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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. ACTAVIS LLC and ACTAVIS ELIZABETH LLC, Defendants.	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 defendants Actavis LLC and Actavis Elizabeth LLC (collectively "Defendants"), 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, Actavis LLC is a corporation organized and existing under the laws of the State of Delaware, having principal places of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Actavis LLC was formerly known as Actavis Inc., a Delaware corporation.

6. On information and belief, Actavis Elizabeth LLC is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202.

7. On information and belief, Actavis Elizabeth LLC is a wholly owned subsidiary of Actavis LLC.

8. On information and belief, Actavis LLC is a wholly owned subsidiary of Actavis, Inc. On information and belief, Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

9. On information and belief, Actavis LLC 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. 207970 (hereinafter "the Actavis 505(b)(2) application") concerning a proposed drug product, Cabazitaxel Injection, 10 mg/mL ("Actavis's Proposed Generic 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 Actavis LLC. On information and belief, Actavis LLC 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. On information and belief, Actavis LLC, formerly as Actavis Inc., a Delaware corporation, maintains principal places of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Actavis LLC, formerly as Actavis Inc., a Delaware corporation, is registered with the New Jersey Department of Treasury under the business entity identification number 0101005391. On information and belief, Actavis LLC, formerly as Actavis Inc., a

Delaware corporation, maintains a corporate agent for service of process at 80 Main Street, 5th Floor, West Orange, New Jersey 07052.

12. On information and belief, Actavis LLC has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, Actavis LLC 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. On information and belief, Actavis LLC is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Actavis LLC 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, Actavis, Inc. as the parent company and Actavis LLC as the trade name holds an active wholesale drug license for the State of New Jersey under License No. 5003899.

13. On information and belief, Actavis LLC 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 *Novartis Pharmaceuticals Corporation v. Actavis LLC. et al.*, Civil Action No. 2:12-cv-03967 (SDW)(SCM), D.I. 354 at 8, 15-19 (D.N.J. May 16, 2014); and *Novartis Pharmaceuticals Corporation v. Actavis LLC. et al.*, Civil Action No. 2:13-cv-01028 (SDW)(MCA), D.I. 119 at 9, 15-18 (D.N.J. Mar. 13, 2013).

14. Actavis LLC is also subject to personal jurisdiction in the State of New Jersey because, *inter alia*, Actavis LLC 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. Actavis LLC sent its April 23, 2015 Paragraph IV Notice Letter (the "April 23 Letter") to Sanofi U.S.'s commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807. Plaintiffs' cause of action arose from Actavis LLC's contact with Sanofi U.S. in Bridgewater, New Jersey. Actavis LLC states that it intends to engage in the commercial manufacture, use, and/or sale of Actavis's Proposed Generic 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.

15. On information and belief, upon approval of the Actavis 505(b)(2) application, Actavis LLC and/or its subsidiaries, affiliates or agents will market, sell and/or distribute Actavis's Proposed Generic 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 Actavis 505(b)(2) application, Actavis LLC and/or its subsidiaries, affiliates or agents will place Actavis'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.

17. This Court has personal jurisdiction over Actavis Elizabeth LLC. On information and belief, Actavis Elizabeth LLC 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. On information and belief, Actavis Elizabeth LLC maintains a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202. On information and belief, Actavis

Elizabeth LLC is registered with the New Jersey Department of Treasury under the business entity identification number 0600272818. On information and belief, Actavis Elizabeth LLC, formerly as Actavis Inc., a Delaware corporation, maintains a corporate agent for service of process at 80 Main Street, 5th Floor, West Orange, New Jersey 07052.

18. On information and belief, Actavis Elizabeth LLC has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, Actavis Elizabeth LLC 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. On information and belief, Actavis Elizabeth LLC is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Actavis Elizabeth LLC 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, Actavis, Inc. as the parent company and Actavis Elizabeth LLC as the trade name holds an active wholesale drug license for the State of New Jersey under License No. 5003329.

19. On information and belief, Actavis Elizabeth LLC 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 *Janssen Pharmaceuticals, Inc. et al. v. Actavis Elizabeth LLC. et al.*, Civil Action No. 2:13-cv-04507 (CCC)(MF), D.I. 150 at 10, 23-38 (D.N.J. Sep. 3, 2014); *Shire LLC et al. v. Actavis Elizabeth LLC. et al.*, Civil Action No. 2:11-cv-03781 (SRC)(CLW), D.I. 231 at 5, 40-47 (D.N.J. Jan. 17,

2013); and *Depomed, Inc. v. Actavis Elizabeth LLC. et al.*, Civil Action No. 3:12-cv-01358 (JAP)(TJB), D.I. 40 at 3, 23-27 (D.N.J. Apr. 13, 2012).

20. On information and belief, upon approval of the Actavis 505(b)(2) application, Actavis Elizabeth LLC and/or its subsidiaries, affiliates or agents will market, sell and/or distribute Actavis's Proposed Generic 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 Actavis 505(b)(2) application, Actavis Elizabeth LLC and/or its subsidiaries, affiliates or agents will place Actavis'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.

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

JEVTANA®

23. 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

24. 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).

25. The '592 patent is owned by Aventis.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

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

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

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

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

30. In its April 23 Letter, and pursuant to 21 U.S.C. §355(b)(3)(B) and 21 C.F.R. §314.52(c), Actavis LLC notified Plaintiffs that it had submitted to the FDA the Actavis 505(b)(2) application, seeking approval to engage in the commercial manufacture, use, or sale of Actavis's Proposed Generic Product before the expiration of the '592 patent. The April 23 Letter was received by Plaintiffs on April 24, 2015.

31. In its April 23 Letter, Actavis LLC notified Plaintiffs, as part of the Actavis 505(b)(2) application, it had filed certification of the type described in 21 U.S.C. § 355(b)(2)(A)(iv) (a "Paragraph IV Certification") with respect to the '592 patent. On information and belief, Actavis LLC certified that the '592 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Actavis's Proposed Generic Product.

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

COUNT I

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 Actavis 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 Actavis's Proposed Generic Product throughout the United States prior to the expiration of the

'592 patent, Defendants committed an act of infringement of the '592 patent under 35 U.S.C. § 271(e)(2). On information and belief, Defendants were aware of the '592 patent at the time the Actavis 505(b)(2) application was submitted.

35. If Defendants commercially make, use, offer to sell, or sell Actavis's Proposed Generic Product within the United States, or import Actavis's Proposed Generic Product into the United States, or induces or contributes to any such conduct during the term of the '592 patent, they would further infringe the '592 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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

37. Actavis LLC'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 Defendants have infringed one or more claims of the '592 patent by filing NDA No. 207970 relating to Actavis's Proposed Generic Product before the expiration of the '592 patent;

B. A judgment that the manufacture, use, offer for sale, sale and/or importation of Actavis's Proposed Generic 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 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 Actavis'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;

E. An order that the effective date of any approval of Actavis LLC's NDA No. 207970 relating to Actavis'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;

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 1, 2015

Respectfully submitted,

By: s/ Charles M. Lizza

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