UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

THE UNITED STATES OF AMERICA and THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, Plaintiffs, v. MYLAN PHARMACEUTICALS INC. and LUPIN PHARMACEUTICALS, INC., and LUPIN LIMITED, 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 ("University of Illinois") (together, "Plaintiffs"), by their undersigned attorneys, for their Complaint against defendants Mylan Pharmaceuticals Inc. ("Mylan"), Lupin Pharmaceuticals, Inc., and Lupin Limited (together, "Lupin" and, collectively, "Defendants") 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 the Defendants' filing of Abbreviated New Drug Applications ("ANDAs") with the United States Food and Drug Administration (the "FDA") seeking approval to commercially manufacture and market generic versions of the pharmaceutical drug product Prezista® prior to the expiration of United States Patent No. 7,470,506 B1 (the "'506 patent"), which covers 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 Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia, 26504.

5. On information and belief, Lupin Pharmaceuticals, Inc. ("LPI") is a corporation organized and existing under the laws of the State of Virginia, having a principal place of business at Harborplace Tower, 111 South Calvert Street 21st floor Baltimore MD 21202. On information and belief, LPI is a wholly-owned subsidiary of Defendant Lupin Limited.

6. On information and belief, Defendant Lupin Limited is a corporation organized and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India. On information and belief, Lupin Limited, by itself and through its wholly-owned subsidiary, LPI, 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. Lupin Ltd. has previously submitted to the jurisdiction of this Court, and has availed itself of the jurisdiction of this Court by filing lawsuits and asserting counterclaims in lawsuits filed in the United States Court for the District of New Jersey.

JURISDICTION AND VENUE

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

8. This Court has personal jurisdiction over Mylan by virtue of, *inter alia*, its presence in New Jersey, having conducted 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.

9. This Court has personal jurisdiction over Lupin by virtue of, *inter alia*, its having conducted 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.

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

THE PATENT-IN-SUIT

11. 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.

12. As authorized by a license agreement with the University of Illinois, the government granted a non-exclusive license of the '506 patent to 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. ("Tibotec").

PREZISTA®

13. Tibotec holds approved New Drug Application No. 21-976 for Duranavir Ethanolate Tablets, 75 mg, 150 mg, 300 mg, 400 mg, and 600 mg dosage strengths, which are sold by Tibotec under the trade name Prezista®.

14. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '506 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to Prezista®.

DEFENDANTS' ANDAs

15. On information and belief, Mylan submitted ANDA No. 202-136 to the FDA pursuant to 12 U.S.C. § 355(j), seeking approval to commercially manufacture, use, and market Darunavir Ethanolate Tablets, 75 mg, 150 mg, 300 mg, 400 mg, and 600 mg dosage strengths.

16. On information and belief, Lupin submitted ANDA No. 202-073 to the FDA pursuant to 12 U.S.C. § 355(j), seeking approval to commercially manufacture, use, and market Darunavir Ethanolate Tablets, 400 mg and 600 mg dosage strengths. The Darunavir Ethanolate Tablets described in Mylan's ANDA No. 202-136 and Lupin's ANDA No. 202-073 (collectively, the "Defendants' ANDAs") are herein referred to as "Defendants' Products."

17. The Defendants' ANDAs refer to, and rely upon, the Prezista® NDA and contain data that, according to the Defendants, demonstrate the bioequivalence of the Defendants' Products to Prezista®.

18. The government and the University of Illinois received letters from each of the Defendants, dated October 1, 2010, and attached memoranda (collectively, the "Defendants' Notifications"), stating that the Defendants had included certifications in their respective ANDAs, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '506 patent is invalid,

unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Defendants' Products (the Paragraph IV certifications). The Plaintiffs received notice of the Defendants' ANDA on October 1, 2010 and are filing this complaint within the 45 day interval specified by 21 U.S.C. § 355(c)(3)(C).

COUNT ONE: INFRINGEMENT OF THE '506 PATENT

19. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-17 of this Complaint.

20. Defendants have infringed the '506 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Defendants' ANDAs, by which the Defendants' seek approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Defendants' Products prior to the expiration of the '506 patent.

21. Defendants' commercial manufacture, use, offer to sell, or sale of the Defendants' Products within the United States, or importation of the Defendants' Products into the United States, during the term of the '506 patent would further infringe the '506 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

22. The Plaintiffs will be substantially and irreparably harmed if the Defendants are not enjoined from infringing the '506 patent.

23. The Plaintiffs have no adequate remedy at law.

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

COUNT TWO: INDUCEMENT OF INFRNGEMENT OF THE '506 PATENT

25. Under 35 USC 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer."

26. The proposed generic versions of Prezista as described in ANDA Nos. 202-136 and 202-073, if utilized in treatment according to their proposed indications, will infringe every limitation of at least one claim of the '506 patent.

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

28. In addition, if ANDA Nos. 202-136 and 202-073 are approved, Defendants will be knowingly, intentionally, deliberately and actively involved in inducing treating physicians, among others, to utilize Defendants' Products in a manner that infringes the '506 patent.

29. Defendants are therefore liable under 35 U.S.C. 271(e)(2) for inducement of infringement of the '506 patent.

PRAYER FOR RELIEF

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

A. A Judgment that Defendants have infringed U.S. Patent No. 7,470,506 B1;

B. A Judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining the Defendants, their 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 the Defendants' Products within the United States, or importing the Defendants' Products into the United States, prior to the expiration of the '506 patent;

C. A Judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA Nos. 202-136 and 202-073 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 '506 patent, including any extensions;

D. If Defendants commercially manufacture, use, offer to sell, or sell the Defendants' Products within the United States, or import the Defendants' Products into the United States, prior to the expiration of the '506 patent, including any extensions, a Judgment awarding Plaintiffs monetary relief together with interest;

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

F. Costs and expenses in this action; and

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

Dated: November 15, 2010

Respectfully submitted,

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LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby certify that the matter captioned TIBOTEC INC. and TIBOTEC PHARMACEUTICALS v. LUPIN LIMITED, LUPIN PHARMACEUTICALS INC., MYLAN PHARMACEUTICALS INC. and MYLAN INC., is a related patent infringement case because the matter involves all of the same defendants and the same Abbreviated New Drug Application seeking FDA approval to market a generic version of the same drug product, Prezista®.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: November 15, 2010

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