IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI and SANOFI-AVENTIS U.S. LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No.: _____
AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, and AMNEAL PHARMACEUTICALS CO. INDIA PRIVATE LIMITED,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi and Sanofi-Aventis U.S. LLC ("Sanofi U.S.") (collectively, "Plaintiffs") for their Complaint against defendants Amneal Pharmaceuticals LLC ("Amneal Pharma"), Amneal Pharmaceuticals of New York, LLC ("Amneal NY"), and Amneal Pharmaceuticals Co. India Private Limited ("Amneal 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 Amneal Pharma is a company organized and existing under the laws of the state of Delaware, having its principal place of business at 440 U.S. Highway 22 East, Suite 104, Bridgewater, NJ 08807.

4. On information and belief, defendant Amneal NY is a company organized and existing under the laws of the State of Delaware, having its principal place of business at 85 Adams Avenue, Hauppauge, NY 11788.

5. On information and belief, defendant Amneal Ltd. is an Indian corporation, having its principal place of business at 882/1-871, Village Rajoda, Near Hotel Kankavati, Bavla Taluka, Ahmedabad-382220, Gujarat, India.

6. On information and belief, Amneal NY is a wholly owned subsidiary of Amneal Pharma.

7. On information and belief, Amneal Ltd. is a wholly owned subsidiary of Amneal Pharma.

JURISDICTION AND VENUE

8. 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.

9. This Court has personal jurisdiction over Amneal Pharma. On information and belief, Amneal Pharma is a Delaware company registered with the Delaware Department of State: Division of Corporations under file number 3809030, and it maintains a registered agent for service of process in Delaware.

10. On information and belief, Amneal Pharma 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 Amneal Pharma has continuous and systematic contacts with Delaware.

11. On information and belief, Amneal Pharma 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, Amneal Pharma 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.

12. On information and belief, Amneal Pharma holds a Delaware controlled substances distributor/manufacturer license (No. DM 0006588) and a Delaware pharmacy wholesale license (No. A4-0001536).

13. On information and belief, Amneal Pharma has previously availed itself of this forum by submitting to the jurisdiction of this Court and asserting counterclaims in other civil actions initiated in this jurisdiction including, for example, *Galderma Labs. et al. v. Amneal Pharmaceuticals, LLC et al.*, 1:11-cv-01106-LPS (D. Del.) and *Forest Labs., Inc. et al. v. Cobalt Labs., Inc. et al.*, 1:08-cv-0021-LPS (D. Del.).

14. This Court has personal jurisdiction over Amneal NY. Amneal NY is a Delaware company registered with the Delaware Department of State: Division of Corporations under file number 4533207, and it maintains a registered agent for service of process in Delaware.

15. On information and belief, Amneal NY 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, Amneal Pharma 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.

16. On information and belief, Amneal NY holds Delaware controlled substances distributor/manufacturer licenses (Nos. DM-0006604 and DM-0006605) and Delaware pharmacy wholesale licenses (Nos. A4-0001538 and A4-0001537).

17. On information and belief, Amneal NY has previously availed itself of this forum by submitting to the jurisdiction of this Court and asserting counterclaims in other civil actions initiated in this jurisdiction including, for example, *Forest Labs., Inc. v. Amneal Pharms. LLC, et al.*, 14-cv-00508-LPS (D. Del.).

18. This court has personal jurisdiction over Amneal Ltd. On information and belief, Amneal Pharma 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 Amneal Ltd. has continuous and systematic contacts with Delaware.

19. On information and belief, Amneal Ltd. is in the business of researching, developing, and/or manufacturing generic pharmaceutical products that are sold and distributed throughout the United States, including in the state of Delaware. On information and belief, Amneal 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.

20. On information and belief, Amneal Ltd. has previously availed itself of this forum by submitting to the jurisdiction of this Court and asserting counterclaims in other

civil actions initiated in this jurisdiction, including, for example, *Forest Labs., Inc. et al. v. Amneal Pharms, LLC., et al.*, 13-cv-01737-SLR (D. Del.).

21. On information and belief, Defendants collaborate to develop, 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.

22. On information and belief, upon approval of Amneal Pharma's Abbreviated New Drug Application (ANDA) No. 206649, Defendants and/or their affiliates or agents will market and sell Amneal Pharma's Dronedarone Hydrochloride Tablets ("Amneal Pharma's Proposed Generic Product") in Delaware and throughout the United States and will derive substantial revenue therefrom. On information and belief, upon Approval of Amneal Pharma's ANDA, Defendants will sell Amneal Pharma's Proposed Generic Product in the State of Delaware and Amneal NY will be involved in the manufacturing and/or formulation of the product.

23. On information and belief, upon approval of Amneal Pharma's ANDA, Defendants and/or their affiliates or agents will place Amneal Pharma'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.

24. 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.

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

26. 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

27. 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.

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 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.

32. 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).

33. The named inventor on the '215 patent is Davide Radzik. The '215 patent is assigned to Sanofi.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

34. Amneal Pharma submitted ANDA No. 206649 to the FDA seeking approval to engage in the commercial manufacture, use, and/or sale of Dronedarone Hydrochloride Tablets ("Amneal Pharma's Proposed Generic Product").

35. On information and belief, ANDA No. 206649 seeks FDA approval of Amneal Pharma'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.

36. On information and belief, Amneal NY and Amneal Ltd. actively participated in and/or directed activities related to the submission of ANDA No. 206649 and the development of Amneal Pharma'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. On information and belief, upon approval of Amneal Pharma's ANDA, Amneal NY and Amneal Ltd. will be involved in the manufacture, formulation, distribution, and/or marketing of Amneal Pharma's Proposed Generic Product.

37. By letter dated June 17, 2014, and pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95(c), Amneal Pharma notified Plaintiffs that it had submitted ANDA No. 206649 to the FDA seeking approval to engage in the commercial manufacture, use, and/or sale of Amneal Pharma's Proposed Generic Product before the expiration of the '800 patent, the '167 patent, and the '215 patent.

38. In its June 17, 2014 letter, Amneal Pharma 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, Amneal Pharma 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 Amneal Pharma's Proposed Generic Product.

COUNT I
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. 206649 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 Amneal Pharma'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 Amneal Pharma's Proposed Generic Product, for which Amneal Pharma seeks approval in ANDA No. 206649, 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 II
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. 206649 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 Amneal Pharma'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. The commercial manufacture, use, offer for sale, sale, and/or importation of Amneal Pharma's Proposed Generic Product, for which Amneal Pharma seeks approval in

ANDA No. 206649, 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).

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

47. 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. 8,602,215 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. 206649 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 Amneal Pharma'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. The commercial manufacture, use, offer for sale, sale, and/or importation of Amneal Pharma's Proposed Generic Product, for which Amneal Pharma seeks approval in ANDA No. 206649, 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).

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

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 '800 patent by submitting ANDA No. 206649 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Amneal Pharma'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 Amneal Pharma'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 Amneal Pharma'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 Amneal Pharma's ANDA No. 206649 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. 206649 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Amneal Pharma'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 Amneal Pharma'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 Amneal Pharma'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 Amneal Pharma's ANDA No. 206649 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), Defendants have infringed one or more claims of the '215 patent by submitting ANDA No. 206649 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Amneal Pharma'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 Amneal Pharma'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 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 Amneal Pharma'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 Amneal Pharma's ANDA No. 206649 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.

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