EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Federal Trade Commission,	
Petitioner,	
v.	**No. 01: 10-mc-00289-CKK-AK**
Paul M. Bisaro,	
Respondent.	

FEDERAL TRADE COMMISSION'S RESPONSES TO FIRST SET OF INTERROGATORIES OF RESPONDENT PAUL M. BISARO

Petitioner Federal Trade Commission ("FTC" or "Commission") hereby submits the following Responses to the First Set of Interrogatories of Respondent Paul M. Bisaro dated May 21, 2010.

GENERAL OBJECTIONS

1. By answering these interrogatories, the Commission does not waive the previous objections it made to these interrogatories in its June 21, 2010 Objections to First Set of Interrogatories of Respondent Paul M. Bisaro, nor does it waive its right to appeal, or otherwise assign error, to the Court's Order of July 13, 2010, directing it to engage in discovery in this matter.

2. To the extent Respondent's interrogatories seek the production of documents under Rule 34 or otherwise, the Commission objects on the ground that such discovery is beyond the scope of Rule 33 and beyond the scope of the Court's Order of July 13, 2010.

3. The FTC has responded to this interrogatory request to the best of its present ability. The FTC reserves its rights to supplement, revise, correct, or clarify any of the responses set forth herein, if necessary or appropriate.

In addition to these objections, the Commission further objects to Respondent's interrogatories as indicated below.

RESPONSES TO INTERROGATORIES

Interrogatory 1

Describe any communications the FTC had with the FDA relating to any potential marketing exclusivity for generic modafinil arising out of the ANDA Amendment during the period December 19, 2007, through July 22, 2009. For each communication:

a. Identify the date of the communication;

b. Identify the name and title of the individual(s) involved in the communication;

c. Identify the means through which the communication was made;

d. Identify who initiated the communication;

e. Identify the reason for the communication;

f. Identify the topic(s) discussed during the communication; and

g. State whether, during the course of the communication, or as a result of the communication, the FTC communicated to the FDA any confidential information provided to the FTC by Watson.

Response to Interrogatory 1

The FTC objects to Respondent's interrogatories to the extent they seek confidential information that the FTC obtained pursuant to inter-agency communications with the Food and Drug Administration and that is exempt from disclosure by statutes and regulations, including but not limited to 21 C. F. R. § § 20.64(a), 20.61, 20.62, and 314.430(b) (2010). Expressly reserving and without waiving the general objections and this specific objection, the FTC states as follows:

Before January 2009, the FTC's modafinil investigation had focused on a particular patent – U.S. Reissue Patent No. 37,516 (the "'516 patent") – and the potential barriers to competition arising from Cephalon's 2005-2006 patent litigation settlement agreements with Watson and the four first filers for the '516 patent. The initial phase of the modafinil investigation resulted in the FTC filing a complaint against Cephalon in February 2008.[1] The investigation remained open, however, though not active, with respect to the generic companies, including Watson, while the Commission pursued litigation against Cephalon in federal court in the Eastern District of Pennsylvania.

In January 2009, the FTC learned for the first time from the FDA that Cephalon had listed a second patent relating to Provigil, U.S. Patent No. 7,297,346 (the "'346 patent"), in the FDA's Orange Book. While the U.S. Patent and Trademark Office's issuance of the '346 patent to Cephalon in November 2007 and Cephalon's filing of it with the FDA in December 2007 were matters of public record, FTC staff had not been aware of these developments. The FTC also learned, in January 2009, that Watson/Carlsbad had filed an ANDA Amendment with the

[1] *FTC v. Cepahlon, Inc.*, No. 2:08-cv-2141-MSG (E.D. Pa. filed Feb. 13, 2008).

FDA on the same day that Cephalon listed the '346 patent. Together, these events created the possibility – one that did not exist for the '516 patent and was not a focus during the initial phase of the FTC's investigation – that Watson could be a "first filer" for the '346 patent, and therefore might block generic modafinil market entry for other companies. This new information caused the FTC staff to resume the modafinil investigation because it raised a host of questions about whether the '346 patent created any new impediments to generic entry and whether those impediments were the result of an unlawful agreement between Cephalon and Watson.

This new phase of the investigation was prompted by a conversation between the FTC and FDA on January 29, 2009. On that date, in response to the FTC's inquiries about the regulatory status of modafinil, Elizabeth Dickinson, Associate Chief Counsel in the FDA's Office of Chief Counsel, called Saralisa Brau, Deputy Assistant Director in the Health Care Division of the FTC. The two agencies routinely share information concerning the regulatory status of certain drug products, pursuant to a written inter-agency agreement, to advance the FTC's law enforcement and consumer protection missions. The modafinil investigation was no exception. The topics discussed during the call were: (1) Cephalon's later-issued '346 patent relating to Provigil; (2) Cephalon's listing of the '346 patent with the FDA; and (3) the identity of the generic company or companies that had submitted amended ANDAs containing a Paragraph IV certification as to the '346 patent and who might be eligible to claim 180-day marketing exclusivity as a "first filer."

