IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI and SANOFI-AVENTIS U.S. LLC	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No.: _____
	)	
SUN PHARMA GLOBAL FZE and SUN PHARMACEUTICAL INDUSTRIES, LTD.	)	
	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi and Sanofi-Aventis U.S. LLC ("Sanofi U.S.") (collectively, "Plaintiffs") for their Complaint against defendants Sun Pharma Global FZE ("Sun FZE") and Sun Pharmaceutical Industries, Ltd. ("Sun Ltd.") (collectively, "Defendants"), 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 Sun FZE is a limited liability company incorporated under the provisions of Sharjah's Emiri Decree Number (2) of 1995, having a place of business at Office # 43, Block Y, SAIF Zone, P.O. Box 122304, Sharjah, United Arab Emirates. On information and belief, Sun FZE is a wholly owned subsidiary of Sun

Pharma Global Inc., a corporation organized and existing under the laws of the British Virgin Islands, which is in turn a wholly owned subsidiary of defendant Sun Ltd.

4. On information and belief, defendant Sun Ltd. is a company organized and existing under the laws of India, having a principal place of business at Acme Plaza, Andheri-Kurla Rd., Andheri (E), Mumbai – 400 059, India.

JURISDICTION AND VENUE

5. 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.

6. This Court has personal jurisdiction over Sun FZE. On information and belief, Sun FZE 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 Sun FZE has continuous and systematic contacts with Delaware.

7. On information and belief, Sun FZE is in the business of manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the state of Delaware. On information and belief, Sun FZE directly or through its affiliates and agents (including Sun Ltd.) develops, formulates, manufactures, markets, and sells pharmaceutical products, including generic drug products, throughout the United States and in this judicial district.

8. On information and belief, Sun FZE has availed itself of this forum by consenting to personal jurisdiction and asserting counterclaims in other civil actions initiated in

this jurisdiction, including but not limited to *Teijin Ltd. et al. v. Sun Pharma Global FZE et al.* (1:13-cv-1852-SLR) and *UCB, Inc. et al. v. Sun Pharma Global FZE et al.* (1:13-1218-LPS).

9. This court has personal jurisdiction over Sun Ltd. On information and belief, Sun Ltd. 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 Sun Ltd. has continuous and systematic contacts with Delaware.

10. On information and belief, Sun Ltd. develops, formulates, manufactures, markets, and sells pharmaceutical products, including generic drug products, throughout the United States and in this judicial district, directly or through its affiliates and agents, including its wholly owned subsidiary Sun FZE.

11. On information and belief, Sun Ltd. has previously availed itself of this forum by filing lawsuits in this judicial district as a plaintiff, including but not limited to *Sun Pharmaceutical Industries Ltd. v. Wyeth* (1:09-cv-00083-SLR). On information and belief, Sun Ltd. has also availed itself of this forum by consenting to personal jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction, including but not limited to *UCB, Inc. et al. v. Sun Pharma Global FZE et al.* (1:13-1218-LPS).

12. On information and belief, Defendants collaborate to manufacture, import, market, distribute, and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to Abbreviated New Drug Applications (ANDAs)) throughout the United States, including the state of Delaware.

13. On information and belief, upon approval of Sun FZE's ANDA No. 205963, Defendants and/or their affiliates or agents will market and sell Sun FZE's Dronedarone

Hydrochloride Tablets, 400 mg ("Sun FZE's Proposed Generic Product") in Delaware and throughout the United States and will derive substantial revenue therefrom. On information and belief, upon approval of Sun FZE's ANDA, Defendants will sell Sun FZE's Proposed Generic Product in the state of Delaware and throughout the United States, and Sun Ltd. will be involved in the manufacture, distribution, and/or marketing of Sun FZE's Proposed Generic Product.

14. On information and belief, upon approval of Sun FZE's ANDA, Defendants and/or their affiliates or agents will place Sun FZE's Proposed Generic Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will ultimately be purchased and used by consumers in this judicial district.

15. On information and belief, this Court further has personal jurisdiction over Defendants because Defendants regularly do or solicit business in Delaware, engage in other persistent courses of conduct in Delaware, and/or derive 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.

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

17. Alternatively, assuming that the above facts do not establish personal jurisdiction over Sun FZE and Sun Ltd., this Court may exercise jurisdiction over Sun FZE and Sun Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Sun FZE and Sun Ltd. are foreign defendants not subject to personal jurisdiction in the courts of any state; and (c) Sun FZE and Sun Ltd. have sufficient contacts with the United States as a whole, including but not limited to manufacturing and selling generic

pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Sun FZE and Sun Ltd. satisfies due process.

18. 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

19. 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.

20. 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).

21. 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

22. Sun FZE submitted ANDA No. 205963 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun FZE's Proposed Generic Product.

23. On information and belief, ANDA No. 205963 seeks FDA approval of Sun FZE'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.

24. On information and belief, Sun Ltd. actively participated in and/or directed activities related to the submission of ANDA No. 205963 and the development of Sun FZE's Proposed Generic Product, was actively involved in preparing the ANDA, and/or intends to directly benefit from and has a financial stake in the approval of the ANDA. On information and belief, upon approval of ANDA No. 205963, Sun Ltd. will be involved in the manufacture, distribution, and/or marketing of Sun FZE's Proposed Generic Product.

25. By letter dated November 3, 2015, and pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), Sun FZE notified Plaintiffs that it had submitted ANDA No. 205963 to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of Sun FZE's Proposed Generic Product before the expiration of the '900 patent.

26. In its letter, Sun FZE 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, Sun FZE 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 Sun FZE’s Proposed Generic Product.

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

27. Plaintiffs repeat and reallege paragraphs 1 through 26 as if fully set forth herein.

28. By submitting ANDA No. 205963 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 Sun FZE’s Proposed Generic Product throughout the United States prior to the expiration of the ’900 patent, Defendants committed an act of infringement of the ’900 patent under 35 U.S.C. § 271(e)(2).

29. The commercial manufacture, use, offer for sale, sale, and/or importation of Sun FZE’s Proposed Generic Product, for which Sun FZE seeks approval in ANDA No. 205963, 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 Sun FZE’s Proposed Generic Product, if sold, will encourage, recommend and/or promote the practice of one or more claims of the ’900 patent.

30. Plaintiffs will be irreparably harmed by Defendants’ 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 Defendants and respectfully request the following relief:

A. A judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the ’900 patent by submitting ANDA No. 205963 seeking FDA

approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Sun FZE'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 Sun FZE'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 Defendants and their 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 Sun FZE'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 Sun FZE's ANDA No. 205963 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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