Robert J. Fettweis
Tressler, LLP
744 Broad Street – Suite 1510
Newark, NJ 07102
(973) 848-2900
(973) 623-0405 (fax)

Attorneys for Plaintiff
Impax Laboratories, Inc.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IMPAX LABORATORIES, INC., Plaintiff, v. PFIZER INC., PHARMACIA & UPJOHN COMPANY LLC, and PFIZER HEALTH AB, Defendants.	Civil Action No.:_____ ***Document electronically filed.*** **COMPLAINT**

Plaintiff Impax Laboratories, Inc. ("Impax"), by its attorneys, Tressler, LLP, for its Complaint against Defendants Pfizer, Inc., Pharmacia & Upjohn Company, LLC, and Pfizer Health AB (collectively, "Pfizer"), alleges:

JURISDICTION AND VENUE

1. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

3. This Court has personal jurisdiction over Pfizer 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 sale of pharmaceutical products in New Jersey; (3) its assertion of related patents and consent to jurisdiction in this judicial district in Civil Action Nos. 2:08-cv-1331, 2:10-cv-3246, and 2:10-cv-3250; and (4) its assertion of related patents against the same Abbreviated New Drug Application No. 90-235 and consent to jurisdiction in this judicial district in Civil Action No. 2:08-cv-2137.

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

THE PARTIES

5. Plaintiff Impax is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 30831 Huntwood Avenue, Haywood, California.

6. Upon information and belief, Defendant 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.

7. Upon information and belief, Defendant 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, MI. Pfizer, Inc. is the ultimate parent of Pharmacia & Upjohn Company LLC.

8. Upon information and belief, Defendant 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.

FACTUAL BACKGROUND

Orange Book Listing of the '600, '162, '295, and '217 Patents

9. Upon information and belief, U.S. Patent No. 5,382,600 (the "'600 Patent"), entitled "3,3-Diphenylpropylamines And Pharmaceutical Compositions Thereof," was issued by the United States Patent and Trademark Office ("USPTO") on January 17, 1995. Pharmacia AB is listed as the assignee on the face of the '600 Patent.

10. Upon information and belief, U.S. Patent No. 6,630,162 (the "'162 Patent"), entitled "Pharmaceutical Formulation and Its Use," was issued by the USPTO on October 7, 2003. Pharmacia AB is listed as the assignee on the face of the '162 Patent.

11. Upon information and belief, U.S. Patent No. 6,770,295 (the "'295 Patent"), entitled "Therapeutic Formulation For Administering Tolterodine With Controlled Release," was issued by the USPTO on August 3, 2004. Pharmacia AB is listed as the assignee on the face of the '162 Patent.

12. Upon information and belief, U.S. Patent No. 6,911,217 (the "'217 Patent"), entitled "Controlled Release Bead, A Method of Producing the Same and Multiple Unit Formulation Comprising It," was issued by the USPTO on June 28, 2005. Pharmacia AB is listed as the assignee on the face of the '217 Patent. A copy of the '217 Patent is attached as Exhibit A.

13. Upon information and belief, and according to Pfizer's Web site, Pharmacia AB and The Upjohn Company merged to form Pharmacia & Upjohn in 1995.

14. Upon information and belief, and according to Pfizer's Web site, Pharmacia & Upjohn merged with Searle and Monsanto to create Pharmacia Corp. in 2000.

15. Upon information and belief, and according to Pfizer's Web site, Pfizer Inc. and Pharmacia Corp. began operating as a unified company on April 16, 2003.

16. Upon information and belief, Pharmacia & Upjohn LLC is the current holder of approved New Drug Application ("NDA") No. 021228 for tolterodine tartrate extended-release capsules in 2 and 4 mg dosages. Pfizer sells drug products under NDA 021228 in the United States, including in this District, under the registered name Detrol® LA.

