

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

PFIZER INC.,
PHARMACIA & UPJOHN COMPANY LLC, and
PFIZER HEALTH AB,

Plaintiffs,

v.

INVENTIA HEALTHCARE PRIVATE LTD.,

Defendant.

Civil Action No.: 13-cv-2986

Hon. _____

Magistrate Hon. _____

COMPLAINT

Plaintiffs Pfizer Inc., Pharmacia & Upjohn Company LLC, and Pfizer Health AB (collectively, “Pfizer”), by their attorneys, White & Case LLP and Kirkland & Ellis LLP, for their Complaint against Defendant Inventia Healthcare Private Ltd. (“Inventia”), 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 Inventia Healthcare Private Ltd., is a company organized and existing under the laws of India, having a principal place of business at 505 VIP Plaza, Veera Industrial Estate, Link Road, Andheri (West), Mumbai, Maharashtra 400 053, India.

JURISDICTION AND VENUE

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

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

7. Upon information and belief, Inventia conducts business in the State of Illinois and in this District and sells drug products in this state and District, and throughout the United States, either directly or indirectly through one or more distributors registered to do business in the State of Illinois.

8. Inventia has authorized one or more persons residing within this District to accept service of process on its behalf for purposes of this Action for patent infringement.

9. This Court has personal jurisdiction over Inventia by virtue of, inter alia, the allegations of Paragraphs 7 and 8 of this Complaint. Alternatively, this Court has personal jurisdiction over Inventia pursuant to Fed. R. Civ. P. 4(k).

10. Venue is proper in this District pursuant to 28 U.S.C. § 1391.

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

11. 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.**

12. 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

13. 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.**

14. 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

15. 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.

16. 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 the Detrol[®] LA NDA.

Inventia’s ANDA

17. Inventia submitted Abbreviated New Drug Application No. 204562 (the “Inventia 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 “Inventia Product”).

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

19. On or about March 13, 2013, Pfizer received from Inventia a letter and attached memorandum, dated March 8, 2013, setting forth that Inventia 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 Inventia Product.

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

20. Pfizer realleges and incorporates by reference the allegations of Paragraphs 1-19 of this Complaint.

21. Inventia has infringed the ‘162 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting ANDA No. 204562, by which Inventia seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of the Inventia Product prior to the expiration of the ‘162 patent.

22. If Inventia commercially makes, uses, offers to sell, and/or sells the Inventia Product within the United States, or imports the Inventia Product into the United States,

or induces or contributes to any such conduct during the term of the '162 patent, it further would infringe the '162 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

23. Pfizer will be irreparably harmed if Inventia 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

24. Pfizer hereby realleges and incorporates by reference the allegations of Paragraphs 1-19 of this Complaint.

25. Inventia has infringed the '295 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting ANDA No. 204562, by which Inventia seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of the Inventia Product prior to the expiration of the '295 patent.

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

27. Pfizer will be irreparably harmed if Inventia 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 Inventia, as follows:

- A. That Inventia has infringed the '162 patent;
- B. That Inventia has infringed the '295 patent;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Inventia, 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 Inventia Product within the United States, or importing the Inventia 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. 204562 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 Inventia commercially makes, uses, sells, or offers to sell the Inventia Product within the United States, or imports the Inventia 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: April 19, 2013

Respectfully submitted,

By: /s/ Marcus E. Sernel
Marcus E. Sernel, P.C. (#6243853)
Reid P. Huefner (#6291648)
KIRKLAND & ELLIS LLP
300 North LaSalle Street
Chicago, IL 60654
Telephone: (312) 862-2389
Facsimile: (312) 862-2200
marc.sernel@kirkland.com
reid.huefner@kirkland.com

*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

**UNITED STATES DISTRICT COURT
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<div style="display: flex; justify-content: space-between;"><div style="width: 80%;"><p>PFIZER INC., PHARMACIA & UPJOHN COMPANY LLC, and PFIZER HEALTH AB,</p><p style="text-align: right;">Plaintiffs,</p><p style="text-align: center;">v.</p><p>INVENTIA HEALTHCARE PRIVATE LTD.,</p><p style="text-align: right;">Defendant.</p></div><div style="width: 10%; text-align: center; font-size: 2em;">)</div></div>)	Civil Action No.:13-cv-2986 Hon. _____ Magistrate Hon. _____
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LOCAL RULE 3.2 STATEMENT

Pursuant to Local Rule 3.2, Plaintiffs, through their counsel, hereby state that:

- (1) Pfizer Inc. has no shareholder owning more than 5% of its equity;
- (2) Pharmacia & Upjohn Company LLC has the following affiliates and subsidiaries:

Pharmacia & Upjohn Company, Inc.; Pfizer Holdings Luxembourg Sarl; Pharmacia Hepar Inc.; Upjohn International Holding Company; Upjohn Pharmaceuticals Limited (a/k/a UPL - Kalamazoo Branch); Greenstone LLC (formerly Greenstone Ltd.); Pfizer Mexico, S.A. de C.V. (formerly Pharmacia de Mexico, SA de CV); Pharmacia International Inc.; Pfizer (Thailand) Ltd. Representative Office; Wyeth (Thailand) Ltd; Pfizer (Thailand) Ltd (formerly Pharmacia Thailand Ltd. a/k/a Upjohn Co. Ltd); Pharmacia Inter-American Corporation; Pfizer S.A.; Pharmacia & Upjohn Trading Corporation; Pharmacia Limited Company (formerly Pharmacia & Upjohn Limited

Company); Pharmacia Inter-American LLC (formerly known as Pharmacia Inter-American Corporation); The Upjohn Manufacturing Company LLC; The Upjohn Holding Company M LLC; Korea Pharma Holding Company Limited; Pfizer Parke Davis (Thailand) Ltd. (formerly G.D. Searle (Thailand) Ltd.); G.D. Searle International Capital LLC; Searle & Co.; Searle LLC; Continental Pharma, Inc.; and G.D. Searle LLC; and

(3) Regarding Pfizer Health AB, Pfizer Inc. is its ultimate parent company.

Dated: April 19, 2013

Respectfully submitted,

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KIRKLAND & ELLIS LLP
300 North LaSalle Street
Chicago, IL 60654
Telephone: (312) 862-2389
Facsimile: (312) 862-2200
marcus.sernel@kirkland.com
reid.huefner@kirkland.com

*Attorneys for Plaintiffs Pfizer Inc.,
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OF COUNSEL

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Ryan P. Johnson
WHITE & CASE LLP
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New York, New York 10036
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KIRKLAND & ELLIS LLP
300 North LaSalle Street
Chicago, IL 60654
Telephone: (312) 862-2389
Facsimile: (312) 862-2200
marcus.sernel@kirkland.com
reid.huefner@kirkland.com
*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
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Facsimile: (212) 354-8113