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AVENTIS PHARMA S.A. and SANOFI

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. ONCO THERAPIES LIMITED, Defendant.	C.A. No.: _____ **(Filed Electronically)**

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 Onco Therapies Limited (hereinafter "Onco" 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, Onco is a corporation organized and existing under the laws of India, having its principal place of business at Strides House, Bilekahalli, Bannerghatta Road, Bangalore, Karnataka 560076, India.

6. On information and belief, Onco is a wholly-owned subsidiary of Strides Arcolab Limited (hereinafter "Arcolab"). On information and belief, Arcolab is a corporation organized and existing under the laws of India, having its principal place of business at Strides House, Bilekahalli, Bannerghatta Road, Bangalore, Karnataka 560076, India.

7. On information and belief, Onco conducts business through and with Agila Specialties Inc. (hereinafter "Agila"), formerly known as Strides, Inc. On information and belief, Agila is a corporation organized and existing under the laws of New Jersey, having its

principal place of business at 201 South Main Street, Suite 3, Lambertville, New Jersey 08530. On information and belief, Agila is an agent or affiliate of Onco.

8. On information and belief, Onco conducts business through and with Strides Pharma Inc. (hereinafter "Strides Pharma"). On information and belief, Strides Pharma is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 201 South Main Street, Suite 3, Lambertville, New Jersey 08530. On information and belief, Strides Pharma is a wholly-owned subsidiary of Arcolab. On information and belief, Strides Pharma is an agent or affiliate of Onco.

9. On information and belief, Onco assembled and caused to be filed with the United States Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. § 355(j) (Section 505(j) of the Federal Food, Drug and Cosmetic Act), Abbreviated New Drug Application ("ANDA") No. 207381 (hereinafter "the Onco ANDA") concerning a proposed drug product, cabazitaxel injection [60 mg/1.5 mL] [40 mg/mL] ("Onco's Proposed ANDA Product").

JURISDICTION AND VENUE

10. 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).

11. This Court has personal jurisdiction over Onco. On information and belief, Onco conducts business through and with Agila. On information and belief, Agila is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 201 South Main Street, Suite 3, Lambertville, New Jersey 08530. On information and belief, Agila is registered with the New Jersey Department of Treasury under entity identification number 0100791546. On information and belief, Agila maintains a registered

corporate agent at 37 Veronica Avenue, Somerset, New Jersey 08873. On information and belief, Agila is an agent or affiliate of Onco. On information and belief, Onco conducts business through and with Strides Pharma. On information and belief, Strides Pharma is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 201 South Main Street, Suite 3, Lambertville, New Jersey 08530. On information and belief, Strides Pharma is registered with the New Jersey Department of Treasury under entity identification number 0400580219. On information and belief, Strides Pharma maintains a registered corporate agent at 201 South Main Street, Suite 3, Lambertville, New Jersey 08530. On information and belief, Strides Pharma holds an active wholesale drug and medical device license for the State of New Jersey under License No. 5004572.

12. On information and belief, Onco 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.

13. On information and belief, Onco has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, Onco 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.

14. On information and belief, Onco regularly conducts and/or solicits business, directly, or throught its parent company, Arcolab, and/or affiliate or subsidiary companies, Agila, and Strides Pharma, in the State of New Jersey. On information and belief, Onco engages in other persistent courses of conduct, directly, or throught its parent company,

Arcolab, and/or affiliate or subsidiary companies, Agila, and Strides Pharma, in the State of New Jersey, and/or derives substantial revenue from services or things used or consumed in the State of New Jersey.

15. Onco is also subject to personal jurisdiction in the State of New Jersey because, *inter alia*, Onco 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. In its May 5, 2015 Paragraph IV Notice Letter, Onco states that it intends to engage in the commercial manufacture, use, and/or sale of Onco's Proposed ANDA Product before the expiration of U.S Patent No. 8,927,592 (the "'592 patent," copy attached as Exhibit A) throughout the United States, including in this Judicial District.

16. In the alternative, Onco is subject to jurisdiction in the United States under the principles of general jurisdiction, and specially in the State of New Jersey pursuant to Fed. R. Civ. P. 4(k)(2). Onco has contacts with the United States by, *inter alia*, its having filed an ANDA with the FDA.

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

18. On information and belief, upon approval of the Onco ANDA, Onco and/or its affiliates, agents or subsidiaries will place Onco's Proposed ANDA 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.

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

JEVTANA®

20. 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

21. The '592 patent 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).

22. The '592 patent is owned by Aventis.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

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

24. On information and belief, the Onco ANDA seeks FDA approval of Onco'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.

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

26. By letter dated May 5, 2015 (the "May 5 Letter"), and pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. §314.95, Onco notified Plaintiffs that it had amended the Onco ANDA to indicate that Onco seeks approval to engage in the commercial manufacture, use, or sale of Onco's Proposed ANDA Product before the expiration of the '592 patent. The May 5 Letter was received by Plaintiffs on May 6, 2015.

27. In its May 5 Letter, Onco notified Plaintiffs, as part of the Onco ANDA, that it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") with respect to the '592 patent. On information and belief, Onco certified that, the '592 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Onco's Proposed ANDA Product.

28. The Onco ANDA 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

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

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

31. If Onco commercially makes, uses, offers to sell, or sells Onco's Proposed ANDA Product within the United States, or imports Onco'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).

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

33. Onco'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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Onco Therapies Limited has infringed one or more claims of the '592 patent by filing ANDA No. 207381 relating to Onco's Proposed ANDA Product before the expiration of the '592 patent;

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

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

D. A permanent injunction restraining and enjoining Onco Therapies Limited, 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 Onco's Proposed ANDA 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;

E. An order that the effective date of any approval of Onco Therapies Limited's ANDA No. 207381 relating to Onco'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;

F. 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

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

Dated: May 15, 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 that are pending in the United States 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); *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. BPI Labs, LLC et al.*, C. A. No. 15-02521 (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); *Sanofi-Aventis U.S. LLC et al. v. Fresenius Kabi USA, LLC*, C. A. No. 15-02631 (MAS)(LHG); and *Sanofi-Aventis U.S. LLC et al. v. Actavis LLC et al.*, C. A. No. 15-3107 (MAS)(LHG).

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

Dated: May 15, 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.

May 15, 2015

CONNELL FOLEY LLP

By: *s/Liza M. Walsh*

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