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. _____
ACTAVIS ELIZABETH LLC and ACTAVIS, 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 Actavis Elizabeth LLC and Actavis, Inc. (collectively, "Actavis") 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 Actavis' 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 Nos. 6,197,819 ("the '819 patent"), 6,001,876 ("the '876 patent") and 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. Pharmaceutical 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, Actavis Elizabeth LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 200 Elmora Ave., Elizabeth, New Jersey. On information and belief, Actavis Elizabeth LLC is a wholly owned subsidiary and agent of Defendant Actavis, Inc.

7. On information and belief, Actavis, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 60 Columbia Rd., Building B, Morristown, New Jersey. On information and belief, Actavis Elizabeth LLC is a wholly owned subsidiary and agent of Defendant Actavis, Inc.

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 Actavis 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.

14. On October 8, 1996, the United States Patent and Trademark Office 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 C.

15. Northwestern has exclusively licensed the '175 patent to Warner-Lambert Company LLC.

LYRICA®

16. 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®.

17. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '819, '876 and '175 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Lyrica®.

ACTAVIS' ANDA

18. On information and belief, Actavis submitted ANDA No. 91-025 ("the Actavis 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 Actavis ANDA are herein referred to as the "Actavis Products."

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

20. Pfizer and Northwestern received from Actavis a letter, dated March 26, 2009, and attached memoranda (the "Actavis Notification"), stating that Actavis had included a certification in the Actavis ANDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the '819, '876 and '175 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Actavis Products ("the Paragraph IV Certification").

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

21. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-20 of this Complaint.

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

23. Actavis' commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis 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).

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

25. Plaintiffs have no adequate remedy at law.

26. 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

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

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

29. Actavis' commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis 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).

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

31. Pfizer has no adequate remedy at law.

32. This case is an exceptional one, and Pfizer is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 5,563,175

33. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-32 of this Complaint.

34. Actavis has infringed the '175 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA

to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Products prior to the expiration of the '175 patent.

35. Actavis' commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis 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).

36. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the '175 patent.

37. Plaintiffs have no adequate remedy at law.

38. 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 Actavis Elizabeth LLC and Actavis, Inc., and respectfully request the following relief:

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

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

C. A judgment declaring that Actavis has infringed U.S. Patent. No. 5,563,175;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis, 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 Actavis Products within the United States, or importing the Actavis Products into the United States, prior to the expiration of the '819, '876 and '175 patents;

E. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 91-025 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, '876 and '175 patents, including any extensions;

F. If Actavis commercially manufactures, uses, offers to sell, or sells the Actavis Products within the United States, or imports the Actavis Products into the United States, prior to the expiration of any of the '819, '876 and '175 patents, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

G. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

H. Costs and expenses in this action; and

I. Such other relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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