

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

PFIZER INC., WARNER-LAMBERT )  
COMPANY LLC, C.P. PHARMACEUTICALS )  
INTERNATIONAL C.V. and )  
NORTHWESTERN UNIVERSITY, )

Plaintiffs, )

v. )

C.A. No. \_\_\_\_\_

ALEMBIC LIMITED and ALEMBIC )  
PHARMACEUTICALS LIMITED, )

Defendants. )

**COMPLAINT**

Plaintiffs Pfizer Inc., Warner-Lambert Company LLC, C.P. Pharmaceuticals International C.V. (collectively, "Pfizer"), and Northwestern University ("Northwestern," and together with Pfizer, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Alembic Limited and Alembic Pharmaceuticals Limited (collectively, "Alembic") 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 Alembic'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 Lyrica® prior to the expiration of United States Patent No. 6,197,819 ("the '819 patent") which covers Lyrica®.

**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 Warner-Lambert Company LLC is a limited liability company 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 Warner-Lambert Company LLC.

4. Plaintiff C.P. Pharmaceuticals International C.V. is a limited partnership organized and existing under the laws of the Netherlands, having a place of business at 235 East 42nd Street, New York, New York. Pfizer Inc. is the ultimate parent of C.P. Pharmaceuticals International C.V.

5. Plaintiff Northwestern University is an Illinois corporation, having its principal place of business at 633 Clark Street, Evanston, Illinois.

6. On information and belief, Alembic Limited 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 Limited, itself and through its subsidiary and agent, Alembic Pharmaceuticals Limited, 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, Alembic Pharmaceuticals Limited 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 Limited is a subsidiary and agent of Defendant Alembic Limited.

**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 its 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 March 6, 2001, the United States Patent and Trademark Office issued the '819 patent, entitled "Gamma Amino Butyric Acid Analogs and Optical Isomers." At the time of its issue, the '819 patent was assigned to Northwestern, and Northwestern currently holds title to the '819 patent. A copy of the '819 patent is attached hereto as Exhibit A.

12. Northwestern has exclusively licensed the '819 patent to Warner-Lambert Company LLC.

**LYRICA<sup>®</sup>**

13. Pfizer Inc., itself and through its wholly owned subsidiary C.P. Pharmaceuticals International C.V., holds approved New Drug Application Nos. 21-446, 21-723 and 21-724 ("the Lyrica NDAs") for pregabalin capsules in 25, 50, 75, 100, 150, 200, 225 and 300 mg dosage strengths, which are sold by Pfizer Inc. under the trade name Lyrica<sup>®</sup>.

14. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '819 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Lyrica®.

**ALEMBIC'S ANDA**

15. On information and belief, Alembic submitted ANDA No. 203459 (the "Alembic ANDA") to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market pregabalin capsules, in 25, 50, 75, 100, 150, 200, 225 and 300 mg dosage strengths. The pregabalin capsules described in Alembic's ANDA are herein referred to as the "Alembic Products."

16. On information and belief, the Alembic ANDA refers to and relies upon at least one of the Lyrica NDAs and contains data that, according to Alembic, demonstrate the bioequivalence of the Alembic Products and Lyrica®.

17. Pfizer and Northwestern received from Alembic a letter, dated October 26, 2011, and attached memoranda (collectively, the "Alembic Notification"), stating that Alembic had included a certification in the Alembic ANDA that the '819 patent is invalid ("the Paragraph IV Certification").

**COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,197,819**

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

19. Alembic has infringed the '819 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 '819 patent.

20. Alembic's commercial manufacture, use, offer to sell, or sale of the Alembic Products within the United States, or the importation of the Alembic Products into the United States, during the term of the '819 patent would further infringe the '819 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

21. Plaintiffs will be substantially and irreparably harmed if Alembic is not enjoined from infringing the '819 patent.

22. Plaintiffs have no adequate remedy at law.

23. 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 and Northwestern pray for a judgment in their favor and against Defendants Alembic Pharmaceuticals Limited and Alembic Limited, and respectfully request the following relief:

A. A judgment declaring that Alembic has infringed U.S. Patent No. 6,197,819;

B. 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 '819 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. 203459 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 '819 patent, including any extensions;

D. If Alembic commercially manufactures, uses, offers to sell, or sells the Alembic Products within the United States, or if the Alembic Products are imported into the United States, prior to the expiration of the '819 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

MCCARTER & ENGLISH, LLP

*/s/ Maryellen Noreika*

*/s/ Daniel M. Silver*

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