

Walter W. Brown  
Trial Attorney  
Commercial Litigation Branch  
Intellectual Property Staff  
Civil Division  
Department of Justice  
Washington, DC 20530  
(202)307-0341  
walter.brown2@usdoj.gov

*Attorneys for Plaintiff  
United States of America*

Charles M .Lizza  
Sarah A. Sullivan  
SAUL EWING LLP  
One Riverfront Plaza, Suite 1520  
Newark, New Jersey 07102-5426  
(973) 286-6700  
clizza@saul.com

*Attorneys for Plaintiff  
Board of Trustees of  
the University of Illinois*

**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,	)	Civil Action No. _____
		)	
	v.	)	<b>COMPLAINT FOR</b>
		)	<b>PATENT INFRINGEMENT</b>
LUPIN LIMITED.,		)	
		)	<b>(Filed Electronically)</b>
	Defendant.	)	
_____		)	

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 defendant Lupin Limited (“Lupin” or “Defendant”) 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 Lupin’s filing of an 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. 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. Lupin 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 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. Lupin also has consented to jurisdiction in this District in other matters concerning the same ANDA. *See Janssen, et al. v. Lupin Limited, et al.*, Civil Action No. 10-5954 (WHW)(SCM).

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 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.

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 (now known as Janssen Products, L.P.), an Irish corporation having its principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland ("Janssen").

**PREZISTA®**

10. Janssen holds approved New Drug Application No. 21-976 for Darunavir Ethanolate Tablets, in 75 mg, 150 mg, 300 mg, 400 mg, 600 mg, and 800 mg dosage strengths, which are sold by Janssen 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®.

**DEFENDANT'S ANDA**

12. On information and belief, Lupin submitted ANDA No. 202-073 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to commercially manufacture, use, and

market Darunavir Ethanolate Tablets, 800 mg (“Lupin’s Product”).

13. Lupin’s ANDA No. 202-073 relies upon the Prezista® New Drug Application and contains data that, according to Lupin, demonstrate the bioequivalence of Lupin’s Product to Prezista®.

14. On May 14, 2013, the government and the University of Illinois received letters from Lupin, dated May 13, 2013, and attached memoranda (collectively, “Lupin’s Notifications”), stating that Lupin had included a certification 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 Lupin’s Product (the “Paragraph IV Certifications”). The Plaintiffs are filing this complaint within 45 days of receipt of Lupin’s Notifications 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 Lupin’s ANDA No. 202-073, if utilized in treatment according to their proposed indications, will infringe every limitation of at least one claim of the ’506 patent.

18. Lupin 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 Lupin’s ANDA No. 202-073 is approved, Lupin will be knowingly, intentionally, deliberately, and actively involved in inducing treating physicians,

among others, to utilize Lupin's Product in a manner that infringes the '506 patent.

20. Lupin 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 Lupin's ANDA No. 202-073, if utilized in treatment according to their proposed indications, will infringe every limitation of at least one claim of the '506 patent.

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

24. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe the '506 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Lupin's Product in the United States. Upon information and belief, Lupin has had and continues to have knowledge that Lupin's Product is especially adapted for a use that infringes the '506 patent and that there is no substantial noninfringing use for Lupin's Product.

25. The Plaintiffs will be substantially and irreparably harmed if Lupin 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 Lupin, and respectfully request the following relief:

- A. A Judgment that Lupin has 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 Lupin, its officers, agents, servants, employees, and those persons acting in concert or participation with any of them, from commercially manufacturing, using, offering to sell, or selling Lupin's Product within the United States, or importing Lupin's Product into the United States, prior to the expiration of the '506 patent, including any extensions;
- C. A Judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 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 Lupin commercially manufactures, uses, offers to sell, or sells Lupin's Product within the United States, or imports Lupin's Product into the United States, prior to the expiration of the '506 patent, including any extensions, a Judgment awarding Plaintiffs damages in the form of 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: June 27, 2013

STUART F. DELERY  
Acting Assistant Attorney General

PAUL J. FISHMAN  
United States Attorney  
District of New Jersey

s/ Daniel Gibbons  
DANIEL GIBBONS  
Assistant Chief, Civil Division  
United States Attorney's Office  
District of New Jersey  
970 Broad Street, 7th Floor  
Newark, NJ 07102  
Telephone: 973-645-2700  
Facsimile: 973-645-2702  
daniel.gibbonS@usdoj.gov

JOHN FARGO  
Director, Intellectual Property Staff

s/ Walter W. Brown  
WALTER W. BROWN  
Trial Attorney  
Commercial Litigation Branch  
Intellectual Property Staff  
Civil Division  
Department of Justice  
Washington, DC 20530  
Telephone: 202-307-0341  
Facsimile: 202-307-0345  
walter.brown2@usdoj.gov

*Attorneys for Plaintiff  
United States of America*

Respectfully submitted,

s/ Charles M. Lizza  
CHARLES M. LIZZA  
SARAH A. SULLIVAN  
SAUL EWING LLP  
One Riverfront Plaza, Suite 1520  
Newark, New Jersey 07102-5426  
(973) 286-6700  
clizza@saul.com

Of Counsel:  
JASON G. WINCHESTER  
JONES DAY  
77 West Wacker Dr.  
Chicago, Illinois 60601-1692  
(312) 782-3939

*Attorneys for Plaintiff  
Board of Trustees of  
the University of Illinois*