

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
Adam Gahtan
James S. Trainor, Jr.
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.

TORRENT PHARMACEUTICALS LTD., and
TORRENT PHARMA INC.,

Defendants.

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 Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (together, “Torrent”), 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 Torrent Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Torrent House, Off Ashram Road, Ahmedabad, 380009.

5. Upon information and belief, Torrent Pharmaceuticals Ltd. is in the business of, among other things, manufacturing, marketing and selling generic copies of branded pharmaceutical products throughout the United States, including in New Jersey.

6. Upon information and belief, Torrent Pharma Inc. is a corporation organized and existing under the laws of Michigan, having its principal place of business at 5380 Holiday Terrace, Suite 40, Kalamazoo, Michigan 49009.

7. Upon information and belief, Torrent Pharma Inc. is in the business of, among other things, manufacturing, marketing and selling generic copies of branded pharmaceutical products throughout the United States, including in New Jersey.

8. Upon information and belief, Torrent Pharma Inc. is a wholly-owned subsidiary of Torrent Pharmaceuticals Ltd. and operates as Torrent Pharmaceuticals Ltd.'s U.S. agent.

9. Upon information and belief, Torrent Pharma Inc. sells, in New Jersey and throughout the United States, generic drugs manufactured by Torrent Pharmaceuticals Ltd.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

11. This Court has personal jurisdiction over Torrent by virtue of, inter alia: (1) its presence in New Jersey, (2) its systematic and continuous contacts with New Jersey, including its substantial and ongoing sales of generic drugs in New Jersey, and (3) its prior consent to jurisdiction in this Judicial District.

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

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

13. 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 as Exhibit A.

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

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

15. On August 3, 2004, the United States Patent and Trademark Office issued United States Patent No. 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 as Exhibit B.

16. 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

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

18. Pursuant to 21 U.S.C. §§ 355(b)(1), 355(c)(2), and 355(j)(7)(A) 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.

Torrent's ANDA

19. Torrent submitted Abbreviated New Drug Application No. 203016 (the "Torrent ANDA") to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market *tolterodine tartrate* extended-release capsules in 2 mg and 4 mg dosages (the "Torrent Product").

20. The Torrent ANDA refers to and relies upon the Detrol[®] LA NDA and contains data that, according to Torrent, demonstrate the bioequivalence of the Torrent Product and Detrol[®] LA.

21. On or about June 23, 2011, Pfizer received from Torrent a letter and attached memorandum, dated June 17, 2011 (collectively, the “Torrent Notification”), stating that Torrent had included in its ANDA a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the ‘162 and ‘295 patents are invalid, unenforceable, or would not be infringed by the manufacture, use, or sale of the Torrent Product.

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

22. Pfizer hereby realleges and incorporates by reference the allegations of paragraphs 1-21 of this Complaint.

23. Torrent has infringed the ‘162 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting ANDA No. 203016, by which Torrent seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of the Torrent Product prior to the expiration of the ‘162 patent.

24. If Torrent commercially makes, uses, offers to sell, and/or sells the Torrent Product within the United States, or imports the Torrent 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).

25. Pfizer will be irreparably harmed if Torrent 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

26. Pfizer hereby realleges and incorporates by reference the allegations of paragraphs 1-21 of this Complaint.

27. Torrent has infringed the '295 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting ANDA No. 203016, by which Torrent seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of the Torrent Product prior to the expiration of the '295 patent.

28. If Torrent commercially makes, uses, offers to sell, and/or sells the Torrent Product within the United States, or imports the Torrent 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).

29. Pfizer will be irreparably harmed if Torrent is not enjoined from infringing the '295 patent. Pfizer does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Pfizer Inc., Pharmacia & Upjohn Company LLC, and Pfizer Health AB (collectively, "Pfizer") pray for a judgment in their favor and against Defendants Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (together, "Torrent"), as follows:

- A. That Torrent has infringed U.S. Patent No. 6,630,162;
- B. That Torrent has infringed U.S. Patent No. 6,770,295;
- C. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Torrent, 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, or offering to sell the Torrent Product within the United States, or importing the Torrent 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. 203016 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 Pfizer be awarded monetary relief if Torrent commercially makes, uses, sells, or offers to sell the Torrent Product within the United States, or imports the Torrent Product into the United States, prior to the expiration of either of the '162, and '295 patents, including any extensions, and that any such monetary relief be awarded to Pfizer with prejudice interest;

F. That Pfizer be awarded reasonable attorneys' fees, costs, and expenses because this is an exceptional case under 35 U.S.C. § 285; and

G. That Pfizer be awarded such other relief as the Court deems just and proper.

Dated: July 25, 2011
Newark, NJ

Respectfully submitted,

By: s/ Sheila F. McShane
David E. DeLorenzi
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
Adam Gahtan
James S. Trainor, Jr.
WHITE & CASE LLP
1155 Avenue of the Americas
New York, New York 10036
Telephone: (212) 819-8200
Facsimile: (212) 354-8113