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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Aventis Pharma S.A., and sanofi-aventis U.S., LLC (collectively "sanofi-aventis"), for their complaint against Defendants Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries Inc., Sun Pharma Global FZE, and Caraco Pharmaceutical Laboratories, Ltd. (collectively, "Sun") hereby state as follows:

PARTIES

1. Aventis Pharma S.A. is a French corporation with its principal place of business in Paris, France.

2. Sanofi-aventis U.S., LLC is a Delaware corporation with its principal place of business in Bridgewater, NJ.

3. Sanofi-aventis is in the business of developing, manufacturing, and selling a wide variety of consumer products, including pharmaceutical products. Sanofi-aventis U.S., LLC is the holder of approved New Drug Application No. 020-449 for the active ingredient docetaxel, which has the proprietary name Taxotere®. Taxotere® is sold by sanofi-aventis throughout the United States, and it has been approved by the FDA for seven indications. Worldwide, Taxotere® is marketed in over 100 countries and used for the treatment of, among other things, breast, lung, prostate, gastric, and head and neck cancer.

4. Upon information and belief, Defendant Sun Pharmaceutical Industries Ltd. ("Sun Ltd.") is a company organized and existing under the laws of India with a place of business at Acme Plaza, Andheri-Kurla Road, Andheri (East), Mumbai-400 059, India. Upon information and belief, Defendant Sun Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district. Upon information and belief, Sun Ltd. has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

5. Upon information and belief, Sun Pharmaceutical Industries, Inc. ("Sun USA") is a company organized and existing under the laws of the State of Michigan with a principal place of business at 270 Prospect Plains Road, Cranbury, NJ 08512. Upon information and belief, Defendant Sun USA manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district. Upon information and belief, Sun USA is a wholly-owned subsidiary and agent of Defendant Sun Ltd. Upon information and belief, Sun USA has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

6. Upon information and belief, Sun Pharma Global FZE ("Sun FZE") is a company organized and existing under the laws of the United Arab Emirates with a principal place of business at Executive Suite # 43, Block Y, SAIF Zone, PO Box 122304, Sharjah, U.A.E. Upon information and belief, Sun FZE is a wholly-owned subsidiary and agent of Defendant Sun Ltd.

7. Upon information and belief, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") is a company organized and existing under the laws of Michigan with a principal place of business at 1150 Elijah McCoy Drive, Detroit, MI 48202. Upon information and belief, Defendant Caraco manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district. Upon information and belief, a majority of Caraco's common stock is owned by Sun Ltd.

NATURE OF THE ACTION

8. This is a civil action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100, et seq., and in particular under 35 U.S.C. § 271(e). This action relates to a New Drug Application ("NDA") filed by Sun Ltd., Sun USA, Sun FZE, and/or Caraco with the United States Food and Drug Administration ("FDA") for approval to market a

copy of sanofi-aventis' highly successful Taxotere® pharmaceutical products that are sold in the United States.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 35 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Plaintiffs, which manufacture numerous drugs for sale and use throughout the United States, including this judicial district. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

11. This Court has personal jurisdiction over Defendant Sun Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with New Jersey. Among other things, upon information and belief, Sun Ltd., directly or through its subsidiaries Sun USA and/or Caraco, places goods into the stream of commerce for distribution throughout the United States, including the State of New Jersey, and has purposefully availed itself of this forum by filing counterclaims in this jurisdiction.

12. This Court has personal jurisdiction over Defendant Sun USA by virtue of, *inter alia*, its systematic and continuous contacts with New Jersey. Among other things, upon information and belief, Sun USA maintains a principal place of business in the State of New Jersey and directly places goods into the stream of commerce for distribution throughout the United States, including this State.

13. This Court has personal jurisdiction over Defendant Sun FZE by virtue of, *inter alia*, its systematic and continuous contacts with New Jersey, including the substantial revenue it derives from the State of New Jersey through its sister corporations and agents Sun USA and Caraco. Among other things, upon information and belief, Sun FZE caused foreseeable harm and injury to Plaintiffs, one of which is Delaware corporation with a principal place of business in New Jersey, in this judicial district by participating in the commission of the tortious action of patent infringement.

14. This Court has personal jurisdiction over Defendant Caraco by virtue of, *inter alia*, its systematic and continuous contacts with New Jersey. Among other things, upon information and belief, Caraco directly places goods into the stream of commerce for distribution throughout the United States, including the State of New Jersey, and is registered to do business in this State.

