification 4 of the FTC's CID. (*Id.*) On June 11, 2009, Commission staff identified the deficiency of Watson's initial CID response in a letter to counsel, and requested again that Watson provide the reasons why no agreement was reached with Apotex. (*Id.* at Ex. 3.)

19. Again, Watson refused to provide the requested information. In a letter from counsel on June 17, 2009, Watson responded that the company's decision "is inextricably intertwined with legal matters; Watson's internal deliberations regarding this matter implicate legal advice and are protected from disclosure by the attorney-client privilege."(*Id.* at Ex. 4.) At his June 25, 2009 investigational hearing, however, Mr. Buchen identified for the first time two apparently non-privileged bases for not pursuing an agreement with Apotex. (*Id.* at Ex. 5.) Mr. Buchen also identified Mr. Bisaro as the only person at Watson with whom he had spoken regarding relevant discussions with a third party about a possible deal for generic Provigil. (*Id.*)

Mr. Bisaro, as President and CEO of Watson, is well positioned to testify, among other things, about whether a potential business arrangement with a third party to relinquish any modafinil exclusivity is likely to be in the company's economic interest.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: July 21, 2010

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