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. _____
ALPHAPHARM PTY. LTD. and MYLAN PHARMACEUTICALS INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Pfizer Inc., Warner-Lambert Company LLC, and 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 Alphapharm Pty. Ltd. and Mylan Pharmaceuticals Inc. (collectively, "Alphapharm") 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 Alphapharm'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®.

2. A related action, in which Pfizer sued Alphapharm for infringement of United States Patent No. 6,001,876 ("the '876 patent"), was filed in this Court on April 29, 2009. That lawsuit is captioned *Pfizer Inc. et al. v. Alphapharm Pty. Ltd. et al.*, C.A. No. 09-308 (GMS), and is consolidated with other related actions before this Court as *Pfizer Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, C.A. No. 09-307 (GMS).

THE PARTIES

3. 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.

4. 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.

5. 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.

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

7. On information and belief, Alphapharm Pty. Ltd. is a corporation organized and existing under the laws of Australia, having a principal place of business at Chase Building 2, Wentworth Park Road, Glebe, NSW 2037, Australia. On information and belief, Alphapharm Pty. Ltd. designated Mylan Pharmaceuticals Inc. as its U.S. agent for ANDA No.

91-228 (the "Alphapharm ANDA"). On information and belief, Alphapharm Pty. 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. Alphapharm Pty. 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.

8. On information and belief, Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Rd., Morgantown, WV 26505. On information and belief, Mylan Pharmaceuticals Inc. is designated as the U.S. agent for Alphapharm Pty. Ltd. for the Alphapharm ANDA. On information and belief, Mylan Pharmaceuticals Inc. is registered to do business in the State of Delaware, and does business in this judicial district. On information and belief, Mylan Pharmaceuticals Inc. is registered to distribute drugs in the State of Delaware, and is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. Mylan Pharmaceuticals Inc. has previously submitted to jurisdiction in this Court, and has 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

9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Alphapharm 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.

11. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

12. 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.

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

LYRICA®

14. 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®.

15. 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®.

ALPHAPHARM'S ANDA

16. On information and belief, Alphapharm submitted the Alphapharm 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 Alphapharm ANDA are herein referred to as the "Alphapharm Products." On information and belief, the Alphapharm ANDA designates Mylan Pharmaceuticals Inc. as the U.S. agent for Alphapharm Pty. Ltd.

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

18. Pfizer received from Alphapharm a letter, dated March 17, 2009, and attached memoranda (collectively, the "First Alphapharm Notification"), stating that Alphapharm had included a certification in the Alphapharm ANDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the '876 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Alphapharm Products ("the Paragraph IV Certification"). Pfizer sued Alphapharm for infringement of the '876 patent on April 29, 2009, which lawsuit is consolidated with other related actions before this Court as *Pfizer Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, C.A. No. 09-307 (GMS).

19. Pfizer and Northwestern received from Alphapharm a letter, dated March 1, 2010, and attached memoranda (collectively, the "Second Alphapharm Notification"), stating that Alphapharm amended the Alphapharm ANDA to include a certification, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the '819 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Alphapharm Products ("the Paragraph IV Certification"). The Second Alphapharm Notification states that Mylan Pharmaceuticals Inc. is the U.S. agent for Alphapharm Pty. Ltd.

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. Alphapharm has infringed the '819 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Alphapharm ANDA, by which Alphapharm seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Alphapharm Products prior to the expiration of the '819 patent, and amending the Alphapharm ANDA to include a certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) with respect to the '819 patent.

22. Alphapharm's commercial manufacture, use, offer to sell, or sale of the Alphapharm Products within the United States, or importation of the Alphapharm 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 Alphapharm 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.

PRAYER FOR RELIEF

WHEREFORE, Pfizer and Northwestern pray for a judgment in their favor and against Defendants Alphapharm Pty. Ltd. and Mylan Pharmaceuticals Inc., and respectfully request the following relief:

A. A judgment declaring that Alphapharm 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 Alphapharm, 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 Alphapharm Products within the United States, or importing the Alphapharm 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. 91-228 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 Alphapharm commercially manufactures, uses, offers to sell, or sells the Alphapharm Products within the United States, or imports the Alphapharm Products 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

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