17. 21 U.S.C. §§ 355(b)(1) and (c)(2) of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act require NDA holders to disclose to the United States Food and Drug Administration ("FDA") the patent numbers and expiration dates of those patents that the holders believe claim the "drug" for which their NDA is submitted, or patents covering a "method of using such drug."

18. Upon information and belief, pursuant to 21 U.S.C. § 355(b)(1)(G), Pfizer caused the FDA to publish the '600, '162, '295, and '217 Patents in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") in connection with NDA No. 021228. A copy of the electronic version of the Orange Book obtained on December 14, 2010 is attached as Exhibit B.

19. By maintaining the listing of the '600, '162, '295, and '217 Patents in the Orange Book, Pfizer represents that these patents could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. 21 U.S.C. § 355(b)(1)(G).

Impax's Abbreviated New Drug Application

20. Pursuant to the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 355(j), Impax submitted Abbreviated New Drug Application ("ANDA") No. 90-235 ("Impax's ANDA") seeking

FDA approval to engage in the manufacture, use, or sale of its Tolterodine Extended-Release Capsules, 4mg and 2mg (by amendment) ("Impax's proposed Tolterodine ER Capsules").

21. Impax's ANDA refers to the Detrol® LA NDA and contains data that Impax believes demonstrates bioequivalence of Impax's proposed Tolterodine ER Capsules and Detrol® LA.

22. Impax sent a Patent Certification Notice ("Impax's Notice Letter") dated January 29, 2008 to Pfizer Inc. and others, stating that Impax had submitted ANDA No. 90-235 for Impax's proposed Tolterodine ER Capsules. Impax's Notice Letter stated that Impax's ANDA contains a Paragraph IV certification that Impax's manufacture, use, importation, sale, or offer for sale of Impax's proposed Tolterodine ER Capsules will not infringe any valid or enforceable claim of the '600, '162, '295, and '217 Patents. Impax provided with its Notice Letter a detailed statement of the factual and legal bases that the '600, '162, '295, and '217 Patents are invalid, enforceable, or not infringed. Impax also provided with its Notice Letter an Offer of Confidential Access to Impax's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

23. Pursuant to the Offer of Confidential Access, on February 26, 2008, Impax produced information regarding its formulation sufficient for Pfizer to evaluate whether to bring suit on the Orange Book listed patents.

24. Additionally, pursuant to the Discovery Confidentiality Order in Civil Action No. 2:08-cv-2137 pending in this judicial district (D.I. 16), Pfizer has had access to Impax's ANDA since it was produced in November of 2008. For the avoidance of doubt, with regard to the present action, Impax extends permission to Pfizer to review ANDA 90-235, including all

amendments and subsequent FDA correspondence submitted thereto, under the same terms as the Discovery Confidentiality Order entered in the 08-2137 action.

THE CONTROVERSY

U.S. Patent No. 6,911,217

25. Impax's Paragraph IV certification stated that the '600, '162, '295, and '217 Patents are invalid, unenforceable, and/or not infringed by the manufacture, importation, use, or sale of Impax's proposed Tolterodine ER Capsules.

26. In response to Impax's ANDA filing and Paragraph IV certification against the '600, 162, '295, and '217 Patents, Pfizer filed an infringement action under 35 U.S.C. § 271(e)(2)(A) asserting the '600, '162, and '295 Patents against Impax in the U.S. District Court for the Southern District of New York on March 4, 2008.

27. Pfizer's infringement action was subsequently transferred to the U.S. District Court for the District of New Jersey on April 29, 2008.

28. To date, Pfizer has not filed any action alleging that the filing of Impax's ANDA infringes any claims of the '217 Patent.

29. More than 45 days have elapsed since Pfizer received Impax's Notice Letter informing Pfizer of the filing of Impax's ANDA and providing the detailed bases for Impax's Paragraph IV certification. 21 U.S.C. § 355(j)(5)(C).

30. Impax intends to launch Impax's proposed Tolterodine ER Capsules in the United States as soon as legally permissible.

