IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI and SANOFI-AVENTIS U.S. LLC,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No.: _____
	)	
LUPIN ATLANTIS HOLDINGS S.A., LUPIN LTD., and LUPIN PHARMACEUTICALS INC.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi and Sanofi-Aventis U.S. LLC ("Sanofi U.S.") (collectively, "Plaintiffs") for their Complaint against defendants Lupin Atlantis Holdings S.A., Lupin Ltd., and Lupin Pharmaceuticals Inc. (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. Upon information and belief, Defendant Lupin Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400051, Maharashtra, India.

4. Upon information and belief, Defendant Lupin Atlantis Holdings S.A. ("Lupin Atlantis") is a wholly-owned subsidiary of Lupin Ltd., and is a corporation organized

and existing under the laws of Switzerland, with a principal place of business at Bachstrasse 56, 8200 Schaffhausen SH, Switzerland.

5. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") is a wholly-owned subsidiary of Lupin Ltd. and is a corporation organized and existing under the laws of the Commonwealth of Virginia, with a principal place of business located at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202.

JURISDICTION AND VENUE

6. 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.

7. This court has personal jurisdiction over Lupin Atlantis. On information and belief, Lupin Atlantis 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 Lupin Atlantis has continuous and systematic contacts with Delaware.

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

9. On information and belief, Lupin Atlantis has purposefully conducted business in the state of Delaware, continues to conduct business in Delaware, and Delaware is a likely destination of Lupin Atlantis's products or the products of its affiliates or agents.

10. On information and belief, Lupin Atlantis has previously availed itself of this forum by filing lawsuits in this judicial district as a plaintiff, including but not limited to *Lupin Atlantis Holdings S.A. v. Ranbaxy Laboratories Limited, et al*., 10-cv-659-SLR (D. Del. 2010).

11. Alternatively, assuming that the above facts do not establish personal jurisdiction over Lupin Atlantis, this Court may exercise jurisdiction over Lupin Atlantis pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Lupin Atlantis is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Lupin Atlantis has sufficient contacts with the United States as a whole, including but not limited to submitting an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA) and manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Lupin Atlantis satisfies due process.

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

13. On information and belief, Lupin Ltd. is in the business of researching, developing, manufacturing, and/or selling pharmaceutical products that are distributed

throughout the United States, including in the state of Delaware. On information and belief, Lupin Ltd. directly or through its affiliates and agents formulates, manufactures, packages, markets, and/or sells pharmaceutical products throughout the United States, including in this judicial district.

14. On information and belief, Lupin Ltd. has purposefully conducted business in the state of Delaware, continues to conduct business in Delaware, and Delaware is a likely destination of Lupin Ltd.'s products or the products of its affiliates or agents.

15. On information and belief, Lupin Ltd. has previously availed itself of this forum by submitting to the jurisdiction of this court and asserting counterclaims in this judicial district in, for example, *ViiV Healthcare UK Ltd.et al. v. Lupin Ltd., et al*., 14-cv-369-LPS (D. Del. 2014).

16. Alternatively, assuming that the above facts do not establish personal jurisdiction over Lupin Ltd., this Court may exercise jurisdiction over Lupin Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Lupin Ltd. is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Lupin Ltd. has sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Lupin Atlantis satisfies due process.

17. This court has personal jurisdiction over Lupin Pharmaceuticals. On information and belief, Lupin Pharmaceuticals 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 Lupin Pharmaceuticals has continuous and systematic contacts with Delaware.

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

19. On information and belief, Lupin Pharmaceuticals has purposefully conducted business in the state of Delaware, continues to conduct business in Delaware, and Delaware is a likely destination of Lupin Pharmaceutical's products or the products of its affiliates or agents.

20. On information and belief, Lupin Pharmaceuticals has previously availed itself of this forum by submitting to the jurisdiction of this court and asserting counterclaims in this judicial district in, for example, *ViiV Healthcare UK Ltd.et al. v. Lupin Ltd., et al*., 14-cv-369-LPS (D. Del. 2014).

21. On information and belief, upon approval of Lupin Atlantis's ANDA No. 205904, Defendants will market and sell Lupin Atlantis's dronedarone hydrochloride tablets, eq. 400 mg base in Delaware and throughout the United States and will derive substantial revenue therefrom.

22. On information and belief, upon approval of Lupin Atlantis's ANDA No. 205904, Defendants will place Lupin Atlantis'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.

23. 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.

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

25. 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

26. 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 FDA approved NDA No. 022425 on July 1, 2009.

27. 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.

28. 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 United States Patent and Trademark Office (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).

29. 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.

30. 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).

31. 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.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

32. Lupin Atlantis submitted ANDA No. 205904 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of dronedarone hydrochloride tablets, eq. 400 mg base ("Lupin Atlantis's Proposed Generic Product").

33. On information and belief, ANDA No. 205904 seeks FDA approval of Lupin Atlantis'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.

34. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals actively participated in and/or directed activities related to the submission of ANDA No. 205904 and the research and development of Lupin Atlantis's Proposed Generic Product, were actively involved in preparing the ANDA, and/or intend to directly benefit from and have a financial stake in the approval of the ANDA.

35. On information and belief, upon approval of Lupin Atlantis's ANDA, Lupin Ltd. and Lupin Pharmaceuticals will be involved in the manufacture, formulation, distribution, and/or marketing of Lupin Atlantis's Proposed Generic Product.

36. By letter dated April 6, 2015, and pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95(c), Lupin Atlantis notified Plaintiffs that it had submitted ANDA No. 205904 to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of Lupin Atlantis's Proposed Generic Product before the expiration of the '800 patent and the '167 patent.

37. In its April 6, 2015 letter, Lupin Atlantis 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 and the '167 patent. On information and belief, Lupin certified that, in its opinion and to the best of its knowledge, the '800 patent and the '167 patent are invalid and/or will not be infringed by the manufacture, use, or sale of Lupin Atlantis's Proposed Generic Product.

COUNT I
Infringement of U.S. Patent No. 8,318,800 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. 205904 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 Lupin Atlantis'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, Lupin was aware of the '800 patent at the time the ANDA was submitted.

40. The commercial manufacture, use, offer for sale, sale, and/or importation of Lupin Atlantis's Proposed Generic Product, for which Lupin seeks approval in ANDA No. 205904, 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).

41. Plaintiffs will be irreparably harmed by Lupin'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)

42. Plaintiffs repeat and reallege paragraphs 1 through 41 as if fully set forth herein.

43. By submitting ANDA No. 205904 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 Lupin Atlantis'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.

44. Lupin Atlantis'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.

45. Lupin Atlantis'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 Lupin Atlantis's Proposed Generic Product, for which Lupin Atlantis seeks approval in ANDA No. 205904, 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.

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 '800 patent by submitting ANDA No. 205904 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin Atlantis'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 Lupin Atlantis'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 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 Lupin Atlantis'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 ANDA No. 205904 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), Defendants have infringed one or more claims of the '167 patent by submitting ANDA No. 205904 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin Atlantis'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 Lupin Atlantis'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 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 Lupin Atlantis'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 ANDA No. 205904 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 determination that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorneys' fees;

L. Costs and expenses in this action; and

M. 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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