UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

FRESENIUS KABI USA, LLC, *Plaintiff*, v. WATSON LABORATORIES, INC. and ACTAVIS, INC. *Defendants*.	)	Civil Action No. _____

COMPLAINT

Fresenius Kabi USA, LLC ("Fresenius") brings this action for patent infringement against Defendants Watson Laboratories, Inc. and Actavis, Inc. (collectively "Watson").

1. This is an action by Fresenius against Watson for infringement of United States Patent No. 8,476,010 ("the '010 patent"). This action arises out of Watson's filing of an Abbreviated New Drug Application ("ANDA") seeking approval by the United States Food and Drug Administration ("FDA") to sell generic versions of Diprivan®, an innovative intravenously administered sedative and anesthetic, prior to the expiration of the '010 patent.

THE PARTIES

Fresenius

2. Fresenius is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. Fresenius Kabi USA, LLC was formerly known as APP Pharmaceuticals, LLC ("APP").

Watson

3. Upon information and belief, Defendant Actavis, Inc. ("Actavis") is a Nevada corporation with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

4. Upon information and belief, Defendant Watson Laboratories, Inc. ("Watson Labs") is a Nevada corporation with its principal place of business at 311 Bonnie Circle, Corona, CA, 92878.

5. On information and belief, Watson Labs is a wholly-owned subsidiary of Actavis, and is controlled by Actavis.

6. On information and belief, Actavis and Watson Labs submitted, collaborated and/or acted in concert in the preparation or submission of ANDA Number 205307 ("the Watson ANDA").

JURISDICTION AND VENUE

Subject Matter Jurisdiction

7. This action for patent infringement arises under 35 U.S.C. § 271.

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

Personal Jurisdiction Over Watson

9. Upon information and belief, this Court has jurisdiction over Actavis and Watson Labs at least because both have engaged in continuous and systematic contacts with Delaware and/or purposefully availed themselves of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Watson's

pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities.

10. Additionally, Watson Labs has been sued for patent infringement in this district and not only did not contest personal jurisdiction but also purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in this court. *See Merck & Co Inc. v. Watson Laboratories Inc.*, C.A. No. 05-658.

11. Actavis has also been sued for patent infringement in this district and did not contest personal jurisdiction. *See Fresenius Kabi USA, LLC v. Watson Laboratories, Inc., et al.*, C.A. No. 13-1015. Actavis, as Watson Pharmaceuticals Inc., further has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in lawsuits filed in this Court. *See Sunovion Pharmaceuticals Inc. v. Watson Pharmaceuticals Inc.*, C.A. No. 12-993.

Venue

12. Venue is proper in this Judicial District under 28 U.S.C. § 1391 and 1400(b).

BACKGROUND

The Patent-in-Suit: United States Patent No. 8,476,010

13. The '010 patent, entitled "Propofol Formulations with Non-Reactive Container Closures," was duly and lawfully issued on July 2, 2013 to inventors Neil P. Desai, Andrew Yang, and Sherry Xiaopei Ci. The named inventors assigned the '010 patent to APP Pharmaceuticals, LLC, which later changed its name to Fresenius Kabi USA, LLC. Accordingly, Fresenius is the owner of all rights, title, and interest in the '010 patent. The '010 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as "The Orange Book" ("Orange Book") with respect to

Diprivan®. The ’010 patent will expire on June 1, 2025. A true and accurate copy of the ’010 patent is attached hereto as Exhibit A.

The Diprivan® Drug Product

14. Fresenius currently sells, promotes, distributes, and markets Diprivan® (propofol) injectable emulsion in the United States.

15. Diprivan® is indicated, generally speaking, for the induction and maintenance of general anesthesia and sedation in certain patient populations.

16. Fresenius holds an approved New Drug Application (“NDA”) No. 19627 under Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a) in connection with the Diprivan® 1% (propofol) injectable emulsion product containing 10 mg propofol per 1 ml of emulsion.

The Watson ANDA

17. Watson filed with the FDA an ANDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell in and import into the United States a propofol injectable emulsion containing 10mg propofol per 1 ml of emulsion formulation, in 20 mL, 50 mL and 100 mL vials, that Watson asserts is a generic copy of Diprivan® (“Watson’s generic Diprivan® products”) prior to the expiration of the ’010 patent.

18. The ’010 patent had not issued at the time Watson filed its ANDA.

19. The FDA assigned the Watson ANDA the number 205307.

20. Subsequent to the FDA's listing of the '010 patent, Watson filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '010 patent are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Watson's generic Diprivan® products ("Watson's Paragraph IV Certification"). Watson notified Fresenius of this certification, in a letter dated July 22, 2013 ("Watson Notice Letter").

