IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
FRESENIUS KABI USA, LLC	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi-Aventis U.S. LLC (hereinafter "Sanofi U.S."), Aventis Pharma S.A. (hereinafter "Aventis") and Sanofi (collectively, "Plaintiffs") for their Complaint against defendant Fresenius Kabi USA, LLC (hereinafter "Fresenius" or "Defendant"), hereby allege as follows:

THE PARTIES

1. 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.

2. Plaintiff Aventis is a corporation organized and existing under the laws of France, having its principal place of business at 20 avenue Raymond Aron, 92160 Antony, France.

3. 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.

4. Plaintiff Sanofi is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health.

5. On information and belief, Fresenius is a corporation organized and existing under the laws of Delaware, having its corporate headquarters at Three Corporate Drive, Lake Zurich, Illinois 60047.

6. On information and belief, Fresenius assembled and caused to be filed with the United States Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. § 355(b)(2) (Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act), New Drug Application ("NDA") No. 207937 (hereinafter "the Fresenius 505(b)(2) application") concerning a proposed drug product, Cabazitaxel Injection, 60 mg/3 mL solution (20 mg/mL) ("Fresenius's Proposed Generic Product").

JURISDICTION AND VENUE

7. 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(a).

8. This Court has personal jurisdiction over Fresenius. On information and belief, Fresenius is a corporation organized and existing under the laws of the State of Delaware and Fresenius has a registered agent for service of process in Delaware.

9. On information and belief, Fresenius is in the business of, *inter alia*, marketing a portfolio of "pharmaceuticals and medical devices" including "intravenous specialty and generic medicines" and "infusion therapies." *Acetylcysteine Solution, USP 20% in 4 mL*

vials Now Available, FRESENIUS KABI, http://www.fresenius-kabi.us/news-and-media/news-releases/196-acetylcysteine-solution-usp-20-in-4-ml-vials-now-available.html (last visited December 9, 2014).

10. On information and belief, Fresenius expanded its presence in the United States in 2008 with the acquisition of APP Pharmaceuticals, which merged with Fresenius. On information and belief, Fresenius "bec[ame] a globally leading supplier in the field of intravenously administered generic drugs via the acquisition of the U.S. based APP Pharmaceuticals." *History*, FRESENIUS KABI, http://www.fresenius-kabi.us/company/history.html (last visited December 9, 2014). On information and belief, APP Pharmaceuticals was in the business of developing, manufacturing and/or marketing generic pharmaceutical products. On information and belief, APP Pharmaceuticals, LLC maintained a corporate agent at 830 Bear Tavern Road, West Trenton, New Jersey 08628. On information and belief, in 2012 APP Pharmaceuticals, LLC changed its name to Fresenius Kabi USA, LLC.

11. On information and belief, Fresenius expanded its presence in the United States in 2012 with the acquisition of Fenwal Inc. On information and belief, Fenwal Inc. was organized under the laws of the State of Delaware.

12. On information and belief, Fresenius directly or through its affiliates and agents develops, formulates, manufactures, markets, imports and sells pharmaceutical products, including generic drug products, which are copies of products invented and developed by innovator pharmaceutical companies, throughout the United States, including in this Judicial District. On information and belief, Fresenius holds an active pharmacy wholesale license for the State of Delaware under License No. A4-0000901 and an active distributor/manufacturer license for controlled substances for the State of Delaware under License No. DM- 0006436.

13. On information and belief, Fresenius has affiliations with the State of Delaware that are pervasive, continuous, and systematic. On information and belief, Fresenius regularly does or solicits business in the State of Delaware, engages in other persistent courses of conduct in the State of Delaware, and/or derives substantial revenue from services or things used or consumed in the State of Delaware.

