IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI and SANOFI-AVENTIS U.S. LLC	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No.: _____
	)	
WATSON LABORATORIES, INC.	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi and Sanofi-Aventis U.S. LLC ("Sanofi U.S.") (collectively, "Plaintiffs") for their Complaint against defendant Watson Laboratories, Inc. ("Watson" or "Defendant"), hereby allege as follows:

THE PARTIES

1. Plaintiff Sanofi is a corporation organized and existing under the laws of France, having its principal place of business at 54 rue La Boétie, 75008 Paris, France.

2. Plaintiff Sanofi U.S. is a wholly owned U.S. subsidiary of Sanofi and is a company organized and existing under the laws of the state of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. On information and belief, defendant Watson is a corporation organized and existing under the laws of the State of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United

States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338.

5. This Court has personal jurisdiction over Watson. On information and belief, Watson directly or through its affiliates and agents, develops, formulates, manufactures, markets, and sells pharmaceutical products, including generic drug products, throughout the United States and in this judicial district.

6. On information and belief, Watson holds a pharmacy wholesale license for the state of Delaware under License No. A4-0001263 and a distributor/manufacturer license for controlled substances for the state of Delaware under License DS0499.

7. On information and belief, Watson regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that Watson has continuous and systematic contacts with Delaware.

8. On information and belief, Watson has previously availed itself of this forum by filing lawsuits in this judicial district as a plaintiff, including at least the following cases: *Watson Laboratories Inc., v. Barr Laboratories, Inc. et al.* (1:08-cv-00793-GMS), *Kissei Pharmaceutical Co. Ltd. et al. v. Hetero USA Inc., et al.* (1:13-cv-01091-LPS), and *Kissei Pharmaceutical Co. Ltd. et al. v. Sandoz Inc.* (1:13-cv-01092-LPS). On information and belief, Watson has also previously availed itself of this forum by submitting to the jurisdiction of this Court and asserting counterclaims in other civil actions initiated in this jurisdiction including, for example, *Reckitt Benckiser et al. v. Watson Laboratories, Inc.* (1:13-cv-01674-RGA).

9. On information and belief, this Court found that Watson was subject to general personal jurisdiction in Delaware in *Cephalon, Inc. v. Watson Pharmaceuticals, Inc.*, 1:08-cv-330-SLR, 629 F. Supp. 2d 338 (D. Del. 2009).

10. On information and belief, this Court further has personal jurisdiction over Watson because Watson regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware and committed the tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to plaintiff Sanofi U.S., a Delaware corporation.

11. On information and belief, upon approval of Watson's Abbreviated New Drug Application (ANDA) No. 205682, Watson and/or its affiliates or agents will market and sell Watson's dronedarone hydrochloride tablets, 400 mg ("Watson's Proposed Generic Product") in Delaware and throughout the United States and will derive substantial revenue therefrom.

12. This Court has personal jurisdiction over Watson by virtue of, *inter alia*, the above-mentioned facts.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b).

THE PATENT-IN-SUIT

14. Sanofi U.S. holds approved New Drug Application ("NDA") No. 022425 for dronedarone tablets, 400 mg, which are prescribed and sold in the United States under the trademark Multaq®. The U.S. Food and Drug Administration ("FDA") approved NDA No. 022425 on July 1, 2009. Multaq® tablets are indicated to reduce the risk of hospitalization for

atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation.

15. United States Patent No. 9,107,900 ("the '900 patent," copy attached as Exhibit A) is entitled "Use of Dronedarone for the Preparation of a Medicament for Use in the Prevention of Cardiovascular Hospitalization or of Morality [sic]" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on August 18, 2015. The '900 patent claims, *inter alia*, methods of using dronedarone. The '900 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Multaq® tablets (NDA No. 022425).

16. The named inventors on the '900 patent are Davide Radzik, Martin Van Eickels, Nacera Hamdani, and Christophe Gaudin. The '900 patent is assigned to Sanofi.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

17. Watson submitted ANDA No. 205682 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson's Proposed Generic Product.

18. On information and belief, ANDA No. 205682 seeks FDA approval of Watson's Proposed Generic Product for the indication of reducing the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation.

19. By letter dated October 20, 2015, and pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), Watson notified Plaintiffs that it had submitted ANDA No. 205682 to the FDA seeking approval to engage in the commercial manufacture, use,

sale, and/or importation of Watson's Proposed Generic Product before the expiration of the '900 patent.

20. In its letter, Watson notified Plaintiffs that, as a part of its ANDA, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") with respect to the '900 patent. On information and belief, Watson certified that, in its opinion and to the best of its knowledge, the '900 patent is invalid and/or will not be infringed by the manufacture, use, or sale of Watson's Proposed Generic Product.

COUNT I
Infringement of U.S. Patent No. 9,107,900 Under 35 U.S.C. §271(e)(2)

21. Plaintiffs repeat and reallege paragraphs 1 through 20 as if fully set forth herein.

22. By submitting ANDA No. 205682 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson's Proposed Generic Product throughout the United States prior to the expiration of the '900 patent, Watson committed an act of infringement of the '900 patent under 35 U.S.C. § 271(e)(2).

23. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's Proposed Generic Product, for which Watson seeks approval in ANDA No. 205682, will induce infringement of one or more claims of the '900 patent under 35 U.S.C. § 271(b). Specifically, the product label and medication guide that will be included with Watson's Proposed Generic Product, if sold, will encourage, recommend and/or promote the practice of one or more claims of the '900 patent.

24. Plaintiffs will be irreparably harmed by Watson's infringing activities and do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Watson and respectfully request the following relief:

A. A judgment that under 35 U.S.C. § 271(e)(2)(A), Watson has infringed one or more claims of the ’900 patent by submitting ANDA No. 205682 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Watson’s Proposed Generic Product before the expiration of the ’900 patent;

B. A judgment that the manufacture, use, offer for sale, sale, and/or importation of Watson’s Proposed Generic Product will infringe the ’900 patent;

C. A judgment declaring that the ’900 patent remains valid and enforceable;

D. A permanent injunction restraining and enjoining Watson and its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson’s Proposed Generic Product until the expiration of the ’900 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

E. An order that the effective date of any approval of Watson’s ANDA No. 205682 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration of the ’900 Patent or any later date of exclusivity to which Plaintiffs and/or this patent are or become entitled;

F. A determination that this case is “exceptional” under 35 U.S.C. § 285 and an award of attorneys’ fees;

G. Costs and expenses in this action; and

H. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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