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. _____
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, 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 Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's") 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 Dr. Reddy'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 Plaintiff's pharmaceutical product Pristiq® prior to the expiration of United States Patent Nos. 6,673,838 ("the '838 patent") and 8,269,040 ("the '040 patent"), which cover Pristiq® or 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 10017.

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 500 Arcola Road, Collegeville, PA 19426. 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, Dr. Reddy's Laboratories, Ltd. is a company organized and existing under the laws of India, having a principal place of business at 7-1-27, Ameerpet, Hyderabad, 500 016, India. On information and belief, Dr. Reddy's Laboratories, Ltd. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. On information and belief, Dr. Reddy's Laboratories, Ltd. has previously admitted that it is subject to this Court's jurisdiction and has previously submitted to this Court's jurisdiction. Dr. Reddy's Laboratories, Ltd. has purposefully 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, Dr. Reddy's Laboratories, Inc., a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd., is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 200 Somerset

Corp. Blvd., Bridgewater, NJ 08807. On information and belief, Dr. Reddy's Laboratories, Inc., with the assistance and/or direction of Dr. Reddy's Laboratories, Ltd., develops, manufactures, markets, offers to sell, and sells generic drug products for sale and use throughout the United States. Dr. Reddy's Laboratories, Inc. has previously admitted that it is subject to this Court's jurisdiction and has previously submitted to this Court's jurisdiction. Dr. Reddy's Laboratories, Inc. has purposefully 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 Dr. Reddy's 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 PATENTS-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.

12. On September 18, 2012, The United States Patent and Trademark Office issued the '040 patent, entitled "Derivatives of Venlafaxine and Methods of Preparing and Using the Same." At the time of its issue, the '040 patent was assigned to Wyeth LLC, Madison NJ, and Wyeth LLC currently holds title to the '040 patent. A copy of the '040 patent is attached hereto as Exhibit B.

PRISTIQ®

13. 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®.

14. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '838 and '040 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Pristiq®.

DR. REDDY'S ANDA

15. On information and belief, Dr. Reddy's submitted ANDA No. 20-4911 (the "Dr. Reddy's 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 Dr. Reddy's ANDA are herein referred to as the "Dr. Reddy's Products."

16. Dr. Reddy's ANDA refers to and relies upon the Pristiq® NDA and contains data that, according to Dr. Reddy's, demonstrate the bioequivalence of the Dr. Reddy's Products and Pristiq®.

17. In a letter to Pfizer, dated April 23, 2013, Dr. Reddy's stated that Dr. Reddy's ANDA contained a certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV)

(§505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act), that the '838 and the '040 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Dr. Reddy's Products. Dr. Reddy's attached a memorandum to the letter, in which it claimed to give factual and legal bases for its certification.

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

18. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-17 of this Complaint.

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

20. Dr. Reddy's commercial manufacture, use, offer to sell, or sale of the Dr. Reddy's Products within the United States, or importation of the Dr. Reddy's 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).

21. Plaintiffs will be substantially and irreparably harmed if Dr. Reddy's is not enjoined from infringing the '838 patent.

22. Plaintiffs have no adequate remedy at law.

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

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,269,040

24. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-23 of this Complaint.

25. Dr. Reddy's has infringed the '040 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Dr. Reddy's ANDA, by which Dr. Reddy's seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Dr. Reddy's Products prior to the expiration of the '040 patent.

26. Dr. Reddy's commercial manufacture, use, offer to sell, or sale of the Dr. Reddy's Products within the United States, or importation of the Dr. Reddy's Products into the United States during the term of the '040 patent would further infringe the '040 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

27. Plaintiffs will be substantially and irreparably harmed if Dr. Reddy's is not enjoined from infringing the '040 patent.

28. Plaintiffs have no adequate remedy at law.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Dr. Reddy's and respectfully request the following relief:

A. A judgment declaring that Dr. Reddy's has infringed the '838 patent;

B. A judgment declaring that Dr. Reddy's has infringed the '040 patent;

C. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Dr. Reddy's, 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 Dr. Reddy's Products within the United States, or importing the Dr. Reddy's Products into the United States, prior to the expiration of the '838 and '040 patents;

D. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 20-4911 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration of the '838 and '040 patents, including any extensions;

E. If Dr. Reddy's commercially manufactures, uses, offers to sell, or sells the Dr. Reddy's Products within the United States, or imports the Dr. Reddy's Products into the United States, prior to the expiration of any of the '838 and '040 patents, including any extensions, a judgment awarding Pfizer monetary relief together with interest;

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

G. Costs and expenses in this action; and

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

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