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. APOTEX CORP. and APOTEX INC. Defendants.	C.A. No.: _____ ***Electronically Filed***

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 defendants Apotex Corp. and Apotex Inc. (collectively "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff Sanofi U.S. is a 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, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

6. On information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L IT9.

7. On information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc.

8. On information and belief, Apotex Inc. 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. 207736 (hereinafter "the Apotex ANDA") concerning a proposed drug product, Cabazitaxel Injection, 60 mg/1.5 mL ("Apotex's Proposed ANDA Product").

JURISDICTION AND VENUE

9. 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).

10. This Court has personal jurisdiction over Apotex Corp. On information and belief, Apotex Corp. directly or through its subsidiaries, 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, Apotex Corp. holds an active wholesale drug license for the State of New Jersey under License No. 5003192.

11. On information and belief, Apotex Corp. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Apotex Corp. "has successfully secured FDA approval for over 230 ANDAs" and "boast[s] over a billion dollars in sales—and a new ranking in the top 10 generic pharmaceutical companies according to recent IMS HEALTH data." *Apotex Corp: A Global Leader Focused on Excellence*, Pharmacy Times available at http://www.pharmacytimes.com/publications/supplement/2013/Generic-Supplement-2013/Apotex-Corp-A-Global-Leader-Focused-on-Excellence. (last visited January 6, 2015).

12. On information and belief, Apotex Corp. has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, Apotex

Corp. 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.

13. On information and belief, Apotex Corp. regularly conducts and/or solicits 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.

14. On information and belief, Apotex Corp. has previously submitted to the jurisdiction of this Court and have availed themselves of the legal protections of the State of New Jersey, having asserted counterclaims in this jurisdiction, including in the matters of *Novartis Pharmaceuticals Corporation v. Apotex Inc. et al.*, Civil Action No. 2:12-cv-05574 (JLL)(MAH), D.I. 12 at 2-3, 10-12 (D.N.J. Feb. 11, 2013); *Otsuka Pharmaceutical Co., Ltd. v. Apotex Corp. et al.*, Civil Action No. 3:12-cv-05645 (MLC) (LHG), D.I. 27 at 3-5, 15-20 (D.N.J. Dec. 11, 2012); *Actelion Pharmaceuticals Ltd. et al. v. Apotex Inc. et al.*, Civil Action No. 1:12-cv-05743 (NLH)(AMD), D.I. 24 at 13-33 (D.N.J. Nov. 27, 2012); and *Hoffman-La Roche, Inc. v. Apotex Inc. et al.*, Civil Action No. 2:10-cv-06241 (SRC)(MAS), D.I. 14 at 3-4, 20-24 (D.N.J. Jan. 12, 2011).

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

16. On information and belief, upon approval of the Apotex ANDA, Apotex Corp. and/or its subsidiaries, affiliates or agents will place Apotex'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.

17. This Court has personal jurisdiction over Apotex Inc. On information and belief, Apotex Inc. directly or through its subsidiaries, 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, Apotex Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products.

18. On information and belief, Apotex Inc. has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, Apotex Inc. 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.

19. On information and belief, Apotex Inc. regularly conducts and/or solicits 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.

20. On information and belief, Apotex Inc. has previously submitted to the jurisdiction of this Court and have availed themselves of the legal protections of the State of New Jersey, having asserted counterclaims in this jurisdiction, including in the matters of *Novartis Pharmaceutical Corporation v. Apotex Inc. et al.*, Civil Action No. 2:12-cv-05574 (JLL)(MAH), D.I. 12 at 2-3, 10-12 (D.N.J. Feb. 11, 2013); *Otsuka Pharmaceutical Co., Ltd. v. Apotex Corp. et al.*, Civil Action No. 3:12-cv-05645 (MLC) (LHG), D.I. 27 at 3-5, 15-20 (D.N.J. Dec. 11, 2012);

Actelion Pharmaceuticals Ltd. et al. v. Apotex Inc. et al., Civil Action No. 1:12-cv-05743 (NLH)(AMD), D.I. 24 at 13-33 (D.N.J. Nov. 27, 2012); and *Hoffman-La Roche, Inc. v. Apotex Inc. et al.*, Civil Action No. 2:10-cv-06241 (SRC)(MAS), D.I. 14 at 3-4, 20-24 (D.N.J. Jan. 12, 2011).

21. Apotex Inc. is also subject to personal jurisdiction in the State of New Jersey because, *inter alia*, Apotex Inc. 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. Apotex Inc. sent its December 4, 2014 Paragraph IV Notice Letter to Sanofi U.S.'s commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807. Plaintiffs's cause of action arose from Apotex Inc.'s contact with Sanofi U.S. in Bridgewater, New Jersey. Apotex Inc. states that it intends to engage in the commercial manufacture, use, and/or sale of Apotex Inc.'s Proposed ANDA Product before the expiration of U.S Patent Nos. 5,847,170 ("'170 patent") and 7,241,907 ("'907 patent") throughout the United States, including in this Judicial District.

22. In the alternative, Apotex Inc. 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). Apotex Inc. has contacts with the United States by, *inter alia*, its having filed an ANDA with the FDA.