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

BACKGROUND

16. Upon information and belief, Sun Ltd., Sun USA, Sun FZE, and/or Caraco have filed with the FDA in Rockville, Maryland, New Drug Application 22-534 ("the Sun NDA") under 21 U.S.C. § 355(b)(2) (also known as a 505(b)(2) application) to obtain FDA approval for the commercial manufacture, use, and sale of a docetaxel injection product in the following dosage forms: 20 mg/vial and 80 mg/vial. Sun filed its NDA No. 22-534 to obtain approval to market a generic form of docetaxel injection solution, which is currently marketed by sanofi-aventis under the brand name Taxotere® (docetaxel) Injection Concentrate, before the expiration of certain sanofi-aventis patents, including U.S. Patent Nos. 5,438,072; 5,698,582; 5,714,512; and 5,750,561 (collectively, "sanofi-aventis' patents").

17. On behalf of Sun, Dr. Ratnesh Shrivastava and Mr. Arshad Jamil, as Vice President, Intellectual Property Cell and Patent Counsel of Sun Ltd., respectively, sent a letter dated July 10, 2009 to Plaintiffs to provide notice, pursuant to 21 U.S.C. § 355(b)(3)(B), that Sun had filed NDA 22-534 with respect to docetaxel injection solution in two dosage forms (20 mg/vial and 80 mg/vial). The letter further provided that Sun had filed with the FDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), a certification ("Paragraph IV certification") alleging that sanofi-aventis' patents are invalid, not infringed, and/or not enforceable. The letter also included a statement of factual and legal allegations upon which Sun based its certifications to the FDA.

FIRST COUNT FOR INFRINGEMENT OF UNITED STATES PATENT NO. 5,714,512

18. The allegations of the preceding paragraphs 1-16 are repeated, realleged, and incorporated herein by reference.

19. United States Patent No. 5,714,512 B1 ("the '512 patent"), entitled "New Compositions Containing Taxane Derivatives" was duly and legally issued by the United States Patent and Trademark Office on February 3, 1998. Aventis Pharma S.A. is the owner by assignment of the '512 patent and has the right to sue for infringement thereof. A true and correct copy of the '512 patent is attached as Exhibit A.

20. Upon information and belief, Sun's Paragraph IV certification alleged that its docetaxel injection product will not infringe claims 1-23, 28-31, and 34-35 of the '512 patent. Upon information and belief, Sun's Paragraph IV certification alleged that all claims of the '512 patent are invalid.

21. Under 35 U.S.C. § 271(e)(2)(A), Sun's submission to the FDA of NDA No. 22-534 to obtain approval for the commercial manufacture, use, or sale of its docetaxel injection product before the expiration of the '512 patent constitutes infringement of one or more claims of the '512 patent.

22. Upon FDA approval of NDA No. 22-534, Sun will infringe the '512 patent by making, using, offering to sell, selling, and/or importing the docetaxel injection product in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of Sun's NDA shall be no earlier than the expiration date of the '512 patent.

23. Upon information and belief, Sun's docetaxel injection product, when offered for sale, sold, and/or imported, and then used as directed, would be used in a manner that would directly infringe at least one of the claims of the '512 patent.

24. Upon information and belief, the use of Sun's docetaxel injection product constitutes a material part of at least one of the claims of the '512 patent; Sun knows that its docetaxel injection product is especially made or adapted for use in a manner infringing at least one of the claims of the '512 patent; and Sun's docetaxel injection product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

25. Upon information and belief, the offering to sell, sale, and/or importation of Sun's docetaxel product would contributorily infringe at least one of the claims of the '512 patent.

26. Upon information and belief, Sun had knowledge of the '512 patent and, by its promotional activities and package insert for its docetaxel injection product, knows or should know that it will actively aid and abet another's direct infringement of at least one of the claims of the '512 patent.

27. Upon information and belief, the offering to sell, sale, and/or importation of Sun's docetaxel injection product would actively induce infringement of at least one of the claims of the '512 patent.

28. Sanofi-aventis will be substantially and irreparably harmed by Sun's infringing activities unless those activities are enjoined by this Court. Sanofi-aventis has no adequate remedy at law.

SECOND COUNT FOR INFRINGEMENT OF UNITED STATES PATENT No. 5,750,561

29. The allegations of the preceding paragraphs 1-27 are repeated, realleged, and incorporated herein by reference.

30. United States Patent No. 5,750,561 B1 ("the '561 patent"), entitled "Compositions Containing Taxane Derivatives" was duly and legally issued by the United States Patent and Trademark Office on May 12, 1998. Aventis Pharma S.A. is the owner by assignment of the '561 patent and has the right to sue for infringement thereof. A true and correct copy of the '561 patent is attached as Exhibit B.

