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

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SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A., and SANOFI Plaintiffs, v. SANDOZ INC. 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 Sandoz Inc. (hereinafter "Sandoz" 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, Sandoz is a corporation organized and existing under the laws of Colorado, having its corporate headquarters at 100 College Road West, Princeton, New Jersey 08540.

6. On information and belief, Sandoz 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. 208715 (hereinafter "the Sandoz 505(b)(2) application") concerning a proposed drug product, Cabazitaxel Injection (10 mg/mL), 45 mg/4.5 mL and 60 mg/6 mL ("Sandoz's Proposed Generic Product").

JURISDICTION AND VENUE

7. 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).

8. This Court has personal jurisdiction over Sandoz. On information and belief, Sandoz maintains its corporate headquarters and principal place of business within this Judicial District at 100 College Road West, Princeton, New Jersey 08540. On information and belief, Sandoz has an active business entity status registered with the New Jersey Department of Treasury under the business entity identification number 0100097265. On information and belief, Sandoz maintains a corporate agent for service of process at 830 Bear Tavern Road, West Trenton, New Jersey 08628.

9. On information and belief, Sandoz is a "global leader in the generic pharmaceutical sector" and "holds the #1 position globally in . . . generic injectables, opthalmics, dermatology, and antibiotics." *Sandoz Introduces Authorized Generic Version of LESCOL® XL in the US* (Oct. 19, 2015), https://www.sandoz.com/news/media-releases/sandoz-introduces-authorized-generic-version-lescolr-xl-us.

10. On information and belief, Sandoz 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, Sandoz holds an active wholesale drug and medical device license for the State of New Jersey under License No. 5003732.

11. On information and belief, Sandoz has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, Sandoz 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 maintains corporate agents in the State of New Jersey.

12. On information and belief, Sandoz 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 *AMAG Pharmaceuticals, Inc. v. Sandoz Inc.*, Civil Action No. 3:16-cv-01508(PGS)(LHG) (D.N.J. May 10, 2016) (D.I. 18); *Boehringer Ingelheim Pharma GmbH & Co. KG v. Sandoz Inc.*, Civil Action No. 1:15-cv-7461(NLH)(KMW) (D.N.J. Dec. 15, 2015) (D.I. 10); *Otsuka Pharmaceutical Co., Ltd. v. Sandoz Inc.*, Civil Action No. 1:15-cv-01716(JBS)(KMW) (D.N.J. April 13, 2015) (D.I. 54); *AstraZeneca Pharmaceuticals LP v. Sandoz Inc.*, Civil Action No. 14-cv-03547(RMB)(KMW) (D.N.J. July 29, 2014) (D.I. 21); *Janssen Pharmaceuticals, Inc. v. Sandoz Inc.*, Civil Action No. 2:13-cv-06929(CCC)(MF) (D.N.J. Dec. 26, 2013) (D.I. 16); and *Cornerstone Therapeutics Inc. v. Sandoz Inc.*, Civil Action No. 1:13-cv-05723(NLH)(AMD) (D.N.J. Nov. 6, 2013) (D.I. 13).

13. Sandoz is also subject to personal jurisdiction in the State of New Jersey because, *inter alia*, Sandoz 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. Sandoz sent its August 4, 2016 Paragraph IV Notice Letter to Sanofi U.S.'s commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807. Plaintiffs' cause of action arose from Sandoz's contact with Sanofi U.S. in Bridgewater, New Jersey. Sandoz states that it intends to engage in the commercial manufacture, use, and/or

sale of Sandoz's Proposed Generic Product before the expiration of U.S Patent Nos. 5,847,170 ("'170 patent") and 8,927,592 ("'592 patent") throughout the United States, including in this Judicial District.

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

15. On information and belief, upon approval of the Sandoz 505(b)(2) application, Sandoz and/or their affiliates or agents will place Sandoz'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.

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

THE PATENTS-IN-SUIT

17. 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 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.

18. 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).

19. The '170 patent is owned by Aventis.

20. The '592 patent, (copy attached as Exhibit B) 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).

21. The '592 patent is owned by Aventis.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

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

23. On information and belief, the Sandoz 505(b)(2) application seeks FDA approval of Sandoz'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.

24. On information and belief, Sandoz actively participated in and/or directed activities related to the submission of the Sandoz 505(b)(2) application and the development of Sandoz'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 Sandoz's 505(b)(2) application, Sandoz will be involved in the manufacture, distribution, and/or marketing of Sandoz's Proposed Generic Product.

25. By letter dated August 4, 2016 (the "August 4 Letter"), and pursuant to 21 U.S.C. § 355(b)(3)(B) and 21 C.F.R. § 314.52(c), Sandoz notified Plaintiffs that it had submitted to the FDA the Sandoz 505(b)(2) application, seeking approval to engage in the commercial manufacture, use, or sale of Sandoz's Proposed Generic Product before the expiration of the '170 patent and the '592 patent. The August 4 Letter was received by Plaintiffs on August 8, 2016.

26. In its August 4 Letter, Sandoz notified Plaintiffs, as part of the Sandoz 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 '592 patent. On information and belief, Sandoz certified that the '170 patent and the '592 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Sandoz's Proposed Generic Product.

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

COUNT I

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

28. Plaintiffs repeat and reallege paragraphs 1 through 27 above as if fully set forth herein.

29. By submitting the Sandoz 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 Sandoz's Proposed Generic Product throughout the United States prior to the expiration

of the ’170 patent, Sandoz committed an act of infringement of the ’170 patent under 35 U.S.C. § 271(e)(2). On information and belief, Sandoz was aware of the ’170 patent at the time the Sandoz 505(b)(2) application was submitted.

