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Attorneys for Plaintiffs,
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI

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

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

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 an indirectly 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.

FRESENIUS ANDA

6. On information and belief, Fresenius assembled and caused to be filed with the United States Food and Drug Administration ("FDA"), Abbreviated New Drug Application ("ANDA") No. 207591 pursuant to 21 U.S.C. § 355(j) (§ 505(j) of the Federal Food, Drug and Cosmetic Act) (hereinafter "the Fresenius ANDA") concerning a proposed drug product, Cabazitaxel Injection, 60 mg/1.5 mL solution (hereinafter "Fresenius's Proposed ANDA Product").

FRESENIUS B2 NDA

7. On information and belief, Fresenius assembled and caused to be filed with the FDA, New Drug Application ("NDA") No. 207937 pursuant to 21 U.S.C. § 355(b)(2) (§ 505(b)(2) of the Federal Food, Drug and Cosmetic Act) (hereinafter "the Fresenius B2 NDA") concerning a proposed drug product, Cabazitaxel Injection, 60mg/3 mL solution (20mg/mL) (hereinafter "Fresenius's Proposed B2 Product").

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Fresenius. On information and belief, Fresenius has an active business entity status registered with the New Jersey Department of Treasury under the business entity identification number 0600313148. On information and belief, Fresenius maintains a corporate agent for service of process at 830 Bear Tavern Road, West Trenton, New Jersey 08628.

10. 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 April 7, 2015).

11. 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 April 7, 2015). 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.

12. 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. has an active business entity status registered with the New Jersey Department of Treasury. On information and belief, Fenwal Inc. maintains a corporate agent for service of process at 830 Bear Tavern Road, West Trenton, New Jersey 08628.

13. 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 wholesale drug and medical device license for the State of New Jersey under License No. 5003710.

14. On information and belief, Fresenius has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, Fresenius engages in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the

State of New Jersey and to the residents of the State of New Jersey, and maintenance of corporate agents in the State of New Jersey.

15. On information and belief, Fresenius regularly conducts business in the State of New Jersey, engages in other persistent courses of conduct in the State of New Jersey, and/or derives substantial revenue from services or things used or consumed in the State of New Jersey. On information and belief, Fresenius entered into an agreement with InnoPharma to sell, market and distribute InnoPharma's ANDA approved acetylcysteine injection in the United States, including in this Judicial District. On information and belief, InnoPharma has a principal place of business in the State of New Jersey. InnoPharma 1-8-13 press release *available at* http://innopharmainc.com/wp-content/uploads/2014/03/Press-release-ACTY-inj-FINAL-010813.pdf (last visited April 7, 2015).

16. On information and belief, Fresenius entered into a supply agreement with Akorn, Inc. for Fresenius's novel premix intravenous drug products. On information and belief, Akorn, Inc. manufactures and markets sterile specialty pharmaceuticals. On information and belief, Akorn has manufacturing facilities in New Jersey. Akorn, Inc. press release 4-3-2008 *available at* http://www.biospace.com/News/akorn-inc-signs-supply-agreement-with-fresenius/91536 (last visited April 7, 2015).

17. On information and belief, Fresenius regularly solicits business in the State of New Jersey. On information and belief, Fresenius attended Contract Pharma's Tabletop Exhibition on 23 September 2010 in New Brunswick, New Jersey. Pharmaceutical-technology.com press release *available at* http://www.pharmaceutical-technology.com/contractors/contract/fresenius/press4.html (last visited April 7, 2015).

