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. _____
NOVEL LABORATORIES INC.,	)	
Defendant.	)	

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 Defendant Novel Laboratories Inc. ("Novel") 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 Novel'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 Nos. 6,197,819 ("the '819 patent") and 5,563,175 ("the '175 patent"), and United States 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, Novel is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Campus Drive, Somerset, New Jersey. On information and belief, Novel is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

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 Novel by virtue of, inter alia, its incorporation in Delaware, having conducted business in Delaware and having availed itself of the rights and benefits of Delaware law.

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 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 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 B.

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

14. On November 9, 2007, Warner-Lambert Company LLC filed with the USPTO an application, Serial No. 11/983,750, for reissue of U.S. Patent No. 6,001,876, entitled "IsobutylGABA And Its Derivatives For The Treatment of Pain" ("the '876 patent"). On

November 9, 2010, the USPTO reissued the '876 patent as U.S. Reissue Patent No. RE 41,920, also 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.

15. 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®

16. Pfizer holds approved New Drug Application No. 22-488 ("the Lyrica NDA") for a pregabalin oral solution containing 20 mg/mL of pregabalin, for sale by Pfizer Inc. under the trade name Lyrica®.

17. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '819, '175, and RE '920 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Lyrica®.

NOVEL'S ANDA

18. On information and belief, Novel submitted ANDA No. 202269 ("the Novel ANDA") to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market pregabalin oral solution 20 mg/mL. The pregabalin oral solution described in the Novel ANDA is herein referred to as the "Novel Product."

19. The Novel ANDA refers to and relies upon the Lyrica NDA and contains data that, according to Novel, demonstrate the bioequivalence of the Novel Product and Lyrica®.

20. Pfizer and Northwestern received from Novel a letter, dated November 24, 2010, and attached memoranda (the "Novel Notification"), stating that Novel had included a certification in the Novel ANDA, pursuant to 21 U.S.C. §355(j)(2)(B)(i) and/or (ii) and 21 C.F.R. § 314.95, that the '819, '876 and '175 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Novel Product ("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. Novel has infringed the '819 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Novel ANDA, by which Novel seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Novel Product prior to the expiration of the '819 patent.

23. Novel's commercial manufacture, use, offer to sell, or sale of the Novel Product within the United States, or importation of the Novel Product 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 Novel 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. 5,563,175

27. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-26 of this Complaint.

28. Novel has infringed the '175 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Novel ANDA, by which Novel seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Novel Product prior to the expiration of the '175 patent.

29. Novel's commercial manufacture, use, offer to sell, or sale of the Novel Product within the United States, or importation of the Novel Product 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).

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

31. Plaintiffs have no adequate remedy at law.

32. 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 REISSUE PATENT NO. RE 41,920

33. Pfizer realleges and incorporates by reference the allegations of paragraphs 1-32 of this Complaint.

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

35. Novel's commercial manufacture, use, offer to sell, or sale of the Novel Product within the United States, or importation of the Novel Product 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).

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

37. Pfizer has no adequate remedy at law.

38. 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 Novel, Inc. and respectfully request the following relief:

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

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

C. A judgment declaring that Novel has infringed U.S. Reissue Patent No. RE 41,920.

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Novel, 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 Novel Product within the United States, or importing the Novel Product into the United States, prior to the expiration of the '819, '175, and RE '920 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. 202269 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, '175, and RE '920 patents, including any extensions;

F. If Novel commercially manufactures, uses, offers to sell, or sells the Novel Product within the United States, or imports the Novel Product into the United States, prior to the expiration of any of the '819, '175 and RE '920 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.

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