David E. De Lorenzi
Sheila F. McShane
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Telephone: (973) 596-4500
Facsimile: (973) 596-0545

Dimitrios T. Drivas
Jeffrey J. Oelke
James S. Trainor, Jr.
Ryan P. Johnson
WHITE & CASE LLP
1155 Avenue of the Americas
New York, New York 10036
Telephone: (212) 819-8200
Facsimile: (212) 354-8113

Attorneys for Plaintiffs Pfizer Inc., Pharmacia & Upjohn Company LLC, and Pfizer Health AB

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PFIZER INC., PHARMACIA & UPJOHN COMPANY LLC, and PFIZER HEALTH AB, Plaintiffs, v. LUPIN LTD. and LUPIN PHARMACEUTICALS, INC., Defendants.	Civil Action No.:_____ ***Document electronically filed.*** **COMPLAINT**

Plaintiffs Pfizer Inc., Pharmacia & Upjohn Company LLC, and Pfizer Health AB (collectively, "Pfizer"), by their attorneys, White & Case LLP and Gibbons P.C., for their Complaint against Defendants Lupin Ltd., and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"), allege:

THE PARTIES

1. Plaintiff Pfizer Inc., is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 235 East 42nd Street, New York, New York.

2. Plaintiff Pharmacia & Upjohn Company LLC is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 7000 Portage Road, Kalamazoo, Michigan. Pfizer Inc. is the ultimate parent of Pharmacia & Upjohn Company LLC.

3. Plaintiff Pfizer Health AB is a company organized and existing under the laws of Sweden, having a place of business at SE-112 87, Stockholm, Sweden. Pfizer Inc. is the ultimate parent of Pfizer Health AB.

4. Upon information and belief, Defendant Lupin Ltd. is a company organized and existing under the laws of India, having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashta 400 051, India.

5. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Virginia, having a principal place of business at 111 S. Calvert Street, Suite 2100, Baltimore, Maryland 21202. Upon information and belief, Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Lupin Ltd.

JURISDICTION AND VENUE

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

7. Upon information and belief, Lupin is in the business of making and selling generic drug products.

8. Upon information and belief, Lupin conducts business in New Jersey and sells various drug products in the United States, including in the State of New Jersey.

9. Upon information and belief, Lupin is registered to do business in the State of New Jersey and has appointed National Registered Agents, Inc., located at 100 Canal Pointe Blvd., Suite 212, Princeton, NJ 08540, as its registered agent for service in New Jersey.

10. Lupin has been sued in this District and has previously submitted to the jurisdiction of this Court.

11. Lupin has availed itself of the jurisdiction of this Court by asserting counterclaims in lawsuits filed in this Court.

12. This court has personal jurisdiction over Lupin by virtue of, inter alia, the allegations of paragraphs 8-11 of this Complaint.

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

U.S. Patent No. 6,630,162

14. On October 7, 2003, the United States Patent and Trademark Office issued United States Patent No. 6,630,162 (the "'162 patent"), entitled "Pharmaceutical Formulation

and its Use." At the time of its issue, the '162 patent was assigned to Pharmacia AB. Pfizer Health AB currently holds title to the '162 patent. A copy of the '162 patent is attached hereto as **Exhibit A**.

15. The '162 patent is directed to and claims, inter alia, an oral pharmaceutical formulation for administering *tolterodine*, as well as a method of treatment comprising administering a therapeutically effective amount of such a formulation.

U.S. Patent No. 6,770,295

16. On August 3, 2004, the United States Patent and Trademark Office issued United States Patent 6,770,295 (the "'295 patent"), entitled "Therapeutic Formulation for Administering Tolterodine with Controlled Release." At the time of its issue, the '295 patent was assigned to Pharmacia & Upjohn AB. Pfizer Health AB currently holds title to the '295 patent. A copy of the '295 patent is attached hereto as **Exhibit B**.

17. The '295 patent is directed to and claims, inter alia, an improved method of treating unstable or overactive bladder, as well as a formulation therefor.