In February 2009, the FTC requested a meeting with FDA to discuss how the '346 patent might potentially affect the FTC's ongoing modafinil investigation. Ms. Brau of the FTC had approximately three communications with Ms. Dickinson of the FDA to set up the meeting. Ms.

Brau contacted Ms. Dickinson in early February 2009 and they exchanged emails concerning meeting logistics on February 18, 2009, and February 19, 2009. The meeting took place on February 24, 2009. The following people attended:

FTC	FDA
Brad Albert, Deputy Assistant Director, Health Care Division	Rick Blumberg, Deputy Chief Counsel of Litigation, Office of Chief Counsel
Saralisa Brau, Deputy Assistant Director, Health Care Division	Kim Dettelbach, Associate Chief Counsel, Office of Chief Counsel
Michael Kades, Attorney Advisor to then-Commissioner (now Chairman) Leibowitz	Elizabeth Dickinson, Associate Chief Counsel, Office of Chief Counsel
Markus Meier, Assistant Director, Health Care Division	Dave Read, Regulatory Counsel, Center for Drug Evaluation and Research/Office of Generic Drugs

The topics discussed were: (1) the FTC's complaint filed in *FTC v. Cephalon, Inc.*, No. 1:08-cv-00244 (D.D.C. complaint filed Feb. 13, 2008) (later transferred to E.D. Pa.); and (2) the FDA's interpretation and analysis of relevant statutes concerning whether *second* filers on the earlier-listed '516 patent would be blocked from entering the market by any *first* filer(s) eligible to claim 180-day marketing exclusivity on the later-listed '346 patent.

At no time during this meeting or in the course of any communications with the FDA did the FTC reveal to the FDA any confidential information provided to the FTC by Watson.

Interrogatory 2

Describe any communications between the FTC and any third-party (excluding Watson and the FDA) including, but not limited to Apotex, relating to any potential marketing exclusivity for generic modafinil arising out of the ANDA Amendment during the period December 19, 2007, through July 22, 2009. For each communication:

a. Identify the date of the communication;

b. Identify the name and title of the individual(s) involved in the communication;

c. Identify the means through which the communication was made;

d. Identify who initiated the communication;

e. Identify the reason for the communication;

f. Identify the topic(s) discussed during the communication;

g. State whether, during the course of the communication, or as a result of the communication, the FTC communicated to any third-party any confidential information provided to the FTC by Watson; and

h. State whether, during the course of the communication, or as a result of the communication, the FTC communicated to any third-party any confidential information provided to the FTC by the FDA.

Response to Interrogatory 2

The FTC objects to Interrogatory 2 to the extent it seeks privileged information exchanged between Apotex and the FTC pursuant to a common interest privilege as co-plaintiffs in litigation in federal district court in the Eastern District of Pennsylvania challenging

Cephalon's modafinil patent litigation settlement agreements.[2] Expressly reserving and without waiving the general objections and this specific objection, the FTC states as follows:

The FTC had periodic communications with Apotex as part of its modafinil law enforcement investigation from February through May 2009. The FTC did not have communications with any other third party concerning the topics identified in Interrogatory 2, except that FTC staff did have communications relating to these issues with Watson's counsel, Steven C. Sunshine of Skadden, Arps, Slate, Meagher & Flom LLP, from March through May 2009.[3]

FTC staff first contacted Apotex in February 2009 as part of its efforts to understand the implications of the information it had learned about the later-listed '346 patent from the FDA in January and February 2009. Apotex was an obvious choice to contact to explore these issues: it had filed an ANDA for a generic version of modafinil and was blocked from entering by Cephalon's modafinil settlements; it was already selling a generic version of Provigil in Canada; and its Vice President of Global Intellectual Property, Shashank Upadhye, had written a book entitled *Generic Pharmaceutical Patent and FDA Law* (Thompson West Publishing, 2010 ed.), and could likely provide expertise relevant to the questions of interest to the FTC. In particular, the later-listed '346 patent and its potential effect on generic entry presented a novel issue for

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[2]*See FTC v. Cepahlon, Inc.*, No. 2:08-cv-2141-MSG (E.D. Pa. filed Feb. 13, 2008); *Apotex, Inc. v. Cephalon, Inc., et al.*, No. 2:06-cv-02768-MSG (E.D. Pa. filed June 26, 2006).

[3]*See* Brau Decl. ¶¶ 5, 7, 8, 10, attached as Exhibit C to Petitioner FTC's Motion for Leave to Supplement the Record and to Enforce the Subpoena *Ad Testificandum* Forthwith.

FTC staff, and by contacting Mr. Upadhye, staff hoped to gain insights into the applicable legal framework.