14. On information and belief, Fresenius has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, having asserted claims in this jurisdiction, including in the matters of *Fresenius Kabi USA, LLC v. Agila Specialties Pvt. Ltd. et al.*, C. A. No. 1:14-cv-01438-RGA (D. Del. November 26, 2014), *Fresenius Kabi USA, LLC v. Emcure Pharmaceuticals USA, Inc.*, C. A. No. 1:14-cv-01141-RGA (D. Del. September 8, 2014), *Fresenius Kabi USA, LLC v. Watson Laboratories, Inc. et al.*, C. A. No. 1:14-cv-00161-RGA (D. Del. February 6, 2014), *Fresenius Kabi USA, LLC v. Watson Laboratories, Inc. et al.*, C. A. No. 1:13-cv-01015-RGA (D. Del. June 6, 2013), and *Fresenius Kabi USA, LLC v. Dr. Reddy's Laboratories, Ltd. et al.*, C. A. No. 1:13-cv-00925-RGA (D. Del. May 23, 2013). On information and belief, Fresenius has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, having asserted counterclaims in this jurisdiction, including in the matters of *Cubist Pharmaceuticals, Inc. v. Fresenius Kabi USA, LLC*, C.A. No. 1:14-cv-00914-GMS, D.I. 7, at 4, 23-31 (D. Del. August 1, 2014), *Allos Therapeutics, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, C.A. No. 1:14-cv-00778-RGA, D.I. 16, at 5-6, 24-32 (D. Del. July 24, 2014), *Celgene Corp. et al. v. Fresenius Kabi USA, LLC*, C.A. No. 1:14-cv-00571-RGA, D.I. 9, at 2, 8-14 (D. Del. May 9, 2014), and *Pfizer Inc. et al. v. Fresenius Kabi USA, LLC*, C.A. No. 1:13-cv-01893-SLR-SRF, D.I. 7, at 2-3, 11-19 (D. Del. December 5, 2013).

15. Fresenius is also subject to personal jurisdiction in Delaware because, *inter alia*, Fresenius has committed, aided, abetted, contributed to, and/or participated in the commission of a 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. Fresenius states that it intends to engage in the commercial manufacture, use, and/or sale of proposed drug product, Cabazitaxel Injection, 60 mg/3 mL solution (20 mg/mL) ("Fresenius's Proposed Generic Product") before the expiration of U.S Patent Nos. 5,847,179 ("'170 patent") and 7,241,907 ("'907 patent") throughout the United States, including in this Judicial District.

16. On information and belief, upon approval of the Fresenius 505(b)(2) application, Fresenius and/or their affiliates or agents will market, sell and/or distribute Fresenius's Proposed Generic Product throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

17. On information and belief, upon approval of the Fresenius 505(b)(2) application, Fresenius and/or their affiliates or agents will place Fresenius'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. Venue is proper in this Court at least pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

19. Sanofi U.S. holds approved New Drug Application ("NDA") No. 201023 for cabazitaxel injection, 60 mg/ 1.5 mL (40 mg/mL), which is prescribed and sold in the United States under the trademark JEVTANA® KIT (hereinafter "JEVTANA®"). The U.S. Food and

Drug Administration ("FDA") approved NDA No. 201023 on June 17, 2010. JEVTANA® is approved for use in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

20. United States Patent No. 5,847,170 (the "'170 patent," copy attached as Exhibit A) is entitled "Taxoids, Their Preparation And Pharmaceutical Compositions Containing Them" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on December 8, 1998. The '170 patent claims, *inter alia*, cabazitaxel and pharmaceutical compositions containing cabazitaxel. The '170 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for JEVTANA® (NDA No. 201023).

21. The '170 patent is owned by Aventis.

22. United States Patent No. 7,241,907 (the "'907 patent," copy attached as Exhibit B) is entitled "Acetone Solvate of Dimethoxy Docetaxel and its Process of Preparation" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on July 10, 2007. The '907 patent claims, *inter alia*, an acetone solvate of cabazitaxel. The '907 patent is listed in the FDA's Orange Book for JEVTANA® (NDA No. 201023).

23. The '907 patent is owned by Aventis.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

24. On information and belief, Fresenius submitted the Fresenius 505(b)(2) application to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Fresenius's Proposed Generic Product.

25. On information and belief, the Fresenius 505(b)(2) application seeks FDA approval of Fresenius's Proposed Generic Product for use in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

26. On information and belief, Fresenius actively participated in and/or directed activities related to the submission of the Fresenius 505(b)(2) application and the development of Fresenius's Proposed Generic Product, was actively involved in preparing the NDA, and/or intends to directly benefit from and has a financial stake in the approval of the NDA. On information and belief, upon approval of the Fresenius 505(b)(2) application, Fresenius will be involved in the manufacture, distribution, and/or marketing of Fresenius's Proposed Generic Product.

27. By letter dated November 3, 2014 (the "November 3 Letter"), and pursuant to 21 U.S.C. §355(b)(3)(B) and 21 C.F.R. §314.52(c), Fresenius notified Plaintiffs that it had submitted to the FDA the Fresenius 505(b)(2) application, seeking approval to engage in the commercial manufacture, use, or sale of Fresenius's Proposed Generic Product before the expiration of the '170 patent and the '907 patent. The November 3 Letter was received by Plaintiffs on November 4, 2014.

