IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., WYETH LLC, WYETH PHARMACEUTICALS INC., and PF PRISM C.V.	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Pfizer Inc., Wyeth LLC, Wyeth Pharmaceuticals Inc., and PF Prism C.V. (collectively "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") herein allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Lupin's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Pfizer's pharmaceutical product Pristiq® prior to the expiration of United States Patent No. 6,673,838 ("the '838 patent") which covers Pristiq® and its use.

THE PARTIES

2. 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.

3. Plaintiff Wyeth LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 5 Giralda Farms, Madison, NJ 07940. Pfizer Inc. is the ultimate parent of Wyeth LLC.

4. Plaintiff Wyeth Pharmaceuticals 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. Pfizer Inc. is the ultimate parent of Wyeth Pharmaceuticals Inc.

5. Plaintiff PF Prism C.V. is a Netherlands limited partnership (commanditaire vennootschap) having its registered seat in Rotterdam, the Netherlands, and registered at the Trade Register held by the Chamber of Commerce of Rotterdam, the Netherlands, under number 51840456, with main offices at Blaak 40 basement, 3011 TA, Rotterdam, Netherlands. Pfizer Inc. is the ultimate parent of PF Prism C.V.

6. On information and belief, 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. On information and belief, Lupin Ltd., itself and through its wholly owned subsidiary and agent, Lupin Pharmaceuticals, Inc., is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. Lupin Ltd. has previously submitted to jurisdiction in this Court, and has availed itself of the jurisdiction of this

Court by asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

7. On information and belief, 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 2150, Baltimore, Maryland 21202. On information and belief, Lupin Pharmaceuticals, Inc. is registered to do business in the State of Delaware and does business in this judicial district. On information and belief, Lupin Pharmaceuticals, Inc., itself and as the agent and wholly owned subsidiary of Lupin Ltd., is in the business of making and selling generic pharmaceutical products, which it distributes through authorized distributors in the State of Delaware and throughout the United States. Lupin Pharmaceuticals, Inc. has previously submitted to jurisdiction in this Court, and has availed itself of the jurisdiction of this Court by asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

JURISDICTION AND VENUE

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

9. This Court has personal jurisdiction over Lupin by virtue of, inter alia, its presence in Delaware, having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, previously consenting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court, and having engaged in systematic and continuous contacts with the State of Delaware.

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

THE PATENT-IN-SUIT

11. On January 6, 2004, the United States Patent and Trademark Office issued the '838 patent, entitled "Succinate Salt of O-Desmethyl-Venlafaxine." At the time of its issue, the '838 patent was assigned to Wyeth (now known as Wyeth LLC), Madison NJ, and Wyeth LLC currently holds title to the '838 patent. A copy of the '838 patent is attached hereto as Exhibit A.

PRISTIQ®

12. Pfizer Inc., itself and through its wholly owned indirect subsidiary Wyeth Pharmaceuticals, Inc., holds approved New Drug Application No. 21-992 ("the Pristiq® NDA") for O-desmethylvenlafaxine succinate extended release tablets in 50 and 100 mg dosage strengths, which are sold by Pfizer Inc. under the trade name Pristiq®.

13. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '838 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Pristiq®.

LUPIN'S ANDA

14. On information and belief, Lupin submitted ANDA No. 204-172 ("the Lupin ANDA") to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market O-desmethylvenlafaxine succinate extended release tablets in 50 and 100 mg dosage strengths. The O-desmethylvenlafaxine succinate extended release tablets described in the Lupin ANDA are herein referred to as the "Lupin Products."

15. The Lupin ANDA refers to and relies upon the Pristiq® NDA and contains data that, according to Lupin, demonstrate the bioequivalence of the Lupin Products and Pristiq®.

16. Pfizer has received from Lupin a letter, dated May 11, 2012 (the "Lupin Notification"), stating that Lupin had included a certification in the Lupin ANDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the '838 patent is invalid, or will not be infringed by the commercial manufacture, use, or sale of the Lupin Products (the "Paragraph IV Certification").

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,673,838

17. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-16 of this Complaint.

18. Lupin has infringed the '838 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Lupin ANDA, by which Lupin seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Lupin Products prior to the expiration of the '838 patent.

19. Lupin's commercial manufacture, use, offer to sell, or sale of the Lupin Products within the United States, or importation of the Lupin Products into the United States during the term of the '838 patent would further infringe the '838 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

20. Plaintiffs will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '838 patent.

21. Plaintiffs have no adequate remedy at law.

22. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Pfizer Inc., Inc., Wyeth LLC, Wyeth Pharmaceuticals Inc. and PF Prism C.V. pray for a judgment in their favor and against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc., and respectfully request the following relief:

A. A judgment declaring that Lupin has infringed U.S. Patent No. 6,673,838;

B. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Lupin, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling the Lupin Products within the United States, or importing the Lupin Products into the United States, prior to the expiration date of the '838 patent;

C. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 204-172 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '838 patent, including any extensions;

D. If Lupin commercially manufactures, uses, offers to sell, or sells the Lupin Products within the United States, or imports the Lupin Products into the United States, prior to the expiration of '838 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

E. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such other relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Pfizer Inc., Wyeth LLC, Wyeth Pharmaceuticals Inc. and PF Prism C.V.

OF COUNSEL:

Dimitrios T. Drivas
Adam Gahtan
Brendan G. Woodard
Jayashree Mitra
WHITE & CASE LLP
1155 Avenue of the Americas
New York, NY 10036
(212) 819-8200

June 22, 2012