30. If Sandoz commercially makes, uses, offers to sell, or sells Sandoz’s Proposed Generic Product within the United States, or imports Sandoz’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).

31. Plaintiffs will be irreparably harmed if Sandoz is not enjoined from infringing the ’170 patent. Plaintiffs do not have an adequate remedy at law.

32. Sandoz’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. 8,927,592

33. Plaintiffs repeat and reallege paragraphs 1 through 32 above as if fully set forth herein.

34. By submitting the Sandoz 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 Sandoz’s Proposed Generic Product throughout the United States prior to the expiration of the ’592 patent, Sandoz committed an act of infringement of the ’592 patent under 35 U.S.C. § 271(e)(2). On information and belief, Sandoz was aware of the ’592 patent at the time the Sandoz 505(b)(2) application was submitted.

35. If Sandoz commercially makes, uses, offers to sell, or sells Sandoz’s Proposed Generic Product within the United States, or imports Sandoz’s Proposed Generic 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).

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

37. Sandoz'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 Sandoz Inc. has infringed one or more claims of the '170 patent by filing NDA No. 208715 relating to Sandoz'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 Sandoz'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 Sandoz Inc., 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 Sandoz'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 Sandoz's NDA No. 208715 relating to Sandoz'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 Sandoz Inc. has infringed one or more claims of the '592 patent by filing NDA No. 208715 relating to Sandoz's Proposed Generic Product before the expiration of the '592 patent;

G. A judgment that the manufacture, use, offer for sale, sale, and/or importation of Sandoz's Proposed Generic Product will infringe the '592 patent;

H. A judgment declaring that the '592 patent remains valid and enforceable;

I. A permanent injunction restraining and enjoining Sandoz Inc., 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 Sandoz's Proposed Generic 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;

J. An order that the effective date of any approval of Sandoz's NDA No. 208715 relating to Sandoz'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 '592 patent or any later date of exclusivity to which Plaintiffs and/or the '592 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.

Respectfully submitted,

September 16, 2016

By: *s/Liza M. Walsh*
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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

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

September 16, 2016

Respectfully submitted,

By: *s/Liza M. Walsh*
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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

I, Liza M. Walsh, admitted to the bars of the State of New Jersey and this Court, and Partner in the law firm of Walsh Pizzi O'Reilly Falanga 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 is not the subject of any other action pending in any other court or of any pending arbitration or administrative proceeding, but is related to the following actions:

1. Sanofi-Aventis U.S. LLC et al. v. Fresenius Kabi USA, LLC, C. A. No. 14-7869 (MAS)(LHG);

2. *Sanofi-Aventis U.S. LLC et al. v. Accord Healthcare, Inc.*, C. A. No. 14-8079 (MAS)(LHG);

3. *Sanofi-Aventis U.S. LLC et al. v. BPI Labs, LLC et al.*, C. A. No. 14-8081 (MAS)(LHG);

4. *Sanofi-Aventis U.S. LLC et al. v. Fresenius Kabi USA, LLC,* C. A. No. 14-8082 (MAS)(LHG);

5. *Sanofi-Aventis U.S. LLC et al. v. Apotex Corp. et al.*, C. A. No. 15-0287 (MAS)(LHG);

6. *Sanofi-Aventis U.S. LLC et al. v. Breckenridge Pharmaceutical, Inc.*, C. A. No. 15-0289 (MAS)(LHG)*;*

7. *Sanofi-Aventis U.S. LLC et al. v. Mylan Laboratories Ltd.*, C. A. No. 15-0290 (MAS)(LHG);

8. *Sanofi-Aventis U.S. LLC et al. v. Actavis LLC et al.*, C. A. No. 15-0776 (MAS)(LHG);

9. *Sanofi-Aventis U.S. LLC et al v. Apotex Corp. et al*., C.A. No. 15-1835 (MAS)(LHG);

10. *Sanofi-Aventis U.S. LLC et al v. Breckenridge Pharmaceutical, Inc.*, C.A. No. 15-1836 (MAS)(LHG);

11. *Sanofi-Aventis U.S. LLC et al. v. Accord Healthcare, Inc.*, C. A. No. 15-2520 (MAS)(LHG);

12. *Sanofi-Aventis U.S. LLC et al. v. BPI Labs, LLC et al.*, C. A. No. 15-2521 (MAS)(LHG);

13. *Sanofi-Aventis U.S. LLC et al. v. Dr. Reddy's Laboratories, Inc. et al.*, C. A. No. 15-2522 (MAS)(LHG);

14. *Sanofi-Aventis U.S. LLC et al. v. Glenmark Generics Inc., et al.*, C. A. No. 15-2523 (MAS)(LHG);

15. *Sanofi-Aventis U.S. LLC et al. v. Fresenius Kabi USA, LLC,* C. A. No. 15-2631 (MAS)(LHG);

16. *Sanofi-Aventis U.S. LLC et al. v. Actavis LLC et al.*, C. A. No. 15-3107 (MAS)(LHG);

17. *Sanofi-Aventis U.S. LLC et al. v. Mylan Laboratories Ltd.*, C. A. No. 15-3392 (MAS)(LHG); and

18. *Sanofi-Aventis U.S. LLC et al. v. Dr. Reddy's Laboratories, Inc. et al.*, C. A. No. 16-2259 (MAS)(LHG).

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

September16, 2016

Respectfully submitted,

By: *s/Liza M. Walsh*

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