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.	)	Civil Action No. _____
TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD.,	)	
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 Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, "Teva") 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 Teva's filing of Abbreviated New Drug Applications ("ANDAs") 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 6,001,876 ("the '876 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, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania. On information and belief, Teva USA is a wholly owned subsidiary and agent of Defendant Teva Pharmaceutical Industries, Ltd.

7. On information and belief, Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is a corporation organized and existing under the laws of Israel, having a principal place of business at 5 Basel St., Petach Tikva 49131, Israel. On information and belief, Teva Ltd., itself and through its wholly-owned subsidiary and agent, Teva USA, is in the business of making and

selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. Teva Ltd. 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

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 Teva 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 December 14, 1999, the United States Patent and Trademark Office issued 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.

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 under the trade name Lyrica®.

15. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '819 and '876 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Lyrica®.

TEVA'S ANDAs

16. On information and belief, Teva submitted ANDA No. 91-219 to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market pregabalin capsules in 25 and 50 mg dosage strengths. On information and belief, Teva also submitted ANDA No. 91-224 to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market pregabalin capsules in 75, 100, 150, 200, 225 and 300 mg dosage strengths. The pregabalin capsules described in Teva's ANDA Nos. 91-219 and 91-224 (collectively, "the Teva ANDAs") are herein referred to as the "Teva Products."

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

18. Pfizer and Northwestern received from Teva two letters, dated March 16, 2009, and attached memoranda (collectively, the "Teva Notifications"), stating that Teva had

included certifications in the Teva ANDAs, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the '819 and '876 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Teva Products ("the Paragraph IV Certifications").

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

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

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

21. Teva's commercial manufacture, use, offer to sell, or sale of the Teva Products within the United States, or importation of the Teva 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).

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

23. Plaintiffs have no adequate remedy at law.

24. 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. 6,001,876

25. Pfizer realleges and incorporates by reference the allegations of paragraphs 1-24 of this Complaint.

26. Teva has infringed the '876 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Teva ANDAs, by which Teva seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Teva Products prior to the expiration of the '876 patent.

27. Teva's commercial manufacture, use, offer to sell, or sale of the Teva Products within the United States, or importation of the Teva Products into the United States, during the term of the '876 patent would further infringe the '876 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

28. Pfizer will be substantially and irreparably harmed if Teva is not enjoined from infringing the '876 patent.

29. Pfizer has no adequate remedy at law.

30. 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 Defendants Teva USA and Teva Ltd., and respectfully request the following relief:

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

B. A judgment declaring that Teva has infringed U.S. Patent No. 6,001,876;

C. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Teva, 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 Teva Products within the United States, or importing the Teva Products into the United States, prior to the expiration of the '819 and '876 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. 91-219 and 91-224 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 '876 patents, including any extensions;

E. If Teva commercially manufactures, uses, offers to sell, or sells the Teva Products within the United States, or imports the Teva Products into the United States, prior to the expiration of any of the '819 and '876 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.

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