

**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. 09-309 (GMS)

LUPIN LTD. and )  
LUPIN PHARMACEUTICALS, INC., )

Defendants. )

**AMENDED 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 Amended 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 Lyrica® prior to the expiration of United States Patent Nos. 6,197,819 (“the ‘819 patent”) and 5,563,175 (“the ‘175 patent”) which cover Lyrica® 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 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, 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, Maharashtra 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 St., Ste. 2150, Baltimore, Maryland. On information and belief, Lupin Pharmaceuticals, Inc. is registered to do business in the State of Delaware and does business in this 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 PATENTS-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.

13. On October 8, 1996, the United States Patent and Trademark Office issued the '175 patent, entitled "GABA and L-Glutamic Acid Analogs For Antiseizure Treatment." At the time of its issue, the '175 patent was assigned to Northwestern and Warner-Lambert Company. Warner-Lambert Company subsequently became Warner-Lambert Company LLC. Northwestern and Warner-Lambert Company LLC currently hold title to the '175 patent. A copy of the '175 patent is attached hereto as Exhibit B.

14. Northwestern has exclusively licensed the '175 patent to Warner-Lambert Company LLC.

**LYRICA<sup>®</sup>**

15. 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 under the trade name Lyrica<sup>®</sup>.

16. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '819 and '175 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Lyrica<sup>®</sup>.

**LUPIN'S ANDA**

17. On information and belief, Lupin submitted ANDA No. 91-040 (“the Lupin 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 the Lupin ANDA are herein referred to as the “Lupin Products.”

18. The Lupin ANDA refers to and relies upon the Lyrica NDAs and contains data that, according to Lupin, demonstrate the bioequivalence of the Lupin Products and Lyrica®.

19. Pfizer and Northwestern received from Lupin a letter, dated March 23, 2009 (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 ‘819 and ‘175 patents are 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. 6,197,819**

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

21. Lupin has infringed the ‘819 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 ‘819 patent.

22. 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 ‘819 patent would further infringe the ‘819 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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

24. Plaintiffs have no adequate remedy at law.

25. 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. 5,563,175**

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

27. Lupin has infringed the '175 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 '175 patent.

28. 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 '175 patent would further infringe the '175 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

29. Plaintiffs will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '175 patent.

30. Plaintiffs have no adequate remedy at law.

31. 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 Lupin Ltd. and Lupin Pharmaceuticals, Inc., and respectfully request the following relief:

- A. A judgment declaring that Lupin has infringed U.S. Patent No. 6,197,819;
- B. A judgment declaring that Lupin has infringed U.S. Patent. No. 5,563,175;
- C. 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 of the '819 and '175 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. 91-040 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '819 and '175 patents, including any extensions;
- E. 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 any of the '819 and '175 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

MCCARTER & ENGLISH, LLP

*/s/ Jack B. Blumenfeld*

*/s/ Daniel M. Silver*

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

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Michael P. Kelly (#2295)  
Andrew S. Dupre (#4621)  
Daniel M. Silver (#4758)  
Renaissance Centre  
405 North King Street – 8th Floor  
Wilmington, DE 19801  
(302) 984-6300  
[mkelly@mccarter.com](mailto:mkelly@mccarter.com)  
[adupre@mccarter.com](mailto:adupre@mccarter.com)  
[dsilver@mccarter.com](mailto:dsilver@mccarter.com)

*Attorneys for Pfizer Inc., Warner-Lambert  
Company LLC, and C.P. Pharmaceuticals  
International C.V.*

*Attorneys for Northwestern University*

*Of Counsel:*

*Of Counsel:*

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

Kevin M. Flowers  
MARSHALL, GERSTEIN & BORUN LLP  
233 South Wacker Drive  
6300 Sears Tower  
Chicago, IL 60606-6357  
(312) 474-6300

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