UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

THE UNITED STATES OF AMERICA and THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS,	Civil Action No. _____
Plaintiffs,	**COMPLAINT FOR PATENT INFRINGEMENT**
v.	
TEVA PHARMACEUTICALS USA, INC.	**(Filed Electronically)**
Defendant.	

Plaintiffs the United States of America (the"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 defendant Teva Pharmaceuticals USA, Inc. ("Teva") 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 Teva's filing of Abbreviated New Drug Application ("ANDA") 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 Teva is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, PA 19454-1090.

JURISDICTION AND VENUE

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

6. This Court has personal jurisdiction over Teva by virtue of, *inter alia*, its having conducted business in New Jersey, having availed itself of the rights and benefits of New Jersey law, having previously consented to personal jurisdiction in this Court, having availed itself of the jurisdiction of this Court, and having engaged in systematic and continuous contacts with the State of New Jersey.

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

THE PATENT-IN-SUIT

8. 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.

9. 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.). Tibotec Pharmaceuticals ("Tibotec") is an Irish corporation having its principal place of business as Eastgate Village, Eastgate, Little Island, County Cork, Ireland.

PREZISTA®

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

11. 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®.

TEVA’S ANDA

12. On information and belief, Teva submitted ANDA No. 202118 to the FDA pursuant to 12 U.S.C. § 355(j), seeking approval to commercially manufacture, use, and market Darunavir Hydrate Tablets, 75 mg, 150 mg, 400 mg, and 600 mg dosage strengths (“Teva’s Product”).

13. Teva’s ANDA refers to, and relies upon, the Prezista® NDA and contains data that, according to Teva, demonstrates the bioequivalence of Teva’s Product to Prezista®.

14. The government and the University of Illinois received letters from Teva, dated January 31, 2011, and attached memoranda (collectively, "Teva's Notifications"), stating that Teva had included certifications in its ANDA, 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 Teva's Product (the "Paragraph IV certifications"). The Plaintiffs received notice of Teva's ANDA on February 3, 2011 and are filing this complaint within 45 day interval of receipt as specified by 21 U.S.C. § 355(c)(3)(C).

COUNT ONE: INDUCEMENT OF INFRINGEMENT OF THE '506 PATENT

15. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-14 of this Complaint.

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

17. The proposed generic versions of Prezista® as described in ANDA No. 202118, if utilized in treatment according to their proposed indications, will infringe every limitation of at least one claim of the '506 patent.

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

19. In addition, if ANDA No. 202118 is approved, Teva will be knowingly, intentionally, deliberately and actively involved in inducing treating physicians, among others, to utilize Teva's Product in a manner that infringes the '506 patent.

20. Teva 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

21. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-20 of this Complaint.

22. The proposed generic versions of Prezista® as described in ANDA No. 202118, if utilized in treatment according to their proposed indications, will infringe every limitation of at least one claim of the '506 patent.

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

24. Teva's commercial manufacture, use, offer to sell, or sale of Teva's Product within the United States, or importation of Teva's Product into the United States while knowing Teva's Product to be especially made or especially adapted for use in an infringement of the '506 patent, 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).

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

26. The Plaintiffs have no adequate remedy at law.

27. 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 Teva, and respectfully request the following relief:

A. A Judgment that Teva has induced infringement and contributorily 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 Teva, 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 Teva's Product within the United States, or importing Teva's Product 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 No. 202118 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 Teva commercially manufactures, uses, offers to sell, or sells Teva's Product within the United States, or imports Teva's Product 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: March 11, 2011

Respectfully submitted,

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