IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI and SANOFI-AVENTIS U.S. LLC	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No.: _____
	)	
GLENMARK PHARMACEUTICALS INC., USA and GLENMARK PHARMACEUTICALS LIMITED.	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi and Sanofi-Aventis U.S. LLC ("Sanofi U.S.") (collectively, "Plaintiffs") for their Complaint against defendants Glenmark Pharmaceuticals Inc., USA ("Glenmark USA") and Glenmark Pharmaceuticals Limited ("Glenmark 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 Glenmark USA is a Delaware corporation with its principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. On information and belief, Glenmark USA is the North American division of defendant Glenmark Ltd.

4. On information and belief, defendant Glenmark Ltd. is an Indian company having its principal place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, 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 Glenmark USA. On information and belief, Glenmark USA is a corporation organized and existing under the laws of Delaware and Glenmark USA has a registered agent for service of process in Delaware.

7. On information and belief, Glenmark USA 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. On information and belief, Glenmark USA holds a pharmacy wholesale license for the state of Delaware under License No. A4-0001391 and a distributor/manufacturer license for controlled substances for the state of Delaware under License DM-0006376.

8. On information and belief, Glenmark USA 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 Glenmark USA has continuous and systematic contacts with Delaware.

9. On information and belief, Glenmark USA has previously availed itself of this forum by filing lawsuits in this judicial district as a plaintiff, including at least *Glenmark*

Pharmaceuticals Ltd. et al. v. GlaxoSmithKline PLC et al. (1:13-cv-00135-GMS). On information and belief, it has also availed itself of this forum by asserting counterclaims in other civil actions initiated in this jurisdiction.

10. On information and belief, Glenmark USA's predecessor, Glenmark Generics Inc., USA, admitted, without limitation, that this Court has personal jurisdiction over it in *UCB, Inc. et al. v. Glenmark Generics Inc., USA et al.* (1:13-cv-01212-LPS).

11. This court has personal jurisdiction over Glenmark Ltd. On information and belief, Glenmark Ltd. develops, formulates, manufactures, markets, and sells pharmaceutical products, including generic drug products, throughout the United States and in this judicial district, through various directly or indirectly owned subsidiaries, including its wholly owned Delaware corporation Glenmark USA. On information and belief, Glenmark Ltd. and Glenmark USA work in concert for purposes of developing, formulating, manufacturing, marketing, and selling generic drug products throughout the United States including Delaware, and Delaware is a likely destination of Glenmark Ltd.'s generic products.

12. On information and belief, Glenmark 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 Glenmark Ltd. has continuous and systematic contacts with Delaware.

13. On information and belief, Glenmark Ltd. has previously availed itself of this forum by filing lawsuits in this judicial district as a plaintiff, including at least *Glenmark Pharmaceuticals Ltd. et al. v. GlaxoSmithKline PLC et al.* (1:13-cv-00135-GMS). On information and belief, it has also availed itself of this forum by asserting counterclaims in other civil actions initiated in this jurisdiction.

14. On information and belief, Glenmark Ltd.'s predecessor company, Glenmark Generics Ltd., admitted, without limitation, that this Court has personal jurisdiction over it in *UCB, Inc. et al. v. Glenmark Generics Inc., USA et al.* (1:13-cv-01212-LPS).

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. On information and belief, upon approval of Glenmark USA's Abbreviated New Drug Application (ANDA) No. 205903, Defendants and/or their affiliates or agents will market and sell Glenmark USA's dronedarone hydrochloride tablets, 400 mg ("Glenmark USA's Proposed Generic Product") in Delaware and throughout the United States and will derive substantial revenue therefrom.

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

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. Glenmark USA submitted ANDA No. 205903 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Glenmark USA's Proposed Generic Product.

23. On information and belief, ANDA No. 205903 seeks FDA approval of Glenmark USA'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, Glenmark Ltd. actively participated in and/or directed activities related to the submission of ANDA No. 205903 and the development of Glenmark USA'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. 205903, Glenmark Ltd. will be involved in the manufacture, distribution, and/or marketing of Glenmark USA's Proposed Generic Product.

25. By letter dated September 16, 2015, and pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), Glenmark USA notified Plaintiffs that it had submitted ANDA No. 205903 to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of Glenmark USA's Proposed Generic Product before the expiration of the '900 patent.

26. In its letter, Glenmark USA 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, Glenmark USA 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 Glenmark USA'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. 205903 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 Glenmark USA'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 Glenmark USA's Proposed Generic Product, for which Glenmark USA seeks approval in ANDA No. 205903, 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 Glenmark USA'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. 205903 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Glenmark USA'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 Glenmark USA'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 Glenmark USA'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 Glenmark USA's ANDA No. 205903 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

/s/ Derek J. Fahnestock

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