31. Pfizer's filing of an action against Impax in the Southern District of New York asserting infringement of the '600, '162, and '295 Patents, and its continued prosecution of that

action in the District of New Jersey, demonstrates Pfizer's intent to enforce its patent rights against Impax.

32. Upon information and belief, another entity has filed an ANDA seeking FDA approval to engage in the manufacture, use, or sale of controlled-release tolterodine tartrate and has submitted a Paragraph IV certification against, among others, the '217 patent, which may entitle it to 180 days of marketing exclusivity. This entity's generic marketing exclusivity injures Impax because it prevents the FDA from approving Impax's ANDA unless the exclusivity expires or is forfeited.

33. Forfeiture of generic marketing exclusivity may require a final decision or entry of final judgment on a settlement order or consent decree finding the '217 patent invalid or not infringed. *See Granisetron FDA Letter Decision*, FDA Docket No. 2007N-0389 (2008).

34. Based on Pfizer's ongoing litigation against Impax regarding the '600, '162, and '295 Patents, its representation to the FDA and the public regarding the scope of coverage of the '600, '162, '295, and '217 Patents, Pfizer's failure to bring suit against Impax to resolve the questions of infringement regarding the '217 Patent, the potential barrier to the approval of Impax's ANDA caused by another entity's generic marketing exclusivity, and Impax's intent to launch Impax's proposed Tolterodine ER Capsules as soon as legally permissible, under all the circumstances, an actual, substantial, and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Impax and Pfizer as to whether the claims of the '217 Patent are not infringed by Impax's proposed Tolterodine ER Capsules.

COUNT I

Declaration of Non-Infringement of United States Patent No. 6,911,217

35. Impax repeats and incorporates by reference each of the foregoing paragraphs of this Complaint.

36. This Count arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the manufacture, use, offer for sale, sale, or importation of Impax's proposed Tolterodine ER Capsules will not infringe any valid claim of the '217 Patent.

37. Pfizer, through its listing of the '217 Patent in the Orange Book, asserts that the manufacture, use, offer for sale, or sale of Impax's proposed Tolterodine ER Capsules may infringe one or more claims of the '217 Patent.

38. Each claim of the '217 patent requires a controlled-release bead comprising or consisting essentially of "at least (i) a core unit of a substantially water-soluble or water-swellable inert material; (ii) a first layer on the core unit of a substantially water-insoluble polymer; and (iii) a second layer covering the first layer that contains an active ingredient."

39. Impax's proposed Tolterodine ER Capsules do not infringe, literally or under the doctrine of equivalents, any claim of the '217 Patent because Impax's proposed Tolterodine ER Capsules do not meet all of the limitations of the claims of the '217 Patent.

40. Thus, the manufacture, use, offer for sale, or sale of Impax's proposed Tolterodine ER Capsules does not and will not infringe any valid claim of the '217 Patent.

41. A present genuine, justiciable controversy exists between Impax and Pfizer regarding the issue of whether the manufacture, use, offer for sale, or sale of Impax's proposed Tolterodine ER Capsules would infringe any valid claim of the '217 Patent.

42. Impax is entitled to a declaration that the manufacture, use, offer for sale, or sale of Impax's proposed Tolterodine ER Capsules does not and will not infringe any valid claim of the '217 Patent.

PRAYER FOR RELIEF

WHEREFORE, Impax prays that the Court enter judgment in its favor and against Pfizer as follows:

A. Enter a declaratory judgment that Impax's proposed Tolterodine ER Capsules do not infringe any valid claim of U.S. Patent No. 6,911,217;

B. Declare that the case is exceptional under 35 U.S.C. § 285 and award reasonable attorneys' fees, costs, and expenses to Impax; and

C. Grant such other and further relief as the Court deems proper and just.

Dated: December 16, 2010

s/Robert J. Fettweis
Robert J. Fettweis
Tressler, LLP
744 Broad Street – Suite 1510
Newark, NJ 07102
(973) 848-2900
(973) 623-0405 (fax)

Newark #40799