**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| AVENTIS PHARMA S.A., SANOFI-AVENTIS U.S., LLC | ) | |
| Plaintiffs, | ) | Civil Action No._____ |
| v. | ) | |
| SANDOZ INC. | ) | |
| Defendant. | ) | |

## COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Aventis Pharma S.A., and sanofi-aventis U.S. LLC (collectively "sanofi-aventis"), for their complaint against Defendant Sandoz Inc. (hereinafter "Sandoz") 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, Defendant Sandoz is a company organized and existing under the laws of the State of Colorado with a principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540. Upon information and belief, Sandoz is in the business of manufacturing generic pharmaceutical drugs that it distributes and sells in the United States generally, and the State of Delaware specifically.

## 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 Sandoz 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 Defendant Sandoz by virtue of the fact that, *inter alia*, it 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.

7. This Court also has personal jurisdiction over Sandoz by virtue of Sandoz's continuous and systematic contacts with Delaware. Upon information and belief, Sandoz 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. Accordingly, Sandoz has purposefully availed itself of the privilege of conducting business in the State of Delaware so as to reasonably allow jurisdiction to be exercised over it.

8. Upon information and belief, Sandoz has previously availed itself of this forum for purposes of litigating its patent disputes. For example, Sandoz has availed itself of the protections of this forum by filing a lawsuit. *See Sandoz Inc. v. Pfizer, Inc.*, C.A. No. 10-104 (D. Del.). Sandoz has also submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Specifically, Sandoz consented to jurisdiction and filed counterclaims in, *inter alia*, *Genzyme Corp. v. Sandoz Inc.*, C.A. No. 10-429 (D. Del.); *Cephalon Inc. v. Sandoz Inc.*, C.A. No. 10-123 (D. Del.); *Allergan Inc. v. Sandoz Inc.*, C.A. 10-024 (D. Del.); *Daiichi Sankyo Co., LTD. v. Sandoz Inc.,* C.A. No. 09-898 (D. Del.); *Bone Care Int'l LLC v. Sandoz Inc.,* C.A. No. 09-524 (D. Del.); *Pfizer Inc. v. Sandoz Inc.,* C.A. No. 09-310 (D. Del.); *Abbott Labs. v. Sandoz Inc.,* C.A. No. 09-215 (D. Del.); *Medicis Pharms. Corp. v. Mylan Inc. et al.,* C.A. No. 09-033 (D. Del.); *Wyeth v. Sandoz Inc.*, C.A. No. 08-317 (D. Del.); and *AstraZeneca Pharmaceuticals LP v. Sandoz Inc.*, C.A. No. 07-807 (D. Del).

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

## BACKGROUND

10. Upon information and belief, Sandoz filed with FDA in Rockville, Maryland, New Drug Application 201525 (the "Sandoz 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/2 mL, 80 mg/8 mL, and 160 mg/16 mL. Sandoz filed its NDA No. 201525 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, "sanofi-aventis' patents").

11. On behalf of Sandoz, Bernadette Attinger, as Director of Regulatory Affairs, sent a letter dated November 29, 2010, to Plaintiffs to provide notice, pursuant to 21 U.S.C. § 355(b)(2)(A) and (b)(3)(A), that Sandoz had filed NDA 201525 with respect to docetaxel injection solution in three dosage forms (20 mg/2 mL, 80 mg/8 mL, and 160 mg/16 mL). The letter further provided that Sandoz 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 not infringed and/or invalid.

## COUNT ONE: INFRINGEMENT OF UNITED STATES PATENT NO. 5,714,512

12. The allegations of the preceding paragraphs 1-11 are repeated, realleged, and incorporated herein by reference.

13. 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 hereto as Exhibit A.

14. Under 35 U.S.C. § 271(e)(2)(A), Sandoz's submission to FDA of NDA No. 201525 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.

15. Upon FDA approval of NDA No. 201525, Sandoz 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 Sandoz's NDA shall be no earlier than the expiration date of the '512 patent.

16. Upon information and belief, Sandoz'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.

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

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

19. Upon information and belief, Sandoz had prior knowledge of the '512 patent and, by its proposed 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.

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

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

**COUNT TWO: INFRINGEMENT OF UNITED STATES PATENT NO. 5,750,561**

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

23. 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.

24. Under 35 U.S.C. § 271(e)(2)(A), Sandoz's submission to the FDA of NDA No. 201525 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. 201525, Sandoz 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 Sandoz's NDA shall be no earlier than the expiration date of the '561 patent.

26. Upon information and belief, Sandoz'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 Sandoz's docetaxel injection product constitutes a material part of at least one of the claims of the '561 patent; Sandoz 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 Sandoz'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 Sandoz's docetaxel product would contributorily infringe at least one of the claims of the '561 patent.

29. Upon information and belief, Sandoz had prior knowledge of the '561 patent and, by its proposed 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 Sandoz's docetaxel injection product would actively induce infringement of at least one of the claims of the '561 patent.

31. Sanofi-aventis will be substantially and irreparably harmed by Sandoz'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), Sandoz's submission to the FDA of NDA No. 201525 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Sandoz's docetaxel injection product before the expiration of the '512 patent was an act of infringement of the '512 patent;

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

(3) declaring that, under 35 U.S.C. § 271(e)(2)(A), Sandoz's submission to the FDA of NDA No. 201525 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Sandoz's docetaxel injection product before the expiration of the '561 patent was an act of infringement of the '561 patent;

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

(5) ordering that the effective date of any FDA approval of Sandoz'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 Sandoz'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 Sandoz and all persons and entities acting in concert with Sandoz from commercially manufacturing, using, offering for sale, or selling Sandoz's docetaxel injection product within the United States, or importing Sandoz'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 Sandoz and all persons and entities acting in concert with Sandoz from commercially manufacturing, using, offering for sale, or selling Sandoz's docetaxel injection product within the United States, or importing Sandoz'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);

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

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

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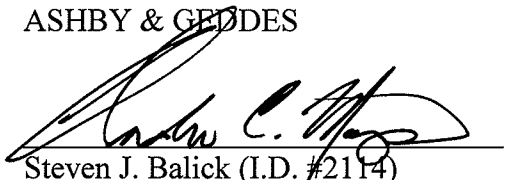

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