IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI and SANOFI-AVENTIS U.S. LLC,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No.: _____
	)	
SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES, LTD., and CARACO PHARMACEUTICAL LABORATORIES, LTD.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi and Sanofi-Aventis U.S. LLC ("Sanofi U.S.") (collectively, "Plaintiffs") for their Complaint against defendants Sun Pharma Global FZE ("Sun FZE"), Sun Pharmaceutical Industries, Ltd. ("Sun Ltd."), and Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") (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 Sun FZE is a limited liability company incorporated under the provisions of Sharjah's Emiri Decree Number (2) of 1995, having a place of business at Office # 43, Block Y, SAIF Zone, P.O. Box 122304, Sharjah, United Arab Emirates. On information and belief, Sun FZE is a wholly owned subsidiary of Sun

Pharma Global Inc., a corporation organized and existing under the laws of the British Virgin Islands, which is in turn a wholly owned subsidiary of defendant Sun Ltd.

4. On information and belief, defendant Sun Ltd. is a company organized and existing under the laws of India, having a principal place of business at Acme Plaza, Andheri-Kurla Rd., Andheri (E), Mumbai – 400 059, India.

5. On information and belief, defendant Caraco is a company organized and existing under the laws of the state of Michigan, having a principal place of business at 1150 Elijah McCoy Drive, Detroit, Michigan 48202. On information and belief, Caraco is the surviving entity of a merger between Caraco and Sun Pharmaceutical Industries, Inc. On information and belief, Caraco is a wholly owned subsidiary of defendant Sun Ltd.

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 and 1338.

7. This Court has personal jurisdiction over Sun FZE. On information and belief, Sun FZE 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 Sun FZE has continuous and systematic contacts with Delaware.

8. On information and belief, Sun FZE 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, Sun FZE directly or through its

affiliates and agents (including Sun Ltd. and Caraco) develops, formulates, manufactures, markets, and sells pharmaceutical products, including generic drug products, throughout the United States and in this judicial district.

9. On information and belief, Sun FZE has availed itself of this forum by consenting to personal jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction, including but not limited to *Teijin Ltd. et al. v. Sun Pharma Global FZE et al.* (1:13-cv-1852-SLR) and *UCB, Inc. et al. v. Sun Pharma Global FZE et al.* (1:13-1218-LPS).

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

11. On information and belief, Sun Ltd. develops, formulates, manufactures, markets, and sells pharmaceutical products, including generic drug products, throughout the United States and in this judicial district, directly or through its affiliates and agents, including its wholly owned subsidiaries Sun FZE and Caraco.

12. On information and belief, Sun Ltd. has previously availed itself of this forum by filing lawsuits in this judicial district as a plaintiff, including but not limited to *Sun Pharmaceutical Industries Ltd. v. Wyeth* (1:09-cv-00083-SLR). On information and belief, Sun Ltd. has also availed itself of this forum by consenting to personal jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction, including but not limited to *UCB, Inc. et al. v. Sun Pharma Global FZE et al.* (1:13-1218-LPS).

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

14. On information and belief, Caraco is in the business of marketing, distributing, and selling pharmaceutical products, including generic pharmaceuticals manufactured by Sun Ltd., throughout the United States, including in the state of Delaware. On information and belief, Caraco holds a lapsed pharmacy wholesale license for the state of Delaware under License No. A4-0000447 and lapsed distributor/manufacturer licenses for controlled substances for the state of Delaware under License Nos. DM-0008209 and DS0215. On information and belief, Caraco currently has pending applications for pharmacy wholesale licenses in the state of Delaware.

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

16. On information and belief, upon approval of Sun FZE's Abbreviated New Drug Application (ANDA) No. 205963, Defendants and/or their affiliates or agents will market and sell Sun FZE's Dronedarone Hydrochloride Tablets, 400 mg ("Sun FZE's Proposed Generic Product") in Delaware and throughout the United States and will derive substantial revenue therefrom. On information and belief, upon approval of Sun FZE's ANDA, Defendants will sell Sun FZE's Proposed Generic Product in the state of Delaware and throughout the United States,

and Sun Ltd. and Caraco will be involved in the manufacture, distribution, and/or marketing of Sun FZE's Proposed Generic Product.

17. On information and belief, upon approval of Sun FZE's ANDA, Defendants and/or their affiliates or agents will place Sun FZE'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.

18. 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.

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

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

21. 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

22. 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.

23. 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).

24. 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.

25. 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).

26. 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.

27. 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).

28. 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.

29. 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).

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

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

31. Sun FZE submitted ANDA No. 205963 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 ("Sun FZE's Proposed Generic Product").

32. On information and belief, ANDA No. 205963 seeks FDA approval of Sun FZE'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.

33. On information and belief, Defendants Sun Ltd. and Caraco actively participated in and/or directed activities related to the submission of ANDA No. 205963 and the development of Sun FZE'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 Sun FZE's ANDA, Sun Ltd. and Caraco will be involved in the manufacture, distribution, and/or marketing of Sun FZE's Proposed Generic Product.

34. By letter dated January 30, 2014, and pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), Sun FZE notified Plaintiffs that it had submitted ANDA No. 205963 to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of Sun FZE's Proposed Generic Product before the expiration of the '493 patent, the '800 patent, the '167 patent, and the '215 patent.

35. In its January 30, 2014 letter, Sun FZE 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, Sun FZE 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 Sun FZE's Proposed Generic Product.

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

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

37. By submitting ANDA No. 205963 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 Sun FZE'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.

38. The commercial manufacture, use, offer for sale, sale, and/or importation of Sun FZE's Proposed Generic Product, for which Sun FZE seeks approval in ANDA No. 205963, 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).

39. 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))

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

41. By submitting ANDA No. 205963 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 Sun FZE'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.

42. The commercial manufacture, use, offer for sale, sale, and/or importation of Sun FZE's Proposed Generic Product, for which Sun FZE seeks approval in ANDA No. 205963, 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).

43. 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))

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

45. By submitting ANDA No. 205963 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 Sun FZE'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.

46. The commercial manufacture, use, offer for sale, sale, and/or importation of Sun FZE's Proposed Generic Product, for which Sun FZE seeks approval in ANDA No.

205963, 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. 205963 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 Sun FZE'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 Sun FZE's Proposed Generic Product, for which Sun FZE seeks approval in ANDA No. 205963, 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. 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. 205963 seeking FDA

approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Sun FZE'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 Sun FZE'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 Sun FZE'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 Sun FZE's ANDA No. 205963 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. 205963 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Sun FZE'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 Sun FZE'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 Sun FZE'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 Sun FZE's ANDA No. 205963 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. 205963 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Sun FZE'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 Sun FZE'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 Sun FZE'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 Sun FZE's ANDA No. 205963 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. 205963 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Sun FZE'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 Sun FZE'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 Sun FZE'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 Sun FZE's ANDA No. 205963 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

Jack B. Blumenfeld (#1014)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
dfahnestock@mnat.com

Attorneys for Plaintiffs Sanofi and Sanofi-Aventis U.S. LLC

OF COUNSEL:

William E. Solander
Daniel J. Minion
James R. Tyminski
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104
(212) 218-2100

March 6, 2014