18. 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 New Jersey, having asserted claims in this jurisdiction, including in the matter of *Fresenius Kabi USA, LLC v. Emcure Pharmaceuticals USA, Inc. et al.*, Civil Action No. 1:14-cv-05584-nlh-js (D.N.J. Sep 8, 2014). 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 New Jersey, having asserted counterclaims in this jurisdiction, including in the matters of *Merck Sharp & Dohme Corp. v. Fresenius Kabi USA, LLC.*, Civil Action No. 2:14-cv-04989 (SRC)(CLW), D.I. 5, at 2-3, 7-13 (D.N.J. Aug. 12 2014); *Merck Sharp & Dohme Corp. v. Fresenius Kabi USA, LLC.*, Civil Action No. 3:14-cv-03917 (PGS)(LHG), D.I. 12, at 4-5, 45-56 (D.N.J. Aug. 4, 2014); *Novartis Pharmaceuticals Corporation v. Fresenius Kabi USA, LLC*, Civil Action No. 2:13-cv-07914 (SDW)(MCA), D.I. 10, at 3, 7-11 (D.N.J. Feb. 13, 2014); *Novartis Pharmaceuticals Corp. et al. v. Wockhardt USA LLC et al.*, Civil Action No: 2:12-cv-03967 (SDW)(SCM), D. I. 125, at 3-4, 7-9 (D.N.J. Jun. 19, 2013); and *Sanofi-Aventis U.S. LLC et al. v. Fresenius Kabi USA, LLC*, Civil Action No. 3:14-cv-08082 (MAS)(LHG), D.I. 11, at 3, 11-14 (D.N.J. Mar. 17, 2015).

19. Fresenius is also subject to personal jurisdiction in the State of New Jersey 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., having commercial headquarters in the State of New Jersey. By letter dated April 2, 2015 ("April 2 ANDA Notice Letter"), Fresenius notified Plaintiffs that it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("ANDA Paragraph IV Certification") with respect to U.S. Patent No. 8,927,592 ("'592 patent"). By letter dated April 2, 2015 ("April 2 B2 Notice Letter"),

Fresenius notified Plaintiffs that it had filed a certification pursuant to 21 U.S.C. §355(b)(2)(A)(iv) ("B2 Paragraph IV Certification") with respect to the '592 patent. Fresenius sent its April 2 ANDA Notice Letter and its April 2 B2 Notice Letter to Sanofi U.S.'s commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807. Plaintiffs' cause of action arose from Fresenius's contacts with Sanofi U.S. in Bridgewater, New Jersey. In its April 2 ANDA Notice Letter, Fresenius states that it intends to engage in the manufacture, use, and/or sale of Fresenius's Proposed ANDA Product before the expiration of the '592 patent throughout the United States, including in this Judicial District. In its April 2 B2 Notice Letter, Fresenius states that it intends to engage in the manufacture, use, and/or sale of Fresenius's Proposed B2 Product before the expiration of the '592 patent throughout the United States, including in this Judicial District.

20. On information and belief, upon approval of the Fresenius ANDA, Fresenius and/or its affiliates or agents will market, sell and/or distribute Fresenius's Proposed ANDA Product throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

21. On information and belief, upon approval of the Fresnenius ANDA, Fresenius and/or its affiliates or agents will place Fresenius's Proposed ANDA Product into the stream of commerce with the reasonable expectation or knowledge and intent that such product will ultimately be purchased and used by consumers in this Judicial District.

22. On information and belief, upon approval of the Fresenius B2 NDA, Fresenius and/or its affiliates or agents will market, sell and/or distribute Fresenius's Proposed B2 Product throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

23. On information and belief, upon approval of the Fresenius B2 NDA, Fresenius and/or its affiliates or agents will place Fresenius's Proposed B2 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.

24. Venue is proper in this Court at least pursuant to 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b).

JEVTANA®

25. Sanofi U.S. holds approved 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 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.

THE PATENT-IN-SUIT

26. The '592 patent (copy attached as Exhibit A) is entitled "Antitumoral Use Of Cabazitaxel" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on January 6, 2015. The '592 patent claims, *inter alia*, methods for treating or increasing the survival of patients with prostate cancer, including the use of JEVTANA® in accordance with the labeling approved by the FDA. The '592 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for JEVTANA® (NDA No. 201023).

27. The '592 patent is owned by Aventis.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT BY FRESENIUS ANDA

28. On information and belief, Fresenius submitted the Fresenius ANDA to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Fresenius's Proposed ANDA Product.

