IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi and Sanofi-Aventis U.S. LLC ("Sanofi U.S.") (collectively, "Plaintiffs") for their Complaint against defendant Sandoz Inc. ("Sandoz" 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 Sandoz is a company organized and existing under the laws of the State of Colorado having a principal place of business at 100 College Road West, Princeton, NJ 08540.

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, 1338.

5. This Court has personal jurisdiction over Sandoz. On information and belief, Sandoz 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 Sandoz has continuous and systematic contacts with Delaware.

6. On information and belief, Sandoz is in the business of formulating, developing, manufacturing, marketing, and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, including in the state of Delaware. On information and belief, Sandoz directly or through its affiliates and agents formulates, manufactures, packages, markets, and/or sells pharmaceutical products throughout the United States and in this judicial district.

7. On information and belief, Sandoz has purposefully conducted business in the state of Delaware, continues to conduct business in Delaware, and Delaware is a likely destination of Sandoz's products.

8. On information and belief, Sandoz has collaborated with and/or entered into contracts with Delaware corporations, including Momenta Pharmaceuticals, Inc., concerning the manufacture, marketing, distribution, and/or sale of pharmaceutical products in the United States.

9. On information and belief, Sandoz holds a pharmacy wholesale license for the state of Delaware under License No. A4-0000260 and a distributor/manufacturer license for controlled substances for the state of Delaware under License No. DS0131.

10. On information and belief, Sandoz has previously availed itself of this forum by consenting to the jurisdiction of this Court and asserting counterclaims in other civil actions initiated in this jurisdiction including, for example, *Teva Pharms. USA, Inc. et al. v. Sandoz, Inc. et al.*, 14-cv-001171-GMS. On information and belief, Sandoz has availed itself of this forum by maintaining lawsuits in this judicial district as a plaintiff, including, for example, *Sandoz, Inc. v. Pfizer, Inc. et al.*, 10-cv-00104-LPS.

11. On information and belief, upon approval of Sandoz's Abbreviated New Drug Application (ANDA) No. 205744, Sandoz and/or its affiliates or agents will market and sell Sandoz's dronedarone hydrochloride tablets 400 mg (eq base) ("Sandoz's Proposed Generic Product") in Delaware and throughout the United States and will derive substantial revenue therefrom.

12. On information and belief, upon approval of Sandoz's ANDA No. 205744, Sandoz and/or its affiliates or agents will place Sandoz'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.

13. On information and belief, this Court further has personal jurisdiction over Sandoz because Sandoz 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.

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

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

THE PATENTS-IN-SUIT

16. 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.

17. 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.

18. United States Patent No. 8,318,800 ("the '800 patent," copy attached as Exhibit A) is entitled "Solid Pharmaceutical Compositions Containing Benzofuran Derivatives" and was duly and legally issued by the USPTO on November 27, 2012. The '800 patent claims, *inter alia*, pharmaceutical compositions containing dronedarone. The '800 patent is listed in the Orange Book for Multaq® tablets (NDA No. 022425).

19. The named inventors on the '800 patent are Bernard Abramovici, Jean-Claude Gautier, Jean-Claude Gromenil, and Jean-Marie Marrier. The '800 patent is assigned to Sanofi.

20. United States Patent No. 8,410,167 ("the '167 patent," copy attached as Exhibit B) is entitled "Use of Dronedarone for the Preparation of a Medicament for Use in the Prevention of Cardiovascular Hospitalization or of Mortality" and was duly and legally issued by the USPTO on April 2, 2013. The '167 patent claims, *inter alia*, methods of decreasing the risk

of cardiovascular hospitalization in certain patients by administering dronedarone. The ’167 patent is listed in the Orange Book for Multaq® tablets (NDA No. 022425).

21. The named inventors on the ’167 patent are Davide Radzik, Martin Van Eickels, Nacéra Hamdani, and Christophe Gaudin. The ’167 patent is assigned to Sanofi.

22. United States Patent No. 8,602,215 (“the ’215 patent,” copy attached as Exhibit C) is entitled “Methods for Reducing the Risk of an Adverse Dronedarone/Beta-Blockers Interaction in a Patient Suffering from Atrial Fibrillation” and was duly and legally issued by the USPTO on December 10, 2013. The ’215 patent claims, *inter alia*, methods for managing the risk of dronedarone/beta-blocker interaction in patients with paroxysmal or persistent atrial fibrillation or atrial flutter. The ’215 patent is listed in the Orange Book for Multaq® tablets (NDA No. 022425).

23. The named inventor on the ’215 patent is Davide Radzik. The ’215 patent is assigned to Sanofi.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

24. Sandoz submitted ANDA No. 205744 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of dronedarone hydrochloride tablets 400 mg (eq base) (“Sandoz’s Proposed Generic Product”).

25. On information and belief, ANDA No. 205744 seeks FDA approval of Sandoz’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.

26. By letter dated November 13, 2014, and pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95(c), Sandoz notified Plaintiffs that it had submitted ANDA

No. 205744 to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of Sandoz's Proposed Generic Product before the expiration of the '800 patent, the '167 patent, and the '215 patent.

