IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi and Sanofi-Aventis U.S. LLC ("Sanofi U.S.") (collectively, "Plaintiffs") for their Complaint against defendants Alembic Pharmaceuticals Limited ("Alembic") and Alembic Limited (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 Alembic is a company organized and existing under the laws of India having a principal place of business at Alembic Road, Vadodara, 390 003, Gujarat, India. On information and belief, Alembic is a subsidiary of Alembic Limited.

4. On information and belief, defendant Alembic Limited is a corporation organized and existing under the laws of India, having a principal place of business at Alembic Road, Vadodara, 390 003, Gujarat, 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, 1338.

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

7. On information and belief, Alembic 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, Alembic directly or through its affiliates and agents (including Alembic Limited), formulates, manufactures, packages, markets, and/or sells pharmaceutical products throughout the United States and in this judicial district.

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

9. On information and belief, Alembic 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, *Teijin Limited et al. v. Alembic Pharmaceuticals Limited et al.* (13-cv-01939-SLR).

10. This Court has personal jurisdiction over Alembic Limited. On information and belief, Alembic Limited 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 Alembic Limited has continuous and systematic contacts with Delaware.

11. On information and belief, Alembic Limited is in the business of formulating, manufacturing, marketing, distributing, and/or selling pharmaceutical products throughout the United States, including in the state of Delaware. On information and belief, Alembic Limited directly or through its affiliates and agents (including Alembic), formulates, manufactures, packages, markets, and/or sells pharmaceutical products throughout the United States and in this judicial district

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

13. On information and belief, Alembic Limited 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, *Pfizer Inc. et al. v. Alembic Limited et al.* (11-cv-01213-GMS).

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

15. On information and belief, upon approval of Alembic's Abbreviated New Drug Application (ANDA) No. 205933, Defendants and/or their affiliates or agents will market and sell Alembic's dronedarone hydrochloride (EQ 400 mg base) oral tablets ("Alembic's Proposed Generic Product") in Delaware and throughout the United States and will derive substantial revenue therefrom.

16. On information and belief, upon approval of Alembic's ANDA No. 205933, Defendants and/or their affiliates or agents will place Alembic'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.

17. 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.

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

19. Alternatively, assuming that the above facts do not establish personal jurisdiction over Defendants, this Court may exercise jurisdiction over Defendants pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Defendants are foreign companies not subject to personal jurisdiction in the courts of any state; and (c) Defendants 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 Defendants satisfies due process.

20. 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

21. 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.

22. United States Patent No. 7,323,493 ("the '493 patent," copy attached as Exhibit A) is entitled "Solid Pharmaceutical Composition Containing Benzofuran Derivatives" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on January 29, 2008. The '493 patent claims, *inter alia*, pharmaceutical compositions containing dronedarone. The '493 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Multaq® tablets (NDA No. 022425).

23. The named inventors on the '493 patent are Bernard Abramovici, Jean-Claude Gautier, Jean-Claude Gromenil, and Jean-Marie Marrier. The '493 patent is assigned to Sanofi.

24. United States Patent No. 8,318,800 ("the '800 patent," copy attached as Exhibit B) 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 issued from a continuation of the application that issued as the '493 patent. The '800 patent is listed in the Orange Book for Multaq® tablets (NDA No. 022425).

25. 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.

26. United States Patent No. 8,410,167 ("the '167 patent," copy attached as Exhibit C) 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).

27. 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.

28. United States Patent No. 8,602,215 ("the '215 patent," copy attached as Exhibit D) 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).

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

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

30. Alembic submitted ANDA No. 205933 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of dronedarone hydrochloride (EQ 400 mg base) oral tablets (“Alembic’s Proposed Generic Product”).

31. On information and belief, ANDA No. 205933 seeks FDA approval of Alembic’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.

32. On information and belief, Alembic Limited actively participated in and/or directed activities related to the submission of ANDA No. 205933 and the development of Alembic’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 Alembic’s ANDA, Ale mbic Limited will be involved in the manufacture, distribution, and/or marketing of Alembic’s Proposed Generic Product.

33. By letter dated March 31, 2014, and pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95(c), Alembic notified Plaintiffs that it had submitted ANDA No. 205933 to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of Alembic’s Proposed Generic Product before the expiration of the ’493 patent, the ’800 patent, the ’167 patent, and the ’215 patent.