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,476,010 BY WATSON

21. The allegations of paragraphs 1-20 are realleged and incorporated herein by reference.

22. The use of Watson's generic Diprivan® products is covered by one or more claims of the '010 patent.

23. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's generic Diprivan® products would infringe one or more claims of the '010 patent.

24. Watson has infringed the '010 patent by submitting and maintaining the Watson ANDA before the FDA seeking approval to market Watson's generic Diprivan® products containing propofol before the expiration of the '010 patent.

25. Upon information and belief, Defendants Watson Labs and Actavis acted in concert and actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the submission and maintenance of the Watson ANDA to the FDA.

26. Defendants Watson Labs and Actavis induced the infringement of the '010 patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of

Watson's ANDA with the Paragraph IV Certification and in the preparation to sell Watson's generic Diprivan® product in the United States.

27. Watson was aware that filing Watson's Paragraph IV Certification with respect to the '010 patent after the '010 patent's listing within the Orange Book constituted an act of infringement of the '010 patent and was aware of the '010 patent soon after its issuance.

28. Use of Watson's generic Diprivan® products in accordance with and as directed by Watson's proposed labeling for that product would infringe one or more claims of the '010 patent.

29. Upon information and belief, Watson intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's generic Diprivan® products with its proposed labeling immediately and imminently upon approval of the Watson ANDA.

30. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '010 patent when the Watson ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

31. Upon information and belief, Watson knows that Watson's generic Diprivan® product and the proposed labeling for Watson's generic Diprivan® product is especially made or adapted for use in infringing the '010 patent and that Watson's generic Diprivan® product and the proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to the infringement of the '010 patent immediately and imminently upon approval of the Watson ANDA.

32. The foregoing actions by Watson constitute and/or would constitute infringement of the ’010 patent, active inducement of infringement of the ’010 patent and/or contribution to the infringement by others of the ’010 patent.

33. Upon information and belief, Watson acted without a reasonable basis for believing that it would not be liable for infringing the ’010 patent, actively inducing infringement of the ’010 patent, and/or contributing to the infringement by others of the ’010 patent.

34. Fresenius will be substantially and irreparably harmed by Watson’s infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Watson is not enjoined from the commercial manufacture, use, offer to sell, sale in, and importation into the United States of Watson’s generic Diprivan® products.

35. Watson’s activities render this case an exceptional one, and Fresenius is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Fresenius respectfully requests the following relief:

a. A judgment that Watson’s submission of the Watson ANDA No. 205307 infringes one or more claims of the ’010 patent and that the making, using, offering to sell, or selling in the United States, or importing into the United States of Watson’s generic Diprivan® products prior to the expiration of the ’010 patent will infringe, actively induce infringement, and/or contribute to the infringement of one or more claims of the patent;

b. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Watson ANDA No. 205307 seeking approval to manufacture, use, offer for sale, sell in and import into the United States a propofol injectable emulsion containing 10mg propofol per 1 ml of emulsion formulation, in 20 mL, 50 mL and 100 mL vials, or any product or

compound the use of which infringes the ’010 patent, shall be a date that is not earlier than the expiration of the patent;

c. An Order permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Watson’s generic Diprivan® products, or any other product or compound the use of which infringes the ’010 patent, or inducing or contributing to the infringement of the ’010 patent until after the expiration of the patent;

d. An Order enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of the Watson ANDA No. 205307 before the expiration of the ’010 patent;

e. An award of Plaintiff’s damages or other monetary relief to compensate Plaintiff if Defendants engage in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Defendants’ generic Diprivan® products, or any product or compound the use of which infringes the ’010 patent, or the inducement or contribution of the foregoing, prior to the expiration of the patent in accordance with 35 U.S.C. § 271(e)(4)(C);

f. A judgment that this is an exceptional case and awarding Plaintiff its attorneys’ fees under 35 U.S.C. § 285;

g. An award of Plaintiff’s reasonable costs and expenses in this action; and

h. An award of any further and additional relief to Plaintiff as this Court deems just and proper.

Dated: February 6, 2014

Respectfully submitted,

FARNAN LLP

/s/ Brian E. Farnan
Brian Farnan(Bar No. 4089)
919 North Market Street
12th Floor
Wilmington, DE 19801
Phone: 302-777-0300
Fax: 302-777-0301
bfarnan@farnanlaw.com

Of Counsel:

Daryl L. Wiesen
John T. Bennett
Sundar Subramanyam
Sam Sherry
Todd Marabella
Jennifer L. Ford
GOODWIN PROCTER LLP
Exchange Place
53 State Street
Boston, MA 02109
(617) 570-1000
(617) 523-1231 (fax)
DWiesen@goodwinprocter.com
JBennett@goodwinprocter.com
SSubramanyam@goodwinprocter.com
SSherry@goodwinprocter.com
TMarabella@goodwinprocter.com
JFord@goodwinprocter.com

Attorneys for Plaintiff
Fresenius Kabi USA, LLC