

**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.	)	
	)	
	)	
APOTEX, INC.,	)	
APOTEX CORP.,	)	
	)	
Defendants.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs, Aventis Pharma S.A., and sanofi-aventis U.S., LLC (collectively, “sanofi-aventis”), for their complaint against Defendants Apotex, Inc. and Apotex Corp. (collectively, “Apotex”) hereby state as follows:

**THE 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, New Jersey.

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, Defendant Apotex, Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex, Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc. Upon information and belief, Defendant Apotex, Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

4. Upon information and belief, Apotex Inc. has availed itself of the legal protections of the State of Delaware, having filed counterclaims seeking judicial relief from this Court in, among other cases, *Sanofi-Aventis, et al v. Apotex Inc. et al*, Civil No. 07-792.

5. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida, 33326. Upon information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc. Apotex Corp. is registered to do business in Delaware and The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware, 19801, is its registered agent in Delaware.

6. Upon information and belief, Apotex Corp. has availed itself of the legal protections of the State of Delaware, having filed counterclaims seeking judicial relief from this Court in, among other cases, *Sanofi-Aventis, et al v. Apotex Inc. et al*, Civil No. 07-792. Apotex Corp. has also admitted to personal jurisdiction in this court in the aforementioned action.

### **NATURE OF THE ACTION**

7. 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 Apotex 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**

8. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

9. 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.

10. This court has personal jurisdiction over Defendant Apotex, Inc. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including the substantial revenue it derives from the State of Delaware through its sister corporation and agent Apotex Corp, as well as its purposeful availment of this forum, such as its filing of claims and counterclaims in this jurisdiction.

11. This Court has personal jurisdiction over Defendant Apotex Corp. because it is incorporated under the laws of the State of Delaware, is registered to do business in the State of Delaware, and has a registered agent in the State of Delaware, and by virtue of, *inter alia*, its engaging in systematic and continuous contact with the State of Delaware, deriving substantial revenue from generic drugs consumed in the State of Delaware, as well as its purposeful availment of this forum, such as its filing of claims and counterclaims in this jurisdiction.

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

### **BACKGROUND**

13. Upon information and belief, Defendants have filed with the FDA in Rockville, Maryland, New Drug Application 22-312 (“the Apotex 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: 40 mg/ml, 20 mg/0.5 ml and 80 mg/2ml. Apotex filed its NDA No. 22-312 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.

14. On behalf of Apotex, Bernice Tao, as Director of Regulatory Affairs US for Apotex, Inc., sent a letter dated June 27, 2008 to Plaintiffs to provide notice, pursuant to 21 U.S.C. § 355(b)(3)(B), that Apotex had filed NDA 22-312 with respect to docetaxel injection solution in a variety of dosage forms (40 mg/ml, 20 mg/0.5 ml and 80 mg/2ml). The letter further provided notice that Apotex had filed with the FDA, pursuant to 21 U.S.C.

§ 355(b)(2)(A)(iv), a certification (“Paragraph IV certification”) alleging that U.S. Patent Nos. 4,814,470; 5,438,072; 5,698,582; 5,714,512; and 5,750,561 (collectively, “sanofi-aventis’ patents”) are invalid, not infringed, and/or not enforceable. The letter also included a statement of factual and legal allegations upon which Apotex based its certifications to the FDA.

**APOTEX’S FAILURE TO COMPLY WITH  
ITS OFFER OF CONFIDENTIAL ACCESS**

15. In a letter dated June 27, 2008, Apotex offered sanofi-aventis confidential access to the Apotex NDA. Its offer of confidential access permitted one outside law firm to have access to the Apotex NDA for the purpose of determining if U.S. Patent Nos. 5,438,072, 5,698,582, 5,714,512 and 5,750,561 had been infringed by Apotex.

16. Counsel for sanofi-aventis contacted Apotex on July 11, 2008 in an attempt to modify the offer of confidential access to allow for outside experts and one in-house counsel at sanofi-aventis to have access to the Apotex NDA.

17. Almost two weeks later, on July 23, 2008, Apotex responded by email to the July 11, 2008 letter and proposed further modifications to the offer that would have prohibited outside experts from having access to the Apotex NDA.

18. Counsel for sanofi-aventis responded to Apotex’s July 23, 2008 email in a letter dated July 25, 2008, requesting that permission be given for one outside expert to review the Apotex NDA.

19. Apotex responded to sanofi-aventis on July 29, 2008 and allowed for an outside expert to have access to the Apotex NDA.

20. On July 30, 2008, counsel for sanofi-aventis accepted Apotex’s terms and faxed a signed offer of confidential access to Apotex.