Staff was primarily interested in two threshold questions in February 2009. First, FTC staff sought to understand the regulatory significance of the '346 patent, and specifically whether any first filer(s) to the '346 patent could potentially block any second filers to the earlier-listed '516 patent from entering the market. This issue was relevant to the FTC's ongoing investigation because if any exclusivity Watson might have with respect to the '346 patent did *not* block entry of other generic filers, then any agreement Watson might have with Cepahlon was unlikely to harm competition. Second, FTC staff sought to understand practically how a generic company would be aware of a later-issued patent so that it would be in the position to file an ANDA amendment on precisely the same day that the brand company listed such later-issued patent with the FDA. Put simply, FTC staff was trying to assess whether a generic company was likely to have such information independently or whether such information was likely available to the generic only as a result of collusion with the brand company to create an additional barrier to impede potential generic entry. The answers to these questions would influence the future of the ongoing investigation.

From February 2, 2009, through March 3, 2009, Markus H. Meier, Assistant Director in the Health Care Division of the FTC and Saralisa C. Brau, Deputy Assistant Director in the Health Care Division of the FTC, had approximately four communications with Shashank Upadhye, Vice President, Global Intellectual Property, Apotex, Inc. Mr. Meier and Ms. Brau called Mr. Upadhye on February 2, 2009, February 24, 2009, and March 3, 2009. Mr. Upadhye sent an email to Mr. Meier on February 3, 2009.

The topics discussed during these communications were: (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 on the later-listed '346 patent would block Apotex's ability to launch generic Provigil; (4) what it would take Apotex to launch a generic version of Provigil in the U.S., assuming it was interested in doing so; and (5) how a generic company could know the date on which a brand would list a later-issued patent with the FDA so that it could try to be a first filer by submitting its amended ANDA with the FDA on the same day.

In addition to the four earlier contacts with Mr. Upadhye, on March 13, 2009, Mr. Meier and Ms. Brau called Mr. Upadhye regarding the possibility of a business arrangement between Watson and Apotex. This call to Mr. Upadhye was a direct result of a conversation that took place earlier that day with Watson's counsel, Mr. Sunshine. From March 2, 2009, through March 13, 2009, Mr. Meier and Ms. Brau had initiated a number of telephone calls to Mr. Sunshine to discuss developments in the modafinil investigation.[4] During these conversations with Mr. Sunshine, FTC staff posited hypothetical scenarios 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. In the context of these discussions, and in response to a question from Mr. Meier, Mr. Sunshine affirmed that Watson would be interested in hearing from a third party, Apotex, about a business proposal relating to relinquishment, and Mr. Sunshine then identified Watson's General Counsel, David Buchen, as the appropriate contact person.

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[4]*See* Brau Decl. ¶¶ 5, 7, 8.

After receiving Mr. Sunshine's explicit approval to put Apotex in touch with Watson concerning potential relinquishment, FTC staff then called Mr. Upadhye on March 13, 2009, to inform Apotex of Watson's interest and that if Apotex were likewise interested, he should contact Mr. Buchen at Watson. The FTC did not "broker a deal" between Watson and Apotex. In fact, after informing Apotex of Watson's interest, with the express assent of Watson's counsel, Mr. Sunshine, the FTC played no further role in any discussions between the two companies. The FTC did not attempt at any time to propose terms or otherwise direct the course of the discussions between Apotex and Watson.

From approximately March 18 through May 6, 2009, Mr. Meier and Ms. Brau initiated periodic follow-up calls to Mr. Upadhye of Apotex to inquire about the status of the discussions with Watson. These calls occurred on approximately March 18, March 30, April 7, April 22, and May 6, 2009. The reason for the calls was simple: if, on the one hand, Watson were 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. If, on the other hand, Watson chose not to relinquish its potential exclusivity, the FTC would need to assess whether the reason for the decision was attributable to an unlawful agreement with Cephalon not to relinquish. On May 6, 2009, Mr. Upadhye told Mr. Meier and Ms. Brau that discussions with Watson had stalled and that Watson did not appear interested in pursuing a business arrangement with Apotex.

At no time during the course of any communications with Apotex did the FTC reveal to Apotex any confidential information provided to the FTC by Watson. Although staff cannot specifically recall if Watson's name came up in any telephone conversation with Mr. Upadhye

before March 13, 2009, Watson's name did come up after March 13, 2009, once the FTC had received Mr. Sunshine's explicit approval to put Apotex in touch with Watson concerning potential relinquishment. FTC staff did not improperly reveal any confidential FDA information to Apotex.

Respectfully submitted,

As to Objections:

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Dated: July 21, 2010

VERIFICATION

I, Markus H. Meier, declare:

1. I am the Assistant Director of the Health Care Division in the Bureau of Competition of the Federal Trade Commission and make this verification on and for its behalf. As Assistant Director of the Health Care Division, I have overall supervisory responsibility for the Commission's investigation of Watson.

2. I have read the foregoing Petitioner Federal Trade Commission's Responses to First Set of Interrogatories of Respondent Paul M. Bisaro.

3. All of the information contained in the foregoing is either based on my personal knowledge or facts I have learned in my official capacity.

4. I am informed and believe that the matters stated therein are true and correct and hereby certify that the foregoing answers are true to the best of the Federal Trade Commission's present knowledge, information, and belief.

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

Executed this 21st day of July, 2010.

Markus H. Meier
Assistant Director
Bureau of Competition
Federal Trade Commission