34. In its March 31, 2014 letter, Alembic 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 '493 patent, the '800 patent, the '167 patent, and the '215 patent. On information and belief, Alembic certified that, in its opinion and to the best of its knowledge, the '493 patent, 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 Alembic's Proposed Generic Product.

COUNT I
Infringement of U.S. Patent No. 7,323,493 Under 35 U.S.C. §271(e)(2)

35. Plaintiffs repeat and reallege paragraphs 1 through 34 as if fully set forth herein.

36. By submitting ANDA No. 205933 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 Alembic's Proposed Generic Product throughout the United States prior to the expiration of the '493 patent, Defendants committed an act of infringement of the '493 patent under 35 U.S.C. §271(e)(2). On information and belief, Defendants were aware of the '493 patent at the time the ANDA was submitted.

37. The commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's Proposed Generic Product, for which Alembic seeks approval in ANDA No. 205933, will infringe, induce infringement, and/or contributorily infringe one or more claims of the '493 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

38. Plaintiffs will be irreparably harmed by Defendants' infringing activities and do not have an adequate remedy at law

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

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

40. By submitting ANDA No. 205933 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 Alembic's Proposed Generic Product throughout the United States prior to the expiration of the '800 patent, Defendants committed an act of infringement of the '800 patent under 35 U.S.C. §271(e)(2). On information and belief, Defendants were aware of the '800 patent at the time the ANDA was submitted.

41. The commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's Proposed Generic Product, for which Alembic seeks approval in ANDA No. 205933, 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).

42. Plaintiffs will be irreparably harmed by Defendants' infringing activities and do not have an adequate remedy at law.

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

43. Plaintiffs repeat and reallege paragraphs 1 through 42 as if fully set forth herein.

44. By submitting ANDA No. 205933 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 Alembic's Proposed Generic Product throughout the United States prior to the expiration of the '167 patent, Defendants committed an act of infringement of the

’167 patent under 35 U.S.C. §271(e)(2). On information and belief, Defendants were aware of the ’167 patent at the time the ANDA was submitted.

45. Alembic’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. Alembic’s Proposed Generic Product label will instruct doctors, caregivers, and/or patients to practice the methods claimed in the ’167 patent.

46. The commercial manufacture, use, offer for sale, sale, and/or importation of Alembic’s Proposed Generic Product, for which Alembic seeks approval in ANDA No. 205933, 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).

47. Plaintiffs will be irreparably harmed by Defendants’ infringing activities and do not have an adequate remedy at law.

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

48. Plaintiffs repeat and reallege paragraphs 1 through 47 as if fully set forth herein.

49. By submitting ANDA No. 205933 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 Alembic’s Proposed Generic Product throughout the United States prior to the expiration of the ’215 patent, Defendants committed an act of infringement of the ’215 patent under 35 U.S.C. §271(e)(2).

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

51. The commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's Proposed Generic Product, for which Alembic seeks approval in ANDA No. 205933, 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).

52. 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 '493 patent by submitting ANDA No. 205933 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's Proposed Generic Product before the expiration of the '493 patent;

B. A judgment that the manufacture, use, offer for sale, sale, and/or importation of Alembic's Proposed Generic Product will infringe the '493 patent;

C. A judgment declaring that the '493 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 Alembic's Proposed Generic Product until the expiration of the '493 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 Alembic's ANDA No. 205933 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 '493 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), Defendants have infringed one or more claims of the '800 patent by submitting ANDA No. 205933 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's Proposed Generic Product before the expiration of the '800 patent;

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

H. A judgment declaring that the '800 patent remains valid and enforceable;

I. 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 Alembic's Proposed Generic Product until the expiration of the '800 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 Alembic's ANDA No. 205933 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;

K. A judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '167 patent by submitting ANDA No. 205933 seeking FDA

approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's Proposed Generic Product before the expiration of the '167 patent;

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

M. A judgment declaring that the '167 patent remains valid and enforceable;

N. 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 Alembic's Proposed Generic Product until the expiration of the '167 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 Alembic's ANDA No. 205933 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;

P. A judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '215 patent by submitting ANDA No. 205933 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's Proposed Generic Product before the expiration of the '215 patent;

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

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

S. 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 Alembic's Proposed Generic Product until the expiration of the '215 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

T. An order that the effective date of any approval of Alembic's ANDA No. 205933 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;

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

V. Costs and expenses in this action; and

W. 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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April 4, 2014