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. 09-307 (GMS) CONSOLIDATED
TEVA PHARMACEUTICALS USA, INC., et al.,	)	
Defendants.	)	

AMENDED 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 Amended Complaint against Defendant Sandoz Inc. ("Sandoz") 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 Sandoz'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 U.S. Patent No. 6,197,819 ("the '819 patent"), and U.S. Reissue Patent No. RE 41,920 ("the RE '920 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, Sandoz is a corporation organized and existing under the laws of the State of Colorado, having a principal place of business at 506 Carnegie Center, Ste 400, Princeton, New Jersey. Upon information and belief, Sandoz 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. Sandoz 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

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

8. This Court has personal jurisdiction over Sandoz 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.

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

THE PATENTS-IN-SUIT

10. 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.

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

12. On December 14, 1999, the USPTO issued U.S. Patent No. 6,001,876 ("the '876 patent"), entitled "Isobutyl GABA and Its Derivatives for the Treatment of Pain." At the time of its issue, the '876 patent was assigned to Warner-Lambert Company, which subsequently became Warner-Lambert Company LLC. Warner-Lambert Company LLC currently holds title to the '876 patent. A copy of the '876 patent is attached hereto as Exhibit B.

13. On November 9, 2007, Warner-Lambert Company LLC filed with the USPTO an application, Serial No. 11/983,750, for reissue of the '876 patent. On November 9, 2010, the USPTO reissued the '876 patent as U.S. Reissued Patent No. RE 41,920, entitled "IsobutylGABA And Its Derivatives For The Treatment of Pain" ("the RE '920 patent"). At the time of its reissue, the RE '920 patent was assigned to Warner-Lambert Company LLC. Warner-Lambert Company LLC currently holds title to the RE '920 patent. A copy of the RE '920 patent is attached hereto as Exhibit C.

14. Pursuant to 35 U.S.C. § 252, the RE '920 patent contains claims that are substantially identical to claims of the '876 patent, and the RE '920 patent constitutes a continuation of the '876 patent and has effect continuously from the issue date of the '876 patent.

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 ("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®.

16. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '819 and RE '920 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Lyrica®.

SANDOZ'S ANDA

17. On information and belief, Sandoz submitted ANDA No. 91-229 ("the Sandoz 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 Sandoz ANDA are herein referred to as the "Sandoz Products."

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

19. Pfizer and Northwestern received from Sandoz a letter, dated March 25, 2009, and attached memoranda (the "Sandoz Notification"), stating that Sandoz had included a certification in the Sandoz ANDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the '819 and RE '920 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Sandoz 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. Sandoz has infringed the '819 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Sandoz ANDA, by which Sandoz seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Sandoz Products prior to the expiration of the '819 patent.

22. Sandoz's commercial manufacture, use, offer to sell, or sale of the Sandoz Products within the United States, or importation of the Sandoz 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 Sandoz 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. REISSUE PATENT NO. RE 41,920

26. Pfizer realleges and incorporates by reference the allegations of paragraphs 1-25 of this Complaint.

27. Sandoz has infringed the RE '920 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Sandoz ANDA, by which Sandoz seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Sandoz Products prior to the expiration of the RE '920 patent.

28. Sandoz's commercial manufacture, use, offer to sell, or sale of the Sandoz Products within the United States, or importation of the Sandoz Products into the United States during the term of the RE '920 patent would further infringe the RE '920 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

29. Pfizer will be substantially and irreparably harmed if Sandoz is not enjoined from infringing the RE '920 patent.

30. Pfizer has no adequate remedy at law.

31. This case is an exceptional one, and Pfizer is 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 Defendant Sandoz, Inc. and respectfully request the following relief:

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

B. A judgment declaring that Sandoz has infringed U.S. Reissue Patent No. RE 41,920;

C. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Sandoz, 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 Sandoz Products within the United States, or importing the Sandoz Products into the United States, prior to the expiration of the '819 and RE '920 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. 91-229 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 RE '920 patents, including any extensions;

E. If Sandoz commercially manufactures, uses, offers to sell, or sells the Sandoz Products within the United States, or imports the Sandoz Products into the United States, prior to the expiration of any of the '819 and RE '920 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

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