IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION 600 Pennsylvania Ave., N.W., Washington, DC 20580, Petitioner, v. **PAUL M. BISARO,** President and CEO, Watson Pharmaceuticals, Inc. 360 Mt. Kemble Avenue, Morristown, NJ 07962 Respondent.	)	Misc. No.

DECLARATION OF JAMES RHILINGER, ESQ.

Pursuant to 28 U.S.C. § 1746, I declare as follows:

1. I am an attorney employed by the U.S. Federal Trade Commission ("FTC" or "Commission"), in Washington, D.C. I am assigned to the FTC's investigation of Cephalon, Inc. ("Cephalon"), Watson Pharmaceuticals, Inc. ("Watson"), and Carlsbad Technologies, Inc. ("Carlsbad"), among other companies, concerning agreements regarding any modafinil products, including the branded drug Provigil and its generic equivalents.

2. I submit this declaration in support of the Petition of the Federal Trade Commission for an Order Enforcing Subpoena *Ad Testificandum* Issued in Furtherance of a Law Enforcement Investigation. I have read the petition and exhibits thereto (those exhibits are hereinafter referred to as "Pet. Exh."), and verify that Pet. Exh. 2 (this declaration is Pet. Exh. 1) through Pet. Exh. 8 are true and correct copies of the original documents contained in the Commission's files. 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. Watson is a publicly held company that develops, manufactures and markets bioequivalent generic pharmaceutical products. It is incorporated in the State of Nevada, with its principal place of business at 311 Bonnie Circle, Corona, California, and offices in Morristown, New Jersey. Paul M. Bisaro is the company's President and Chief Executive Officer, and works in Watson's New Jersey offices. Watson transacts business throughout the United States, including Washington, D.C. Watson is engaged in, and its businesses affect, "commerce," as that term is defined in Section 4 of the Federal Trade Act ("FTC Act"), 15 U.S.C. § 44.

4. Cephalon markets the patented drug Provigil, which contains modafinil. Provigil is a "wakefulness-enhancing" drug with annual sales of over $800 million.

5. The Commission issued an omnibus Resolution Authorizing Use of Compulsory Process in a Nonpublic Investigation, FTC File No. 0610182, dated August 30, 2006, "[t]o determine whether Cephalon, Inc., Teva Pharmaceuticals, Inc. (and its affiliate Teva Pharmaceuticals USA, Inc.), Barr Laboratories, Inc., Ranbaxy Laboratories, Inc., Mylan Pharmaceuticals, Inc., Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec 45, as amended, by entering into agreements regarding any modafinil products." Pet Exh. 2. The Commission resolved that "all compulsory processes available to it be used in connection with this investigation." *Id.* The FTC's investigation of modafinil products is nationwide in scope and is being conducted from the FTC's office in Washington, D.C., where attorneys in the Health Care Division of the Commission's Bureau of

Competition are working on this matter, and where relevant documents and information are located.

6. Carlsbad, Watson's development partner, and several other generic pharmaceutical companies, filed abbreviated new drug applications ("ANDAs") to obtain Food and Drug Administration ("FDA") approval to develop, manufacture, and sell generic versions of Provigil. Each of the generic firms listed in the process resolution, other than Watson/Carlsbad, filed their ANDAs on the same day, and before any other filers, and thus were eligible under applicable law for 180 days of joint marketing exclusivity for their modafinil product at such time the ANDA is approved.

7. Cephalon sued each of the generic companies identified in the process resolution, alleging that the generic manufacturers were infringing Cephalon's U.S. Reissued Patent No. 37,516 ("the '516 Patent") by filing their ANDAs. Cephalon subsequently settled each of these patent suits in 2005 and 2006, including a settlement on August 2, 2006 with Watson and Carlsbad. Under the terms of the settlement agreements, Watson and the other generic manufacturers agreed not to market generic Provigil until 2012.