21. On Friday, August 1, 2008, counsel for sanofi-aventis contacted, by email and voicemail, Ms. Eiko Yap, assistant to Apotex Vice President for Global Intellectual Property, Shashank Upadhye, to request that a countersigned copy of the offer of confidential access and the Apotex NDA be produced to counsel for sanofi-aventis. In two email messages from that day, counsel for sanofi-aventis included copies of the offer of confidential access regarding the Apotex NDA as signed by counsel for sanofi-aventis.

22. Having not heard a response from Apotex, counsel from sanofi-aventis again contacted Ms. Yap by email on Monday, August 4, 2008, requesting production of a countersigned copy of the offer of confidential access and the Apotex NDA. In addition, counsel for sanofi-aventis contacted Mr. Upadhye directly by voicemail on the morning of August 4, 2008. In the email message to Ms. Yap from August 4, 2008, counsel for sanofi-aventis included a copy of the offer of confidential access regarding the Apotex NDA as signed by counsel for sanofi-aventis.

23. In a telephone call on the morning of August 5, 2008, Ms. Eiko Yap responded to counsel for sanofi-aventis and promised that the countersigned offer of confidential access and the Apotex NDA would be produced to counsel for sanofi-aventis as soon as possible.

24. In an email message from 11:29 PM on the night of August 5, 2008, Apotex Vice President for Global Intellectual Property, Shashank Upadhye, responded to the August 4, 2008 voicemail left by sanofi-aventis counsel and asserted that he would be unable to produce the countersigned offer of confidential access and the Apotex NDA because counsel had not specified a product name or molecule in his voicemail message from the morning of August 4, 2008.

25. Counsel for sanofi-aventis responded to Mr. Upadhye's August 5, 2008 message by an electronically delivered letter on August 6, 2008.

26. On the morning of August 8, 2008, on the eve of the expiration of the 45-day period for filing this action under the Hatch-Waxman Act and contemporaneous with the filing of this complaint, Apotex returned a countersigned offer of confidential access accompanied by 13 pages that purport to be a part of the Apotex NDA, which, in complete form, upon information and belief, runs into the many thousands of pages. Apotex's untimely and de minimis production of a portion of its NDA complies with neither its Offer of Confidential Access nor the requirements of 21 U.S.C. § 355(j).

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

27. The allegations of the preceding paragraphs 1-26 are repeated, realleged, and incorporated herein by reference.

28. 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.

29. Upon information and belief, Apotex's Paragraph IV certification alleged that its docetaxel injection product will not infringe claims 2-5, 8-12, 18-23, 28-31, and 34-35 of the '512 patent. Upon information and belief, Apotex's Paragraph IV certification alleged that all claims of the '512 patent are invalid.

30. Under 35 U.S.C. § 271(e)(2)(A), Apotex's submission to the FDA of NDA No. 22-312 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.

31. Upon FDA approval of NDA No. 22-312, Apotex 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 Apotex's NDA shall be no earlier than the expiration date of the '512 patent.

32. Upon information and belief, Apotex'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.

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

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

35. Upon information and belief, Apotex 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.

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

37. Sanofi-aventis will be substantially and irreparably harmed by Apotex'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**

38. The allegations of the preceding paragraphs 1-37 are repeated, realleged, and incorporated herein by reference.

39. 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.

40. Upon information and belief, Apotex's Paragraph IV certification alleged that its docetaxel injection product will not infringe any claim of the '561 patent.

41. Under 35 U.S.C. § 271(e)(2)(A), Apotex's submission to the FDA of NDA No. 22-312 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.

42. Upon FDA approval of NDA No. 22-312, Apotex 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 Apotex's NDA shall be no earlier than the expiration date of the '561 patent.

43. Upon information and belief, Apotex'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.

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

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

46. Upon information and belief, Apotex 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.

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

48. Sanofi-aventis will be substantially and irreparably harmed by Apotex'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), Apotex's submission to the FDA of NDA No. 22-312 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Apotex's docetaxel injection product before the expiration of the '512 patent was an act of infringement of the '512 patent;

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

(3) declaring that, under 35 U.S.C. § 271(e)(2)(A), Apotex's submission to the FDA of NDA No. 22-312 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Apotex's docetaxel injection product before the expiration of the '561 patent was an act of infringement of the '561 patent;

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

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

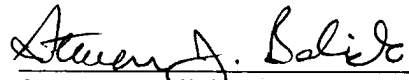
(6) ordering that the effective date of any FDA approval of Apotex's docetaxel injection product shall be no earlier than the expiration of the '561 patent, in accordance with 35 U.S.C. § 271(e)(4)(A);

(7) enjoining Apotex and all persons and entities acting in concert with Apotex from commercially manufacturing, using, offering for sale, or selling Apotex's docetaxel injection product within the United States, or importing Apotex'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 Apotex and all persons and entities acting in concert with Apotex from commercially manufacturing, using, offering for sale, or selling Apotex's docetaxel injection product within the United States, or importing Apotex'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 awarding sanofi-aventis any further and additional relief as this Court deems just and proper.

ASHBY & GEDDES



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