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

TIBOTEC INC. and TIBOTEC PHARMACEUTICALS, Plaintiffs, v. LUPIN LIMITED, LUPIN PHARMACEUTICALS INC., Defendants.	)	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Tibotec Inc. and Tibotec Pharmaceuticals (collectively, "Tibotec"), for their Complaint against Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals Inc. ("Lupin Pharmaceuticals") (collectively "Lupin") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent No. 7,700,645 ("the '645 Patent") arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq. This action arises out of Lupin's filing of an amended Abbreviated New Drug Application ("ANDA")

seeking approval to sell generic copies of Plaintiffs' highly successful PREZISTA® (darunavir) 75 mg, 150 mg, and 300 mg products prior to the expiration of the '645 Patent.

THE PARTIES

2. Plaintiff Tibotec Inc. is a corporation organized under the laws of the State of Delaware, having its headquarters and principal place of business at 1020 Stony Hill Road, Suite 300, Yardley, PA 19067.

3. Plaintiff Tibotec Pharmaceuticals (formerly known as Tibotec Pharmaceuticals Ltd.) is an Irish corporation having its principal place of business as Eastgate Village, Eastgate, Little Island, County Cork, Ireland.

4. On information and belief, Lupin Ltd. is an Indian corporation having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (E), Mumbai 400 051, India, and having a registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India. On information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market through various operating subsidiaries, including Lupin Pharmaceuticals.

5. On information and belief, Lupin Pharmaceuticals is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a place of principal business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202. On information and belief, Lupin Pharmaceuticals is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. Lupin Pharmaceuticals is a wholly-owned subsidiary of Lupin Ltd.

JURISDICTION AND VENUE

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

7. On information and belief, this Court has personal jurisdiction over Lupin Ltd. because Lupin Ltd. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Ltd. has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district.

8. On information and belief, this Court has personal jurisdiction over Lupin Pharmaceuticals because Lupin Pharmaceuticals has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district.

9. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals operate and act in concert as an integrated, unitary business. For example, Lupin Ltd. includes within its Annual Report the activities of Lupin Pharmaceuticals, including revenue earned.

10. On information and belief, Lupin Pharmaceuticals is registered to do business in New Jersey.

11. On information and belief, Lupin Pharmaceuticals has appointed National Registered Agents, Inc. of Princeton, New Jersey as its registered agent for the receipt of service of process.

12. Lupin Ltd. and Lupin Pharmaceuticals have stipulated and/or consented to personal jurisdiction in this district in numerous prior patent cases.

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

BACKGROUND

14. On April 20, 2010, the United States Patent and Trademark Office ("the PTO") issued the '645 Patent, entitled "Pseudopolymorphic Forms of a HIV Protease Inhibitor." A true and correct copy of the '645 Patent is attached hereto as Exhibit A.

15. Tibotec Pharmaceuticals (formerly known as Tibotec Pharmaceuticals Ltd.) holds title to the '645 Patent.

16. The '645 Patent claims a novel ethanolate form of darunavir useful for the treatment of human immunodeficiency virus ("HIV") infections.

17. The '645 Patent expires on December 26, 2026.

18. The United States Food and Drug Administration ("FDA") has awarded 6 months of pediatric exclusivity for PREZISTA®. The period of pediatric exclusivity applicable to the '645 Patent does not expire until June 26, 2027.

19. Tibotec Inc. is the holder of approved New Drug Application ("NDA") No. 21-976 for darunavir ethanolate tablets, the product covered by the '645 Patent and which Tibotec markets and sells under the trademark PREZISTA®.

20. PREZISTA® (darunavir) is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations" also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under the provisions of 21 U.S.C. § 355(j).

21. The FDA's "Orange Book" also lists patents associated with approved drugs. The '645 Patent is listed in the "Orange Book" in association with PREZISTA® (darunavir).

22. On information and belief, Lupin Ltd., itself and/or through its subsidiary, agent and alter ego, Lupin Pharmaceuticals, submitted ANDA No. 202-073 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of darunavir ethanolate tablets in 75 mg, 150 mg and 300 mg dosages ("Lupin's 75 mg, 150 mg and 300 mg Tablets") as generic versions of the PREZISTA® 75 mg, 150 mg and 300 mg tablets.

23. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals collaborated in the research, development, preparation and filing of ANDA No. 202-073 for Lupin's 75 mg, 150 mg and 300 mg Tablets.

24. On information and belief, Lupin Pharmaceuticals will market and/or distribute Lupin's 75 mg, 150 mg and 300 mg Tablets if ANDA No. 202-073 is approved by the FDA.

25. On information and belief, Lupin Pharmaceuticals participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 202-073.

26. On or about June 7, 2011, Tibotec received a letter dated June 3, 2011 ("the Lupin Paragraph IV Letter") stating that Lupin had submitted ANDA No. 202-073 seeking approval to manufacture, use and sell Lupin's 75 mg, 150 mg, and 300 mg Tablets prior to the expiration of the '645 Patent.

27. The Lupin Paragraph IV Letter also states that the Lupin ANDA No. 202-073 included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '645 Patent is invalid.

28. In the Lupin Paragraph IV Letter, Lupin did not dispute that the commercial manufacture, use, or sale of Lupin's 75 mg, 150 mg, and 300 mg Tablets would infringe one or more claims of the '645 Patent.

29. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals continue to collaborate in seeking approval of ANDA No. 202-073 from the FDA and intend to collaborate in the commercial manufacture, marketing and sale of Lupin's 75 mg, 150 mg and 300 mg Tablets (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves ANDA No. 202-073.

30. Plaintiffs commenced this action within forty-five days of the date they received Lupin's Paragraph IV Notice of ANDA No. 202-073 containing the Paragraph IV certification.

COUNT I

Patent Infringement by Lupin

31. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 30 hereof, as if fully set forth herein.

32. Lupin has infringed the '645 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202-073 with a Paragraph IV certification and seeking FDA approval of ANDA No. 202-073 prior to the expiration of the '645 Patent.

33. Lupin's Paragraph IV Letter does not dispute that Lupin's 75 mg, 150 mg and 300 mg Tablets infringe one or more claims of the '645 Patent.

34. Lupin had actual and constructive notice of the '645 Patent prior to filing ANDA No. 202-073.

35. Plaintiffs have no adequate remedy at law to redress the infringement by Lupin.

36. Plaintiffs will be irreparably harmed if Lupin is not enjoined from infringing or actively inducing or contributing to infringement of the '645 Patent.

PRAYER

WHEREFORE, Plaintiffs respectfully request relief and judgment as follows:

(a) a judgment that Lupin has infringed the '645 Patent under 35 U.S.C. § 271(e)(2)(A);

(b) a judgment that the effective date of any FDA approval for the making, using, selling, offering for sale, or importing of the generic darunavir ethanolate tablets described in ANDA No. 202-073 by Lupin is not earlier than the day after the expiration of the period of pediatric exclusivity applicable to the '645 Patent;

(c) a judgment declaring that the making, using, selling, offering to sell, or importing of the generic darunavir ethanolate tablets described in ANDA No. 202-073 would constitute infringement of the '645 Patent, or inducing or contributing to such conduct, by Lupin pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(d) a judgment permanently enjoining Lupin and each of its officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially manufacturing, selling or offering for sale, using, or importing the darunavir ethanolate compositions claimed in the '645 Patent or otherwise infringing one or more claims of the '645 Patent;

(e) a declaration that this case is exceptional;

(f) an award of Plaintiffs' costs, expenses, reasonable attorneys' fees and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

(g) such other and further relief as the Court may deem just and proper.

Respectfully submitted,

/s/ John E. Flaherty

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