8. On February 13, 2008, the Commission filed a complaint against Cephalon, alleging that its settlement agreements provided compensation to the generic firms for foregoing generic entry, were anticompetitive and an abuse of monopoly power, and so were unlawful under Section 5 of the FTC Act. *FTC v. Cephalon, Inc.*, 08-cv-2141-MSG (E.D. Pa.).

9. In December 2007, Cephalon listed a new patent with the FDA relating to Provigil: U.S. Patent No. 7,297,346 ("the '346 Patent"). On the same day, Watson/Carlsbad filed a certification with the FDA that its generic version of modafinil did not infringe the '346 patent, or that the patent was invalid. By doing so, Watson/Carlsbad created the possibility that Watson

was a "first filer" for the '346 patent, and thereby could block market entry for later-filing generics.

10. As part of its continuing investigation of "agreements regarding any modafinil products," the Commission issued Civil Investigative Demands ("CIDs") on May 19, 2009 to Watson and 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 modafinil. Such an agreement, if it exists, could unlawfully delay generic entry and may constitute an "unfair method of competition" in violation of the FTC Act. The Commission issued a CID to Watson on May 19, 2009, to which Watson only provided a partial response. Accordingly, Commission staff wrote to Watson's counsel, identified information Watson had failed to provide, and requested that Watson supplement its initial responses. Watson's counsel denied that the initial responses were deficient and again failed to provide the requested information, in part, on the basis of attorney-client privilege.

11. On June 25, 2009, pursuant to a subpoena *ad testificandum,* David A. Buchen, Watson's Senior Vice President, General Counsel, and Secretary, appeared and testified at an investigational hearing. Mr. Buchen did not fully respond to the Commission's questions, including those inquiring whether Watson had entered into any agreements that would prohibit or otherwise limit its ability to relinquish any marketing exclusivity rights for modafinil. Mr. Buchen 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.

12. The Commission issued a subpoena *ad testificandum* dated July 22, 2009 to Mr. Bisaro, directing him to appear for an investigational hearing in Washington, D.C. on July 31, 2009. Pet. Exh. 3. This subpoena was served on Mr. Bisaro both at Watson's Corona,

California headquarters and on his counsel in Washington, D.C., and Mr. Bisaro has not contested service.

13. On July 30, 2009, Mr. Bisaro filed a petition to quash the July 22, 2009 subpoena. Pet. Exh. 4. On November 13, 2009, Commissioner Pamela Jones Harbour, acting as the Commission's delegate, denied the July 30 petition. Pet. Exh. 5. On November 27, 2009, Mr. Bisaro and Watson requested review by the full Commission of the November 13 decision. Pet. Exh. 6.

14. On April 2, 2010, the full Commission denied Watson's request for review, and ordered that Mr. Bisaro appear at an investigational hearing on April 15, 2010 or as otherwise agreed by Commission staff. Pet. Exh. 7. In a letter dated April 13, 2010, Watson's attorneys informed Commission staff that Mr. Bisaro would not appear at the April 15, 2010 investigational hearing and does not intend to comply with the July 22, 2009 subpoena issued by the Commission. Pet. Exh. 8.

15. Commission staff met with counsel for Mr. Bisaro on April 19, 2010, at counsel's request, to discuss Mr. Bisaro's testimony. At the meeting, counsel reiterated that Mr. Bisaro would not appear to testify at an investigational hearing, as required by the July 22, 2009 subpoena and the Commission's ruling of April 2, 2010.

16. The Commission requires the testimony of Mr. Bisaro to provide crucial information not yet provided by Watson. Mr. Buchen identified Mr. Bisaro as the only person at Watson with whom he spoken about certain key issues in this investigation. Mr. Bisaro's failure to comply with the subpoena materially impedes the Commission's investigation to determine whether Watson has entered into any agreements that unlawfully restrict competition for generic

Provigil potentially costing consumers hundreds of millions of dollars a year.

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

Executed on: April 23, 2010

James Rhilinger, Esq.