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. ANCHEN PHARMACEUTICALS, INC., et al., Defendants.	)	C.A. No. 12-808 (SLR) CONSOLIDATED
PFIZER INC., WYETH LLC, WYETH PHARMACEUTICALS INC., and PF PRISM C.V., Plaintiffs, v. BRECKENRIDGE PHARMACEUTICAL, INC., and ALEMBIC PHARMACEUTICALS LTD., Defendants.	)	C.A. No. 12-810-SLR

AMENDED COMPLAINT

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

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the States, Title 35 of the United States Code, arising from Alembic Pharmaceutical Ltd.'s filing of 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") and United States Patent No. 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. 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 Areola 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, Alembic Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, having a place of business at Alembic Road, Vadodara, Gujarat 390 003, India. On information and belief, Alembic Pharmaceuticals Ltd. is in the business of making and selling generic pharmaceutical products, which are distributed in the State of Delaware and throughout the United States.

7. On information and belief, Breckenridge Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Florida, having a principal

of business at 1141 South Rogers Circle, Suite 3, Boca Raton, Florida 33487. On information belief, Breckenridge Pharmaceutical, Inc. is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in Delaware, and throughout the United States.

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 Alembic 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, 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®.

ALEMBIC'S ANDA

15. On information and belief, Alembic submitted ANDA No. 204003 ("the Alembic 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 Alembic ANDA are herein referred to as the "Alembic Products."

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

17. In a letter to Pfizer dated May 18, 2012, Alembic stated that the Alembic ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '838 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Alembic Products. The May 18, 2012 letter also stated that Breckenridge Pharmaceutical Ltd. would be the exclusive marketer of the Alembic Products under the Breckenridge label in the United States. Alembic attached a memorandum to the letter, in which claimed to give detailed factual and legal bases for its certification.

18. In a letter to Pfizer dated September 18, 2012, Alembic stated that it had amended the Alembic ANDA to include a certification, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the '040 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Alembic Products. The September 18, 2012 letter also stated that Breckenridge Pharmaceutical Ltd. would be the exclusive marketer of the Alembic Products under the Breckenridge label in the United States. Alembic attached a memorandum to the letter, in which it claimed to give detailed factual and legal bases for its certification.

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

19. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-18 of this Amended Complaint.

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

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

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

23. Plaintiffs have no adequate remedy at law.

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

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

25. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-24 of this Amended Complaint.

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

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

28. Plaintiffs will be substantially and irreparably harmed if Alembic is not enjoined from infringing the '040 patent.

29. Plaintiffs have no adequate remedy at law.

30. 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., Wyeth LLC, Wyeth Pharmaceuticals Inc., and PF Prism C.V. pray for a judgment in their favor and against Defendants Breckenridge Pharmaceutical Inc., and Alembic Pharmaceuticals Ltd., and respectfully request the following relief:

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

B. A judgment declaring that Alembic has infringed U.S. Patent No. 8,269,040;

C. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Alembic, 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 Alembic Products within the United States, or importing the Alembic 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. 204003 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 Alembic commercially manufactures, uses, offers to sell, or sells the Alembic Products within the United States, or imports the Alembic Products into the United States, prior to the expiration of any of the '838 and '040 patents, including any extensions, a judgment awarding Plaintiffs 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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