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

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

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI

Plaintiffs,

v.

APOTEX CORP. and APOTEX INC.

Defendants.

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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.
- 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);



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