31. Upon information and belief, Sun's Paragraph IV certification alleged that its docetaxel injection product will not infringe claims 3, 4, 6, 7, and 11 of the '561 patent. Upon information and belief, Sun's Paragraph IV certification alleged that all claims of the '561 patent are invalid.

32. Under 35 U.S.C. § 271(e)(2)(A), Sun's submission to the FDA of NDA No. 22-534 to obtain approval for the commercial manufacture, use, or sale of its docetaxel injection product before the expiration of the '561 patent constitutes infringement of one or more claims of the '561 patent.

33. Upon FDA approval of NDA No. 22-534, Sun will infringe the '561 patent by making, using, offering to sell, selling, and/or importing the docetaxel injection product in the United States, and by actively inducing and contributing to infringement by others under 35

U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of Sun's NDA shall be no earlier than the expiration date of the '561 patent.

34. Upon information and belief, Sun's docetaxel injection product, when offered for sale, sold, and/or imported, and then used as directed, would be used in a manner that would directly infringe at least one of the claims of the '561 patent.

35. Upon information and belief, the use of Sun's docetaxel injection product constitutes a material part of at least one of the claims of the '561 patent; Sun knows that its docetaxel injection product is especially made or adapted for use in a manner infringing at least one of the claims of the '561 patent; and Sun's docetaxel injection product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

36. Upon information and belief, the offering to sell, sale, and/or importation of Sun's docetaxel product would contributorily infringe at least one of the claims of the '561 patent.

37. Upon information and belief, Sun had knowledge of the '561 patent and, by its promotional activities and package insert for its docetaxel injection product, knows or should know that it will actively aid and abet another's direct infringement of at least one of the claims of the '561 patent.

38. Upon information and belief, the offering to sell, sale, and/or importation of Sun's docetaxel injection product would actively induce infringement of at least one of the claims of the '561 patent.

39. Sanofi-aventis will be substantially and irreparably harmed by Sun's infringing activities unless those activities are enjoined by this Court. Sanofi-aventis has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, sanofi-aventis respectfully requests that this Court enter judgment in its favor as follows:

(1) declaring that, under 35 U.S.C. § 271(e)(2)(A), Sun's submission to the FDA of NDA No. 22-534 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Sun's docetaxel injection product before the expiration of the '512 patent was an act of infringement of the '512 patent;

(2) declaring that Sun's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Sun's docetaxel injection product would constitute infringement of the '512 patent;

(3) declaring that, under 35 U.S.C. § 271(e)(2)(A), Sun's submission to the FDA of NDA No. 22-534 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Sun's docetaxel injection product before the expiration of the '561 patent was an act of infringement of the '561 patent;

(4) declaring that Sun's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Sun's docetaxel injection product would constitute infringement of the '561 patent;

(5) ordering that the effective date of any FDA approval of Sun's docetaxel injection product shall be no earlier than the expiration of the '512 patent, in accordance with 35 U.S.C. § 271(e)(4)(A);

(6) ordering that the effective date of any FDA approval of Sun's docetaxel injection product shall be no earlier than the expiration of the '561 patent, in accordance with 35 U.S.C. § 271(e)(4)(A);

(7) enjoining Sun and all persons and entities acting in concert with Sun from commercially manufacturing, using, offering for sale, or selling Sun's docetaxel injection product within the United States, or importing Sun's docetaxel injection product into the United States, until the expiration of the '512 patent, in accordance with 35 U.S.C. § 271 (e)(4)(B);

(8) enjoining Sun and all persons and entities acting in concert with Sun from commercially manufacturing, using, offering for sale, or selling Sun's docetaxel injection product within the United States, or importing Sun's docetaxel injection product into the United States, until the expiration of the '561 patent, in accordance with 35 U.S.C. § 271 (e)(4)(B);

(9) awarding sanofi-aventis its costs and expenses in this action; and

(10) awarding sanofi-aventis any further and additional relief as this Court deems just and proper.

Dated: August 24, 2009

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is the subject of the following actions:

Aventis Pharma S.A. et al v. Hospira Inc., Civil Action No. 1:07-cv-00721-GMS (District of Delaware) consolidated with *Aventis Pharma S.A. et al v. Apotex Inc. et al*, Civil Action No. 1:08-cv-00496-GMS (District of Delaware).

Both cases involve United States Patent Nos. 5,714,512 ("the '512 patent") and 5,750,561 ("the '561 patent").

Dated: August 24, 2009

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