27. In its November 13, 2014 letter, Sandoz 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 '800 patent, the '167 patent, and the '215 patent. On information and belief, Sandoz certified that, in its opinion and to the best of its knowledge, the '800 patent, the '167 patent, and the '215 patent are invalid and/or will not be infringed by the manufacture, use, or sale of Sandoz's Proposed Generic Product.

COUNT I
Infringement of U.S. Patent No. 8,318,800 Under 35 U.S.C. §271(e)(2)

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

29. By submitting ANDA No. 205744 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 Sandoz's Proposed Generic Product throughout the United States prior to the expiration of the '800 patent, Sandoz committed an act of infringement of the '800 patent under 35 U.S.C. §271(e)(2). On information and belief, Sandoz was aware of the '800 patent at the time the ANDA was submitted.

30. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Proposed Generic Product, for which Sandoz seeks approval in ANDA No. 205744, will infringe, induce infringement, and/or contributorily infringe one or more claims of the '800 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

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

COUNT II
Infringement of U.S. Patent No. 8,410,167 Under 35 U.S.C. §271(e)(2)

32. Plaintiffs repeat and reallege paragraphs 1 through 31 as if fully set forth herein.

33. By submitting ANDA No. 205744 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 Sandoz's Proposed Generic Product throughout the United States prior to the expiration of the '167 patent, Sandoz committed an act of infringement of the '167 patent under 35 U.S.C. §271(e)(2). On information and belief, Sandoz was aware of the '167 patent at the time the ANDA was submitted.

34. Sandoz's Proposed Generic Product will have the same clinical instructions on use, be administered in the same manner, and achieve the same results as Plaintiffs' Multaq® product.

35. Sandoz's Proposed Generic Product label will instruct doctors, caregivers, and/or patients to practice the methods claimed in the '167 patent.

36. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Proposed Generic Product, for which Sandoz seeks approval in ANDA No. 205744, will infringe, induce infringement, and/or contributorily infringe one or more claims of the '167 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

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

COUNT III
Infringement of U.S. Patent No. 8,602,215 Under 35 U.S.C. §271(e)(2)

38. Plaintiffs repeat and reallege paragraphs 1 through 37 as if fully set forth herein.

39. By submitting ANDA No. 205744 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 Sandoz's Proposed Generic Product throughout the United States prior to the expiration of the '215 patent, Sandoz committed an act of infringement of the '215 patent under 35 U.S.C. §271(e)(2). On information and belief, Sandoz was aware of the '215 patent at the time the ANDA was submitted

40. Sandoz's Proposed Generic Product will have the same clinical instructions on use, be administered in the same manner, and achieve the same results as Plaintiffs' Multaq® product.

41. Sandoz's Proposed Generic Product label will instruct doctors, caregivers, and/or patients to practice the methods claimed in the '215 patent.

42. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Proposed Generic Product, for which Sandoz seeks approval in ANDA No. 205744, will infringe, induce infringement, and/or contributorily infringe one or more claims of the '215 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

43. Plaintiffs will be irreparably harmed by Sandoz' 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 Sandoz and respectfully request the following relief:

A. A judgment that under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed one or more claims of the ’800 patent by submitting ANDA No. 205744 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s Proposed Generic Product before the expiration of the ’800 patent;

B. A judgment that the manufacture, use, offer for sale, sale, and/or importation of Sandoz’s Proposed Generic Product will infringe the ’800 patent;

C. A judgment declaring that the ’800 patent remains valid and enforceable;

D. A permanent injunction restraining and enjoining Sandoz 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 Sandoz’s Proposed Generic Product until the expiration of the ’800 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 Sandoz’s ANDA No. 205744 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 ’800 Patent or any later date of exclusivity to which Plaintiffs and/or this patent are or become entitled;

F. A judgment that under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed one or more claims of the ’167 patent by submitting ANDA No. 205744 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s Proposed Generic Product before the expiration of the ’167 patent;

G. A judgment that the manufacture, use, offer for sale, sale, and/or importation of Sandoz’s Proposed Generic Product will infringe the ’167 patent;

H. A judgment declaring that the ’167 patent remains valid and enforceable;

I. A permanent injunction restraining and enjoining Sandoz 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 Sandoz's Proposed Generic Product until the expiration of the '167 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

J. An order that the effective date of any approval of Sandoz's ANDA No. 205744 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 '167 patent or any later date of exclusivity to which Plaintiffs and/or this patent are or become entitled;

K. A judgment that under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed one or more claims of the '215 patent by submitting ANDA No. 205744 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Proposed Generic Product before the expiration of the '215 patent;

L. A judgment that the manufacture, use, offer for sale, sale, and/or importation of Sandoz's Proposed Generic Product will infringe the '215 patent;

M. A judgment declaring that the '215 patent remains valid and enforceable;

N. A permanent injunction restraining and enjoining Sandoz 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 Sandoz's Proposed Generic Product until the expiration of the '215 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

O. An order that the effective date of any approval of Sandoz's ANDA No. 205744 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 '215 patent or any later date of exclusivity to which Plaintiffs and/or this patent are or become entitled;

P. A determination that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorneys' fees;

Q. Costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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