Detrol® LA

18. Pharmacia & Upjohn Company LLC holds an approved New Drug Application (the "Detrol® LA NDA") for *tolterodine tartrate* extended-release capsules, in 2 and 4 mg dosages, which are sold by Pfizer Inc., under the trade name Detrol® LA.

19. Pursuant to 21 U.S.C. § 355(b)(1), and attendant United States Food and Drug Administration ("FDA") regulations, the '162 and '295 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Detrol® LA.

Lupin's ANDA

20. Lupin submitted Abbreviated New Drug Application No. 204-689 (the "Lupin ANDA") to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market *tolterodine tartrate* extended-release capsules, in 2 and 4 mg dosages (the "Lupin Product").

21. The Lupin ANDA refers to and relies upon the Detrol® LA NDA and contains data that, according to Lupin, demonstrate the bioequivalence of the Lupin Product and Detrol® LA.

22. On or about February 11, 2013, Pfizer received from Lupin a letter and attached memorandum, dated February 8, 2013, stating that Lupin had included in its ANDA a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that each of the '162 and '295 patents is invalid, unenforceable, or would not be infringed by the manufacture, use, or sale of the Lupin Product.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,630,162

23. Pfizer realleges and incorporates by reference the allegations of paragraphs 1-22 of this Complaint.

24. Lupin has infringed the '162 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting ANDA No. 204-689, by which Lupin seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of the Lupin Product prior to the expiration of the '162 patent.

25. If Lupin commercially makes, uses, offers to sell, and/or sells the Lupin Product within the United States, or imports the Lupin Product into the United States, or induces or contributes to any such conduct during the term of the '162 patent, it would further infringe the '162 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

26. Pfizer will be irreparably harmed if Lupin is not enjoined from infringing the ‘162 patent. Pfizer does not have an adequate remedy at law.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,770,295

27. Pfizer hereby realleges and incorporates by reference the allegations of paragraphs 1-22 of this Complaint.

28. Lupin has infringed the ‘295 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting ANDA No. 204-689, by which Lupin seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of the Lupin Product prior to the expiration of the ‘295 patent.

29. If Lupin commercially makes, uses, offers to sell, and/or sells the Lupin Product within the United States, or imports the Lupin Product into the United States, or induces or contributes to any such conduct during the term of the ‘295 patent, it would further infringe the ‘295 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

30. Pfizer will be irreparably harmed if Lupin is not enjoined from infringing the ‘295 patent. Pfizer does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Pfizer prays for a judgment in its favor and against Lupin, as follows:

A. That Lupin has infringed the ‘162 patent;

B. That Lupin has infringed the ‘295 patent;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Lupin, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from making, using, selling, offering to

sell the Lupin Product within the United States, or importing the Lupin Product into the United States prior to the expiration of the '162 and '295 patents;

D. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 204-689 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '162 and '295 patents, including any extensions;

E. That Plaintiffs be awarded monetary relief if Lupin commercially makes, uses, sells, or offers to sell the Lupin Product within the United States, or imports the Lupin Product into the United States, prior to the expiration of any of the '162 and '295 patents, including any extensions, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest; and

F. That Plaintiffs be awarded such other relief as the Court deems just and proper.

Dated: March 21, 2013
New York, NY

Respectfully submitted,

By: s/ Sheila F. McShane
David E. De Lorenzi
Sheila F. McShane
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Telephone: (973) 596-4500
Facsimile: (973) 596-0545

Attorneys for Plaintiffs Pfizer Inc., Pharmacia & Upjohn Company LLC, and Pfizer Health AB

OF COUNSEL

Dimitrios T. Drivas
Jeffrey J. Oelke
James S. Trainor, Jr.
Ryan P. Johnson
WHITE & CASE LLP
1155 Avenue of the Americas
New York, New York 10036
Telephone: (212) 819-8200
Facsimile: (212) 354-8113