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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES and THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, Plaintiffs, v. CIPLA LTD. and CIPLA USA, INC., Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT (Filed Electronically)**

Plaintiffs the United States of America ("government") and the Board of Trustees of the University of Illinois (the "University of Illinois") (together, "Plaintiffs"), by their undersigned attorneys, for their Complaint against defendants Cipla Ltd. and Cipla USA, Inc. (together, "Cipla") herein allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Cipla's Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration (the "FDA")

seeking approval to commercially manufacture and market generic version of the pharmaceutical drug product Prezista® prior to the expiration of United States Patent Nos. 7,470,506 B1 (the "'506 patent") and 8,597,876 B2 (the "'876 patent"). The '506 patent and the '876 patent (the "patents-in-suit") cover methods of using Prezista®.

THE PARTIES

2. Plaintiff the United States of America is the government of the United States of America, which acts through its Department of Health and Human Services, National Institutes of Health, located in Bethesda, Maryland.

3. Plaintiff Board of Trustees of the University of Illinois is a body corporate and politic of the State of Illinois, having a place of business in Urbana, Illinois.

4. On information and belief, Defendant Cipla Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai -- 400 013, India. On information and belief, Cipla Ltd., is in the business of making and selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States through various operating subsidiaries, including Cipla USA, Inc.

5. On information and belief, Defendant Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 9100 S. Dadeland Blvd., Suite 1500, Miami, FL 33156. On information and belief, Cipla USA, Inc. is in the business of, among other things, marketing and selling generic versions of branded pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States. Cipla USA, Inc. is a wholly owned subsidiary of Cipla Ltd.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action, pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Cipla by virtue of, *inter alia*, it conducting business in New Jersey, having availed itself of the rights and benefits of New Jersey law, previously consenting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court, and having engaged in systematic and continuous contacts with the State of New Jersey.

8. On information and belief, Cipla Ltd., directly and/or through Cipla USA, Inc., markets, distributes, and sells generic pharmaceutical products throughout the United States, including in the State of New Jersey, and derives substantial revenues through such sales.

9. On information and belief, Cipla USA, Inc. operates at the direction of Cipla Ltd., and has submitted regulatory filings for generic pharmaceutical products to the FDA on behalf of Cipla Ltd.

10. Cipla has stipulated and/or consented to personal jurisdiction in prior patent cases, including in the related cases: *The United States Department of Health and Human Services, et al. v. Cipla Ltd., et al.*, 14-5135 (WHW) (CLW) ("*Cipla I* Litigation," which involves the same ANDA and the same Cipla proposed generic product at issue in this case, but in different dosage strengths); *Janssen Prods, L.P., et al. v. Lupin Ltd., et al.*, 10-5954 D.N.J. (WHW) (CLW) (which also involves proposed generic versions of Prezista®, and in which Cipla participated during discovery). *See also Astrazeneca et al. v. Ivax Corp., et al.*, 08-4993, D.N.J. (JAP) (TJB); *Prometheus Labs., Inc. v. Roxane Labs., Inc., et al.*, 11-1241 (FSH) (MAH); *Merck, Sharp & Dohme Corp., et al. v. Cipla USA, Inc., et al.*, 13-4017 (JBS) (AMD).

11. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

12. On December 30, 2008, the United States Patent and Trademark Office issued the '506 patent, entitled "Fitness Assay and Associated Methods." At the time of its issue, the '506 patent was assigned to the Plaintiffs, and the Plaintiffs currently hold title to the '506 patent. A copy of the '506 patent is attached hereto as Exhibit A.

13. As authorized by a license agreement with the University of Illinois, the government granted a non-exclusive license of the '506 patent to Janssen R&D Ireland, (formerly known as Tibotec Pharmaceuticals Ltd.) an Irish corporation having its principal place of business as Eastgate Village, Eastgate, Little Island, County Cork, Ireland ("Janssen").

14. On December 3, 2013, the United States Patent and Trademark Office issued the '876 patent, entitled "Method of Treating HIV Infection." At the time of its issue, the '876 patent was assigned to the Plaintiffs, and the Plaintiffs currently hold title to the '876 patent. A copy of the '876 patent is attached hereto as Exhibit B.

15. As authorized by a license agreement with the University of Illinois, the government also granted a non-exclusive license of the '876 patent to Janssen.

PREZISTA®

16. Janssen Products L.P. holds approved New Drug Application No. 21-976 for Duranavir Ethanolate Tablets, in 75 mg, 150 mg, 400 mg, and 600 mg, dosage strengths, which are sold under the trade name Prezista®.

17. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to Prezista®.

CIPLA'S ANDA

18. On or about June 30, 2014, Cipla Ltd., by itself and/or through its subsidiary and agent Cipla USA, Inc., submitted ANDA No. 206288 to the FDA pursuant to 12 U.S.C. § 355(j), seeking approval to commercially manufacture, use, and market Darunavir Hydrate Tablets, in 75 mg, 150 mg, 400 mg, and 600 mg dosage strengths. Plaintiffs timely filed suit under the Hatch Waxman Act relating to this ANDA submission in the *Cipla I* Litigation.

19. On or about February 26, 2015, Cipla amended ANDA No. 206288 to add a request for approval to commercially manufacture, use, and market Darunavir Hydrate Tablets in an 800 mg dosage strength ("Cipla's 800 mg ANDA Product").

20. Cipla's ANDA No. 206288 relies upon the Prezista® New Drug Application and contains data that, according to Cipla, demonstrate the bioequivalence of Cipla's 800 mg ANDA Product to Prezista®.

21. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), the government and the University of Illinois received a letter from Cipla, dated February 26, 2015, and attached memoranda (collectively, "Cipla's Notification"), stating that Cipla included certifications in its ANDA that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Cipla's 800 mg ANDA Product (the "Paragraph IV certification"). Thus, Cipla is seeking approval of its proposed generic product in the 800 mg strength prior to the expiration of the '506 and '876 patents. The Plaintiffs are filing this complaint within the 45 day interval from receipt of the Paragraph IV certification as specified by 21 U.S.C. § 355(c)(3)(C).

COUNT ONE: INDUCEMENT OF INFRINGEMENT OF THE '506 PATENT

22. Plaintiffs reallege and incorporate by reference the allegation of paragraphs 1-21 of this Complaint.

23. Under 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer."

24. The proposed generic version of Prezista® as described in ANDA No. 206288, if utilized in treatment according to their proposed indications, will infringe every limitation of at least claim 1 of the '506 patent.

25. Cipla is thus knowingly, intentionally, and deliberately seeking approval of a product that, if used according to its indications, will infringe the '506 patent.

26. In addition, if ANDA No. 206288 is approved, Cipla will be knowingly, intentionally, deliberately, and actively involved in inducing treating physicians, among others, to utilize Cipla's 800 mg ANDA Product in a manner that infringes the '506 patent.

27. Cipla is therefore liable under 35 U.S.C. § 271(e)(2) for inducement of infringement of the '506 patent.

COUNT TWO: CONTRIBUTORY INFRINGEMENT OF THE '506 PATENT

28. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-27 of this Complaint.

29. The proposed generic version of Prezista® as described in ANDA No. 206288, if utilized in treatment according to their proposed indications, will infringe every limitation of at least claim 1 of the '506 patent.

30. Cipla is thus knowingly, intentionally, and deliberately seeking approval of a product that, if used according to its indications, will infringe the '506 patent.

31. Cipla's commercial manufacture, use, offer to sell, or sale of Cipla's 800 mg ANDA Product within the United States, or importation of Cipla's 800 mg ANDA Product into the United States while knowing Cipla's 800 mg ANDA Product to be especially made or especially adapted for use as indicated in Prezista®, and not a staple article or commodity of

commerce suitable for substantial noninfringing use during the term of the '506 patent will contributorily infringe the '506 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

32. The Plaintiffs will be substantially and irreparably harmed if Cipla is not enjoined from infringing the '506 patent.

33. The Plaintiffs have no adequate remedy at law.

34. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT THREE: INDUCEMENT OF INFRINGEMENT OF THE '876 PATENT

35. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-34 of this Complaint.

36. The proposed generic version of Prezista® as described in ANDA No. 206288, if utilized in treatment according to their proposed indications, will infringe every limitation of at least claim 1 of the '876 patent.

37. Cipla is thus knowingly, intentionally, and deliberately seeking approval of a product that, if used according to its indications, will infringe the '876 patent.

38. In addition, if ANDA No. 206288 is approved, Cipla will be knowingly, intentionally, deliberately, and actively involved in inducing treating physicians, among others, to utilize Cipla's 800 mg ANDA Product in a manner that infringes the '876 patent.

39. Cipla is therefore liable under 35 U.S.C. § 271 (e)(2) for inducement of infringement of the '876 patent.

COUNT FOUR: CONTRIBUTORY INFRINGEMENT OF THE '876 PATENT

40. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-39 of this Complaint.

41. The proposed generic version of Prezista® as described in ANDA No. 206288, if utilized in treatment according to their proposed indications, will infringe every limitation of at least claim 1 of the '876 patent.

42. Cipla is thus knowingly, intentionally, and deliberately seeking approval of a product that, if used according to its indications, will infringe the '876 patent.

43. Cipla's commercial manufacture, use, offer to sell or sale of Cipla's 800 mg ANDA Product within the United States, or importation of Cipla's 800 mg ANDA Product into the United States while knowing Cipla's 800 mg ANDA Product to be especially made or especially adapted for use as indicated in Prezista®, and not a staple article or commodity of commerce suitable for substantial noninfringing use during the term of the '876 patent will contributorily infringe the '876 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

44. The Plaintiffs will be substantially and irreparably harmed if Cipla is not enjoined from infringing the '876 patent.

45. The Plaintiffs have no adequate remedy at law.

46. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

Wherefore, the government and the University of Illinois pray for a Judgment in their favor and against Cipla, and respectfully request the following relief:

A. A Judgment that Cipla has infringed U.S. Patent No. 7,470,506 B1;

B. A Judgment that Cipla has infringed U.S. Patent No. 8,597,876 B2;

C. A Judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Cipla, its officers, agents, servants, employees, and those persons in active concert or participation with any of them, from commercially manufacturing, using, offering to sell, or

selling Cipla's 800 mg ANDA Product within the United States, or importing Cipla's 800 mg ANDA Product into the United States, prior to the expiration of the patents-in-suit;

D. A Judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 206288 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be any earlier than the expiration date of the patents-in-suit, including any extensions;

E. If Cipla commercially manufactures, uses, offers to sell, or sells Cipla's 800 mg ANDA Product within the United States, or imports Cipla's 800 mg ANDA Product into the United States, prior to the expiration of the patents-in-suit including any extensions, a Judgment awarding Plaintiffs monetary relief together with interest;

F. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

G. Costs and expenses in this action; and

H. Such other relief as the Court deems just and proper.

Dated: April 10, 2015

Respectfully submitted,

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