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. _____
APOTEX INC. and APOTEX CORP.,	)	
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 Apotex Inc. and Apotex Corp. (collectively, "Apotex") 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 Apotex filing an Abbreviated New Drug Applications ("ANDAs") with the United States Food and Drug Administration ("FDA") seeking approval to market generic versions of Pfizer's Lyrica® pharmaceutical products prior to the expiration of U.S. Patent No. 6,197,819 ("the '819 patent") and U.S. Patent No. 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. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc. that serves as Apotex Inc.'s United States sales agent and distributor, and sells and offers for sale Apotex Inc.'s drug products in the State of Delaware and throughout the United States.

7. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. Upon information and belief, Apotex Inc. manufactures drug products for the purpose of sale within the State of Delaware and throughout the United Sates by Apotex Corp. Upon information and belief, Apotex Inc. derives substantial revenue from services or things used or consumed in the State of Delaware. Apotex Inc. has previously consented to the jurisdiction of this Court and has purposefully availed itself of the

jurisdiction of this Court by filing lawsuits and 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 Apotex 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 ("the USPTO") 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 USPTO 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®

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 for pregabalin capsules in 25, 50, 75, 100, 150, 200, 225 and 300 mg dosage strengths ("the Lyrica® Capsule NDAs"). Pfizer holds approved NDA No. 22-488 for pregabalin oral solution in 20 mg/mL dosage strength ("the Lyrica® Oral Solution NDA"). Pfizer's pregabalin capsule and oral solution products are trade-named Lyrica®.

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®.

APOTEX'S ANDAs

17. On information and belief, Apotex submitted ANDA No. 203022 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. On information and belief, Apotex also submitted ANDA No. 202998 to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market pregabalin oral solution in 20 mg/mL dosage strength. The pregabalin capsules described in Apotex's ANDA No. 203022 and the pregabalin oral solution described in Apotex's ANDA No. 202998 (collectively, "the Apotex ANDAs") are herein referred to as the "Apotex Products."

18. The Apotex ANDAs refer to and rely upon the Lyrica® NDAs and contain data that, according to Apotex, demonstrate the bioequivalence of the Apotex Products and Lyrica®.

19. Pfizer and Northwestern received from Apotex two letters, dated May 27, 2011 and June 8, 2011 (collectively, the "Apotex Notifications"), stating that Apotex had included a certification in each of the Apotex ANDAs, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the '819 and '175 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Apotex Products ("the Paragraph IV Certifications").

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. Apotex has infringed the '819 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Apotex ANDAs, by which Apotex seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Apotex Products prior to the expiration of the '819 patent.

22. Apotex's commercial manufacture, use, offer to sell, or sale of the Apotex Products within the United States, or importation of the Apotex 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 Apotex 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. Apotex has infringed the '175 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Apotex ANDAs, by which Apotex seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Apotex Products prior to the expiration of the '175 patent.

28. Apotex's commercial manufacture, use, offer to sell, or sale of the Apotex Products within the United States, or importation of the Apotex 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 Apotex 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 Apotex Inc. and Apotex Corp. and respectfully request the following relief:

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

B. A judgment declaring that Apotex 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 Apotex, 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 Apotex Products within the United States, or importing the Apotex 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 Nos. 203022 and 202998 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 Apotex commercially manufactures, uses, offers to sell, or sells the Apotex Products within the United States, or imports the Apotex 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

/s/ Maryellen Noreika

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., Warner-Lambert Company LLC, and C.P. Pharmaceuticals International C. V.

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

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MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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
adupre@mccarter.com
dsilver@mccarter.com

Attorneys for Northwestern University

OF COUNSEL:

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