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. _____
SUN PHARMA GLOBAL INC., SUN PHARMACEUTICAL INDUSTRIES LTD. and SUN PHARMACEUTICAL INDUSTRIES, INC.,	)	
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 Sun Pharma Global Inc., Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, "Sun") 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 Sun'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®.

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, Sun Pharma Global Inc. is a company organized and existing under the laws of the British Virgin Islands, having a principal place of business at Akara Building, 24 De Castro Street, Wickhams Cay 1, Road Town Tortola VG1110, British Virgin Islands. On information and belief, Sun Pharma Global 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. On information and belief, Sun Pharma Global Inc. is a wholly owned subsidiary and agent of Defendant Sun Pharmaceutical Industries Ltd. Sun Pharma Global Inc. has previously submitted to jurisdiction in this Court.

7. On information and belief, Sun Pharmaceutical Industries Ltd. is a company organized and existing under the laws of India, having a principal place of business at Acme Plaza, Andheri Kurla Rd., Andheri East, Mumbai 400 059, India. On information and belief, Sun Pharmaceutical Industries 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. On information and belief, Sun Pharma Global Inc. is a wholly owned subsidiary and agent of Defendant Sun Pharmaceutical Industries Ltd. Sun Pharmaceutical Industries 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.

8. On information and belief, Sun Pharmaceutical Industries, Inc. is a company organized and existing under the laws of the State of Michigan, having a principal place of business at 270 Prospect Plains Road, Cranbury, NJ 08512. On information and belief, Sun Pharmaceutical Industries, Inc. is registered to do business in the State of Delaware, and does business in this judicial district. On information and belief, Sun Pharmaceutical Industries, 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. On information and belief, Sun Pharmaceutical Industries, Inc. is a wholly-owned subsidiary and agent of Defendant Sun Pharmaceutical Industries, Ltd. Sun Pharmaceutical Industries, Inc. has submitted to jurisdiction in this Court.

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 Sun 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 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®.

SUN'S ANDA

16. On information and belief, Sun submitted ANDA No. 91-157 (the "Sun 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 Sun's ANDA are herein referred to as the "Sun Products."

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

18. Pfizer and Northwestern received from Sun a letter, dated April 4, 2009, (the "Sun Notification"), stating that Sun had included a certification in the Sun ANDA, 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 Sun Products ("the Paragraph IV Certification").

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

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

PRAYER FOR RELIEF

WHEREFORE, Pfizer and Northwestern pray for a judgment in their favor and against Defendants Sun Pharma Global, Inc., Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc., and respectfully request the following relief:

A. A judgment declaring that Sun 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 Sun, 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 Sun Products within the United States, or importing the Sun 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. 91-157 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 Sun commercially manufactures, uses, offers to sell, or sells the Sun Products within the United States, or imports the Sun 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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