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

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. DR. REDDY'S LABORATORIES, INC., and DR. REDDY'S LABORATORIES, LTD. Defendants.	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 defendants Dr. Reddy's Laboratories, Inc., and Dr. Reddy's Laboratories, Ltd. (collectively,

"DRL" or "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, defendant Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

6. On information and belief, defendant Dr. Reddy's Laboratories, Ltd. is a company organized and existing under the laws of India, having its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500 034, India.

7. On information and belief, defendant Dr. Reddy's Laboratories, Inc. is a subsidiary of Dr. Reddy's Laboratories, Ltd.

8. On information and belief, defendant Dr. Reddy's Laboratories, Inc., as United States agent for Dr. Reddy's Laboratories, Ltd., 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. 207718 (hereinafter "the DRL ANDA") concerning a proposed drug product, cabazitaxel injection, 60 mg/1.5 mL (40 mg/mL), for intravenous infusion ("DRL'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 Dr. Reddy's Laboratories, Inc. On information and belief, Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 107 College Road East, Princeton, New Jersey 08540. On information and belief, Dr. Reddy's Laboratories, Inc. is registered as a domestic business entity with the New Jersey Department of Treasury under the business entity identification number 0100518911. On information and belief, Dr. Reddy's Laboratories, Inc. conducts business in the State of New Jersey under the alternate name Reddy-Cheminor, Inc. On information and belief, Reddy-Cheminor, Inc. is also registered as a domestic business entity with the New Jersey Department of Treasury under the business entity identification number 0100518911. On information and belief, Reddy-Cheminor, Inc. is registered to conduct business activity of distributing generic pharmaceuticals. On information and belief, Reddy-Cheminor, Inc. maintains a corporate agent for service of process at 66 South Maole Avenue, Ridgewood, New Jersey 07450. On information and belief, Reddy-Cheminor, Inc. is an agent, affiliate or subsidiary of Dr. Reddy's Laboratories, Inc.

11. On information and belief, Dr. Reddy's Laboratories, Inc. 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, Dr. Reddy's Laboratories, Inc. holds an active wholesale drug and medical device license for the State of New Jersey under License No. 5002312.

12. On information and belief, Dr. Reddy's Laboratories, Inc. has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, Dr. Reddy's Laboratories, 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, and maintenance of corporate agents in the State of New Jersey.

13. On information and belief, Dr. Reddy's Laboratories, 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.

14. On information and belief, Dr. Reddy's Laboratories, Inc. 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 claims in this jurisdiction, including in the matter of *Dr. Reddy's Laboratories, Inc. et al. v. Purdue Pharmaceutical Products L.P. et al.*, Civil Action No. 14-3230 (JLL)(JAD) (D.N.J. May 20, 2014). On information and belief, Dr. Reddy's Laboratories, Inc. 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 related matter of *Sanofi-Aventis U.S. LLC et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 15-2522 (MAS)(LHG), D.I. 15 at 4-8, 15-20 (D.N.J. Jun. 26, 2015), and in the matters of *Sucampo AG et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 14-7144 (MAS)(DEA), D. I. 16 at 2-3, 18-25 (D.N.J. Jan. 26, 2015); *Helsinn Healthcare S.A. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 14-4274 (MLC)(DEA), D.I. 13 at 3, 8-12 (D.N.J. Sep. 5, 2014); *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 14-2760 (MLC)(DEA), D.I. 27 at 3, 34-48 (D.N.J. Jul. 31, 2014); *Genzyme Corp. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 13-6827 (JEI)(KMW), D.I. 17 at 6, 16-21 (D.N.J. Jan. 21, 2014).

15. Dr. Reddy's Laboratories, Inc. is also subject to personal jurisdiction in the State of New Jersey because, *inter alia*, it 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. Dr. Reddy's Laboratories, Inc. sent its March 10, 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 Dr. Reddy's Laboratories, Inc.'s contact with Sanofi U.S. in Bridgewater, New Jersey. Dr. Reddy's Laboratories, Inc. states that it intends to engage in the commercial manufacture, use, and/or sale of DRL's Proposed ANDA Product before the expiration of U.S Patent No. 5,847,170 throughout the United States, including in this Judicial District.

16. On information and belief, upon approval of the DRL ANDA, Dr. Reddy's Laboratories, Inc. and/or its subsidiaries, affiliates or agents will market, sell and/or distribute

DRL's Proposed ANDA Product throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

17. On information and belief, upon approval of the DRL ANDA, Dr. Reddy's Laboratories, Inc. and/or its subsidiaries, affiliates or agents will place DRL'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.

18. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. On information and belief, Dr. Reddy's Laboratories, Ltd. 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, Dr. Reddy's Laboratories, Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products.

19. On information and belief, Dr. Reddy's Laboratories, Ltd. has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, Dr. Reddy's Laboratories, Ltd. 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 maintenance of corporate agents in the State of New Jersey.

20. On information and belief, Dr. Reddy's Laboratories, Ltd. 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.

21. On information and belief, Dr. Reddy's Laboratories, Ltd. 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 claims in this jurisdiction, including in the matter of *Dr. Reddy's Laboratories, Inc. et al. v. Purdue Pharmaceutical Products L.P. et al.*, Civil Action No. 14-3230 (JLL)(JAD) (D.N.J. May 20, 2014). On information and belief, Dr. Reddy's Laboratories, Ltd. 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 related matter of *Sanofi-Aventis U.S. LLC et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 15-2522 (MAS)(LHG), D.I. 15 at 4-8, 15-20 (D.N.J. Jun. 26, 2015), and in the matters of *Sucampo AG et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 14-7144 (MAS)(DEA), D. I. 16 at 2-3, 18-25 (D.N.J. Jan. 26, 2015); *Helsinn Healthcare S.A. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 14-4274 (MLC)(DEA), D.I. 13 at 3, 8-12 (D.N.J. Sep. 5, 2014); *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 14-2760 (MLC)(DEA), D.I. 27 at 3, 34-48 (D.N.J. Jul. 31, 2014); *Genzyme Corp. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 13-6827 (JEI)(KMW), D.I. 17 at 6, 16-21 (D.N.J. Jan. 21, 2014).

22. In the alternative, Dr. Reddy's Laboratories, Ltd. 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). Dr. Reddy's Laboratories, Ltd. 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 DRL ANDA, Dr. Reddy's Laboratories, Ltd. and/or its subsidiaries, affiliates or agents will market, sell and/or distribute DRL'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 DRL ANDA, Dr. Reddy's Laboratories, Ltd. and/or its subsidiaries, affiliates or agents will place DRL'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).

JEVTANA®

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 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

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.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

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

30. On information and belief, the DRL ANDA seeks FDA approval of DRL'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.

31. On information and belief, Dr. Reddy's Laboratories, Inc. actively collaborated with Dr. Reddy's Laboratories, Ltd. and/or participated in and/or directed activities related to the submission of the DRL ANDA and the development of DRL'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 DRL ANDA, Dr. Reddy's Laboratories, Inc. will be involved in the manufacture, distribution, and/or marketing of DRL's Proposed ANDA Product.

32. On information and belief, Dr. Reddy's Laboratories, Ltd. actively collaborated with Dr. Reddy's Laboratories, Inc. and/or participated in and/or directed activities related to the submission of the DRL ANDA and the development of DRL'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 DRL ANDA, Dr. Reddy's Laboratories, Ltd. will be involved in the manufacture, distribution, and/or marketing of DRL's Proposed ANDA Product.

33. By letter dated March 10, 2016 (the "March 10, 2016 Notice Letter"), and pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. §314.95, Dr. Reddy's Laboratories, Inc. notified Plaintiffs that it had submitted to the FDA the DRL ANDA, seeking approval to engage in the commercial manufacture, use, or sale of DRL's Proposed ANDA Product before the expiration of the '170 patent. The March 10, 2016 Notice Letter was received by Plaintiff Aventis Pharma S.A. on March 16, 2016.

34. In its March 10, 2016 Notice Letter, Dr. Reddy's Laboratories, Inc. notified Plaintiffs that it had filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") with respect to the '170 patent in support of the DRL ANDA. On information and belief, Dr. Reddy's Laboratories, Inc. certified that the '170 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of DRL's Proposed ANDA Product.

35. The DRL ANDA 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

36. Plaintiffs repeat and reallege paragraphs 1 through 35 above as if fully set forth herein.

37. By submitting the DRL ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of DRL'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).

38. If Defendants commercially make, use, offer to sell, or sell DRL's Proposed ANDA Product within the United States, or import DRL'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).

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

40. Dr. Reddy's Laboratories, 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.

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. 207718 relating to DRL'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 DRL'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 DRL'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 DRL’s ANDA No. 207718 relating to DRL’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 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: April 21, 2016

CONNELL FOLEY LLP

By: *s/Liza M. Walsh*

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