29. On information and belief, the Fresenius ANDA seeks FDA approval of Fresenius's Proposed ANDA 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.

30. On information and belief, Fresenius actively participated in and/or directed activities related to the submission of the Fresenius ANDA and the development of Fresenius's Proposed ANDA Product, was actively involved in preparing the Fresenius ANDA, and/or intends to directly benefit from and has a financial stake in the approval of the Fresenius ANDA. On information and belief, upon approval of the Fresenius ANDA, Fresenius will be involved in the manufacture, distribution, and/or marketing of Fresenius's Proposed ANDA Product.

31. In its April 2 ANDA Notice Letter, Fresenius notified Plaintiffs that it had submitted to the FDA the Fresenius ANDA, seeking approval to engage in the commercial manufacture, use, or sale of Fresenius's Proposed ANDA Product before the expiration of the '592 patent, and that it had filed an ANDA Paragraph IV Certification with respect to the '592 patent. The April 2 ANDA Notice Letter was received by Sanofi U.S. on April 3, 2015.

32. On information and belief, in its April 2 ANDA Notice Letter, Fresenius certified that the '592 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Fresenius's Proposed ANDA Product.

33. The Fresenius ANDA refers to and relies upon Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT BY FRESENIUS B2 NDA

34. On information and belief, Fresenius submitted the Fresenius B2 NDA to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Fresenius's Proposed B2 Product.

35. On information and belief, the Fresenius B2 NDA seeks FDA approval of Fresenius's Proposed B2 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.

36. On information and belief, Fresenius actively participated in and/or directed activities related to the submission of the Fresenius B2 NDA and the development of Fresenius's Proposed B2 Product, was actively involved in preparing the Fresenius B2 NDA, and/or intends to directly benefit from and has a financial stake in the approval of the Fresenius B2 NDA. On information and belief, upon approval of the Fresenius B2 NDA, Fresenius will be involved in the manufacture, distribution, and/or marketing of Fresenius's Proposed B2 Product.

37. In its April 2 B2 Notice Letter, Fresenius notified Plaintiffs that it had submitted to the FDA the Fresenius B2 NDA, seeking approval to engage in the commercial manufacture, use, or sale of Fresenius's Proposed B2 Product before the expiration of the '592 patent and that it had filed a B2 Paragraph IV Certification with respect to the '592 patent. The April 2 B2 Notice Letter was received by Sanofi U.S. on April 3, 2015.

38. On information and belief, in its April 2 B2 Notice Letter, Fresenius certified that the '592 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Fresenius's Proposed B2 Product.

39. The Fresenius B2 NDA refers to and relies upon Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 8,927,592 BY FRESENIUS ANDA

40. Plaintiffs repeat and reallege paragraphs 1 through 39 above as if fully set forth herein.

41. By submitting the Fresenius ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Fresenius's Proposed ANDA Product throughout the United States prior to the expiration of the '592 patent, Fresenius committed an act of infringement of the '592 patent under 35 U.S.C. § 271(e)(2). On information and belief, Fresenius was aware of the '592 patent at the time the Fresenius ANDA was submitted.

42. If Fresenius commercially makes, uses, offers to sell, or sells Fresenius's Proposed ANDA Product within the United States, or imports Fresenius's Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '592 patent, it would further infringe the '592 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

43. Plaintiffs will be irreparably harmed if Fresenius is not enjoined from infringing the '592 patent. Plaintiffs do not have an adequate remedy at law.

44. Fresenius's certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '592 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 8,927,592 BY FRESENIUS B2 NDA

45. Plaintiffs repeat and reallege paragraphs 1 through 44 above as if fully set forth herein.

46. By submitting the Fresenius B2 NDA 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 B2 Product throughout the United States prior to the expiration of the '592 patent, Fresenius committed an act of infringement of the '592 patent under 35 U.S.C. § 271(e)(2). On information and belief, Fresenius was aware of the '592 patent at the time the Fresenius B2 NDA was submitted.

