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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PFIZER INC., PHARMACIA & UPJOHN COMPANY LLC, and PFIZER HEALTH AB, Plaintiffs, v. MYLAN INC., and MYLAN 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, Gibbons P.C., and White & Case LLP, for their Complaint against Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, "Mylan"), 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 Mylan Inc., formerly known as Mylan Laboratories Inc., is a corporation organized under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

5. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia. Upon information and belief, Mylan Pharmaceuticals Inc., is a wholly owned subsidiary of Mylan Inc.

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, Mylan is in the business of making and selling generic drug products.

8. Upon information and belief, Mylan 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, Mylan is registered to do business in New Jersey and has appointed Corporation Service Company, located at 830 Bear Tavern Road, West Trenton, New Jersey 08628, as its registered agent for service in New Jersey.

10. Mylan has sued and been sued in this District.

11. Mylan has submitted to the jurisdiction of this Court.

12. This Court has personal jurisdiction over Mylan 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* 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

16. 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 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.

Mylan's ANDA

20. Mylan submitted Abbreviated New Drug Application No. 201486 (the "Mylan 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 "Mylan Product").

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

22. On or about May 14, 2010, Pfizer received from Mylan a letter and attached memorandum, dated May 13, 2010 (collectively, the "Mylan Notification"), stating that Mylan 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 Mylan Product (the "Paragraph IV Certification").

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

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

24. Mylan has infringed the '162 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting ANDA No. 201486, by which Mylan seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of the Mylan Product prior to the expiration of the '162 patent.

25. If Mylan commercially makes, uses, offers to sell, and/or sells the Mylan Product within the United States, or imports the Mylan 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 Mylan 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. Mylan has infringed the '295 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting ANDA No. 201486, by which Mylan seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of the Mylan Product prior to the expiration of the '295 patent.

29. If Mylan commercially makes, uses, offers to sell, and/or sells the Mylan Product within the United States, or imports the Mylan 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 Mylan 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 pray for a judgment in their favor and against Defendant Mylan, as follows:

A. That Mylan has infringed U.S. Patent No. 6,630,162;

B. That Mylan has infringed U.S. Patent No. 6,770,295;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Mylan, 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 Mylan Product within the United States, or importing the Mylan 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. 201486 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 Mylan commercially makes, uses, sells, or offers to sell the Mylan Product within the United States, or imports the Mylan 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 Plaintiffs with prejudgment interest;

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

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

Dated: June 24, 2010
Newark, NJ

Respectfully submitted,

By: s/ Sheila F. McShane

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