IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMA S.A., SANOFI-AVENTIS U.S. LLC,	)	
Plaintiffs,	)	Civil Action No._____
v.	)	
ACCORD HEALTHCARE, INC. USA,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Aventis Pharma S.A., and sanofi-aventis U.S. LLC (collectively "sanofi-aventis"), for their complaint against Defendant Accord Healthcare, Inc. USA ("Accord"), hereby state as follows:

PARTIES

1. Aventis Pharma S.A. is a French corporation with its principal place of business in Paris, France. Sanofi-aventis U.S. LLC is a Delaware corporation with its principal place of business in Bridgewater, NJ.

2. 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.

3. Upon information and belief, Accord is a corporation organized and existing under the laws of the State of North Carolina, having its principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina, 27703. Upon information and belief, Defendant Accord manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

NATURE OF THE ACTION

4. 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 Accord 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

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

6. This Court has personal jurisdiction over Accord by virtue of, *inter alia*, its systematic and continuous contacts with Delaware. Among other things, upon information and belief, Accord places goods into the stream of commerce for distribution throughout the United States, including the State of Delaware. Accord has also 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 sanofi-aventis, which manufactures numerous drugs for sale and use throughout the United States, including this judicial district.

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

BACKGROUND

8. Upon information and belief, Accord has filed with the FDA in Rockville, Maryland, New Drug Application 201195 ("the Accord 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/0.5 mL and 80 mg/2.0 mL. Accord filed its NDA No. 201195 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. 5,714,512; and 5,750,561 (collectively, the "Patents-in-Suit").

9. On behalf of Accord, Mr. Samir Mehta, who upon information and belief is the President of Accord, sent a letter to Plaintiffs to provide notice, pursuant to 21 U.S.C. § 355(b)(3)(B), that Accord had filed NDA 201195 with respect to docetaxel injection solution in two dosage forms (20 mg/0.5 mL and 80 mg/2.0 mL). Plaintiffs received this letter on November 23, 2010. The letter further provided that Accord had filed with the FDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), a certification ("Paragraph IV certification") alleging that the Patents-in-Suit are invalid, not infringed, and/or not enforceable. The letter also included a statement of factual and legal allegations upon which Accord based its certifications to the FDA.

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

10. The allegations of the preceding paragraphs 1-9 are repeated, realleged, and incorporated herein by reference.

11. 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.

12. Upon information and belief, Accord's Paragraph IV certification alleged that its docetaxel injection product will not infringe claims 1-23, 28, 30-31, and 34-35 of the '512 patent. Upon information and belief, Accord's Paragraph IV certification alleged that claims 24-29 and 32-33 of the '512 patent are invalid.

13. Under 35 U.S.C. § 271(e)(2)(A), Accord's submission to the FDA of NDA No. 201195 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.

14. Upon FDA approval of NDA No. 201195, Accord 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 Accord's NDA shall be no earlier than the expiration date of the '512 patent.

15. Upon information and belief, Accord'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.

16. Upon information and belief, the use of Accord's docetaxel injection product constitutes a material part of at least one of the claims of the '512 patent; Accord 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 Accord's docetaxel injection product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

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

18. Upon information and belief, Accord 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.

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

20. Plaintiffs will be substantially and irreparably harmed by Accord's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

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

21. The allegations of the preceding paragraphs 1-20 are repeated, realleged, and incorporated herein by reference.

22. 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.

23. Upon information and belief, Accord's Paragraph IV certification alleged that its

docetaxel injection product will not infringe claims 1-11 of the '561 patent. Upon information and belief, Accord's Paragraph IV certification contained no allegations regarding the validity of the '561 patent.

24. Under 35 U.S.C. § 271(e)(2)(A), Accord's submission to the FDA of NDA No. 201195 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.

25. Upon FDA approval of NDA No. 201195, Accord 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 Accord's NDA shall be no earlier than the expiration date of the '561 patent.

26. Upon information and belief, Accord'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.

27. Upon information and belief, the use of Accord's docetaxel injection product constitutes a material part of at least one of the claims of the '561 patent; Accord 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 Accord's docetaxel injection product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

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

29. Upon information and belief, Accord 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.

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

31. Plaintiffs will be substantially and irreparably harmed by Accord's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor as follows:

(1) declaring that, under 35 U.S.C. § 271(e)(2)(A), Accord's submission to the FDA of NDA No. 201195 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Accord's docetaxel injection product before the expiration of the '512 patent was an act of infringement of the '512 patent;

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

(3) declaring that, under 35 U.S.C. § 271(e)(2)(A), Accord's submission to the FDA of NDA No. 201195 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Accord's docetaxel injection product before the

expiration of the '561 patent was an act of infringement of the '561 patent;

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

(5) ordering that the effective date of any FDA approval of Accord'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 Accord'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);

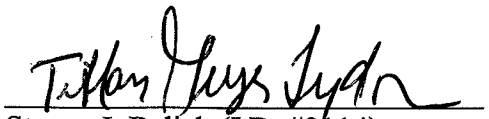
(7) enjoining Accord and all persons and entities acting in concert with Accord from commercially manufacturing, using, offering for sale, or selling Accord's docetaxel injection product within the United States, or importing Accord's docetaxel injection product into the United States, until the expiration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

(8) enjoining Accord and all persons and entities acting in concert with Accord from commercially manufacturing, using, offering for sale, or selling Accord's docetaxel injection product within the United States, or importing Accord'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 Plaintiffs their costs and expenses in this action; and

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

ASHBY & GEDDES



Steven J. Balick (I.D. #2114)
Tiffany Geyer Lydon (I.D. #3950)
Andrew C. Mayo (I.D. #5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888
sbalick@ashby-geddes.com
tlydon@ashby-geddes.com
amayo@ashby-geddes.com

Attorneys for Plaintiffs Aventis Pharma S.A. and sanofi-aventis U.S., LLC

Of Counsel:

George F. Pappas
Christopher N. Sipes
Kevin B. Collins
Michael N. Kennedy
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 662-6000

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