47. If Fresenius commercially makes, uses, offers to sell, or sells Fresenius's Proposed B2 Product within the United States, or imports Fresenius's Proposed B2 Product into the United States, or induces or contributes to any such conduct during the term of the '592 patent, it would further infringe the '592 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

48. Plaintiffs will be irreparably harmed if Fresenius is not enjoined from infringing the '592 patent. Plaintiffs do not have an adequate remedy at law.

49. Fresenius's certification under 21 U.S.C. § 355(b)(2)(A)(iv) against the '592 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 ’592 patent by filing ANDA No. 207591 relating to Fresenius’s Proposed ANDA Product before the expiration of the ’592 patent;

B. A judgment that Fresenius Kabi USA, LLC has infringed one or more claims of the ’592 patent by filing NDA No. 207937 relating to Fresenius’s Proposed B2 Product before the expiration of the ’592 patent;

C. A judgment that the manufacture, use, offer for sale, sale and/or importation of Fresenius’s Proposed ANDA Product and/or Fresenius’s Proposed B2 Product will infringe the ’592 patent;

D. A judgment declaring that the ’592 patent remains valid and enforceable;

E. 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 ANDA Product and/or Fresenius’s Proposed B2 Product until the expiration of the ’592 patent or any later date of exclusivity to which Plaintiffs and/or the ’592 patent are or become entitled to;

F. An order that the effective date of any approval of Fresenius’s ANDA No. 207591 relating to Fresenius’s Proposed ANDA Product under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of the ’592 patent or any later date of exclusivity to which Plaintiffs and/or the ’592 patent are or become entitled;

G. An order that the effective date of any approval of Fresenius’s NDA No. 207937 relating to Fresenius’s Proposed B2 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 '592 patent or any later date of exclusivity to which Plaintiffs and/or the '592 patent are or become entitled;

H. 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

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

April 13, 2015

Respectfully submitted,

By: *s/Liza M. Walsh*

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RULE 11.2 CERTIFICATION

I, Liza M. Walsh, admitted to the bars of the State of New Jersey and this Court, and a Partner in the law firm of Connell Foley LLP representing Plaintiffs Sanofi-Aventis U.S. LLC, Aventis Pharma S.A. and Sanofi in the above-captioned matter, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy in this action is related to the following actions:

- Pending before the District Court for the District of New Jersey: *Sanofi-Aventis U.S. LLC et al. v. Fresenius Kabi USA, LLC*, C. A. No. 14-7869 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. Accord Healthcare, Inc.*, C. A. No. 14-8079 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. BPI Labs, LLC et al.*, C. A. No. 14-8081 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. Fresenius Kabi USA, LLC*, C. A. No. 14-8082 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. Apotex Corp. et al.*, C. A. No. 15-0287 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. Breckenridge Pharmaceutical, Inc.*, C. A. No. 15-0289 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. Onco Therapies Limited*, C. A. No. 15-0290 (MAS)(LHG); and *Sanofi-Aventis U.S. LLC et al. v. Actavis LLC et al.*, C. A. No. 15-0776 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. Apotex Corp. et al.*, C. A. No. 15-1835 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. Breckenridge Pharmaceutical, Inc.*, C. A. No. 15-1836 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. Accord Healthcare, Inc.*, C. A. No. 15-02520 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. Dr. Reddy Laboratories, Inc. et al.*, C. A. No. 15-02522 (MAS)(LHG); *Sanofi-Aventis U.S. LLC et al. v. Glenmark Generics Inc. et al.*, C. A. No. 15-02523 (MAS)(LHG); and *Sanofi-Aventis U.S. LLC et al. v. BPI Labs, LLC et al.*, C. A. No. 15-02521 (MAS)(LHG).

I certify under penalty of perjury that the foregoing is true and correct.

April 13, 2015

CONNELL FOLEY LLP

By: *s/Liza M. Walsh*

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RULE 201.1 CERTIFICATION

We hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the plaintiffs seek, *inter alia*, injunctive relief.

April 13, 2015

CONNELL FOLEY LLP

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