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

24. On information and belief, upon approval of the Apotex ANDA, Apotex Inc. and/or its subsidiaries, affiliates or agents will place Apotex'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.

25. 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

26. 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.

27. 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).

28. The '170 patent is owned by Aventis.

29. 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).

30. The '907 patent is owned by Aventis.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

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

32. On information and belief, the Apotex ANDA seeks FDA approval of Apotex'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.

33. On information and belief, Apotex Inc. actively collaborated with Apotex Corp. and/or participated in and/or directed activities related to the submission of the Apotex ANDA and the development of Apotex'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 Apotex ANDA, Apotex Inc. will be involved in the manufacture, distribution, and/or marketing of Apotex's Proposed ANDA Product.

34. On information and belief, Apotex Corp. actively collaborated with Apotex Inc. and/or participated in and/or directed activities related to the submission of the

Apotex ANDA and the development of Apotex'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 Apotex ANDA, Apotex Corp. will be involved in the manufacture, distribution, and/or marketing of Apotex's Proposed ANDA Product.

35. By letter dated December 4, 2014 (the "December 4 Letter"), and pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. §314.95, Apotex Inc. notified Plaintiffs that it had submitted to the FDA the Apotex ANDA, seeking approval to engage in the commercial manufacture, use, or sale of Apotex's Proposed ANDA Product before the expiration of the '170 patent and the '907 patent. The December 4 Letter was received by Plaintiffs on December 5, 2014.

36. In its December 4 Letter, Apotex Inc. notified Plaintiffs, as part of the Apotex ANDA, 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 '170 patent and the '907 patent. On information and belief, Apotex Inc. 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 Apotex's Proposed ANDA Product.

37. The Apotex ANDA refers to and relies upon the Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

38. In the December 4 Letter, Apotex offered confidential access to portions of the Apotex ANDA on terms and conditions set forth in paragraph 2 of the December 4 Letter ("Apotex Offer"). Apotex requested that Plaintiffs accept the Apotex Offer before receiving access to any portion of the Apotex ANDA. The Apotex Offer contained unreasonable

restrictions that would apply under a protective order. For example, the Apotex Offer required that Plaintiffs' outside counsel do not engage, formally or informally, in any patent prosecution or any FDA counseling, litigation or other work before or involving the FDA on behalf of Plaintiffs.

39. Under 21 U.S.C. § 355(j)(5)(C)(i)(III), an "offer of confidential access shall contain such restrictions . . . on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

40. Since rejecting the Apotex Offer, Plaintiffs attempted to negotiate with Apotex to obtain a copy of excerpts of the Apotex ANDA under restrictions "as would apply had a protective order been issued." Those negotiations were unsuccessful. For example, Apotex's final proposal continued to unreasonably impose patent prosecution and FDA restrictions on Plaintiffs' outside counsel.

41. Plaintiffs are not aware of any other means of obtaining information regarding Apotex's Proposed ANDA Product within the 45-day statutory period. Without such information, Plaintiffs will use the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards such information as is required to confirm its allegations of infringement and to present to the Court evidence that Apotex's Proposed ANDA Product falls within the scope of one or more claims of the '170 and '907 patents.

COUNT I

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

42. Plaintiff repeats and realleges paragraphs 1 through 41 above as if fully set forth herein.

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

44. If Defendants commercially make, use, offer to sell, or sell Apotex's Proposed ANDA Product within the United States, or import Apotex's Proposed ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '170 patent, they would further infringe the '170 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

45. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '170 patent. Plaintiffs do not have an adequate remedy at law.

46. Apotex Inc.'s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(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

47. Plaintiffs repeat and reallege paragraphs 1 through 46 above as if fully set forth herein.

48. By submitting the Apotex ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Apotex's Proposed ANDA Product throughout the United States prior to the expiration of the '907 patent, Defendants committed an act of infringement of the '907 patent under 35 U.S.C. § 271(e)(2). On

information and belief, Defendants were aware of the '907 patent at the time the Apotex ANDA was submitted.

49. If Defendants commercially make, use, offer to sell, or sell Apotex's Proposed ANDA Product within the United States, or import Apotex's Proposed ANDA Product into the United States, or induce or contribute 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).

50. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '907 patent. Plaintiffs do not have an adequate remedy at law.

51. Apotex Inc.'s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(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 Defendants have infringed one or more claims of the '170 patent by filing ANDA No. 207736 relating to Apotex's Proposed ANDA Product before the expiration of the '170 patent;

B. A judgment that the manufacture, use, offer for sale, sale and/or importation of Apotex's Proposed ANDA 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 Defendants, and their 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 Apotex's Proposed ANDA 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 Apotex’s ANDA No. 207736 relating to Apotex’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 ’170 patent or any later date of exclusivity to which Plaintiffs and/or the ’170 patent are or become entitled;

F. A judgment that Defendants have infringed one or more claims of the ’907 patent by filing ANDA No. 207736 relating to Apotex’s Proposed ANDA Product before the expiration of the ’907 patent;

G. A judgment that the manufacture, use, offer for sale, sale and/or importation of Apotex’s Proposed ANDA 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 Defendants, and their 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 Apotex’s Proposed ANDA 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 Apotex’s ANDA No. 207736 relating to Apotex’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 ’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.

January 14, 2015

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