28. In its November 3 Letter, Fresenius notified Plaintiffs, as part of the Fresenius 505(b)(2) application, it had filed a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) and 21 C.F.R. §314.52(c)(5) (a "Paragraph IV Certification") with respect to the '170 patent and the '907 patent. On information and belief, Fresenius certified that, the '170 patent and the '907 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Fresenius's Proposed Generic Product.

29. The Fresenius 505(b)(2) application refers to and relies upon the Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 5,847,170

30. Plaintiffs repeat and reallege paragraphs 1 through 29 above as if fully set forth herein.

31. By submitting the Fresenius 505(b)(2) application under 21 U.S.C. § 355(b)(2) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Fresenius's Proposed Generic Product throughout the United States prior to the expiration of the '170 patent, Fresenius committed an act of infringement of the '170 patent under 35 U.S.C. § 271(e)(2). On information and belief, Fresenius was aware of the '170 patent at the time the Fresenius 505(b)(2) application was submitted.

32. If Fresenius commercially makes, uses, offers to sell, or sells Fresenius's Proposed Generic Product within the United States, or imports Fresenius's Proposed Generic Product into the United States, or induces or contributes to any such conduct during the term of the '170 patent, it would further infringe the '170 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

33. Plaintiffs will be irreparably harmed if Fresenius is not enjoined from infringing the '170 patent. Plaintiffs do not have an adequate remedy at law.

34. Fresenius's certification under 21 U.S.C. § 355(b)(2)(A)(iv) against the '170 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 7,241,907

35. Plaintiffs repeat and reallege paragraphs 1 through 34 above as if fully set forth herein.

36. By submitting the Fresenius 505(b)(2) application under 21 U.S.C. § 355(b)(2) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Fresenius's Proposed Generic Product throughout the United States prior to the expiration of the '907 patent, Fresenius committed an act of infringement of the '907 patent under 35 U.S.C. § 271(e)(2). On information and belief, Fresenius was aware of the '907 patent at the time the Fresenius 505(b)(2) application was submitted.

37. If Fresenius commercially makes, uses, offers to sell, or sells Fresenius's Proposed Generic Product within the United States, or imports Fresenius's Proposed Generic Product into the United States, or induces or contributes to any such conduct during the term of the '907 patent, it would further infringe the '907 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

38. Plaintiffs will be irreparably harmed if Fresenius is not enjoined from infringing the '907 patent. Plaintiffs do not have an adequate remedy at law.

39. Fresenius's certification under 21 U.S.C. § 355(b)(2)(A)(iv) against the '907 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Fresenius Kabi USA, LLC has infringed one or more claims of the '170 patent by filing NDA No. 207937 relating to Fresenius's Proposed Generic Product before the expiration of the '170 patent;

B. A judgment that the manufacture, use, offer for sale, sale and/or importation of Fresenius's Proposed Generic Product will infringe the '170 patent;

C. A judgment declaring that the '170 patent remains valid and enforceable;

D. A permanent injunction restraining and enjoining Fresenius Kabi USA, LLC, and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Fresenius's Proposed Generic Product until the expiration of the '170 patent or any later date of exclusivity to which Plaintiffs and/or the '170 patent are or become entitled to;

E. An order that the effective date of any approval of Fresenius's NDA No. 207937 relating to Fresenius's Proposed Generic Product under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(b)(2)) shall be a date that is not earlier than the expiration date of the '170 patent or any later date of exclusivity to which Plaintiffs and/or the '170 patent are or become entitled;

F. A judgment that Fresenius Kabi USA, LLC has infringed one or more claims of the '907 patent by filing NDA No. 207937 relating to Fresenius's Proposed Generic Product before the expiration of the '907 patent;

G. A judgment that the manufacture, use, offer for sale, sale and/or importation of Fresenius's Proposed Generic Product will infringe the '907 patent;

H. A judgment declaring that the '907 patent remains valid and enforceable;

I. A permanent injunction restraining and enjoining Fresenius Kabi USA, LLC, and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the

United States, or importation into the United States, of Fresenius's Proposed Generic Product until the expiration of the '907 patent or any later date of exclusivity to which Plaintiffs and/or the '907 patent are or become entitled to;

J. An order that the effective date of any approval of Fresenius's NDA No. 207937 relating to Fresenius's Proposed Generic Product under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(b)(2)) shall be a date that is not earlier than the expiration date of the '907 patent or any later date of exclusivity to which Plaintiffs and/or the '907 patent are or become entitled;

K. A declaration that this case is "exceptional" within the meaning of 35 U.S.C. § 285 and an award of reasonable attorney fees, costs, expenses, and disbursements of this action; and

L. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

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