

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION**

ALLERGAN, INC.,

Plaintiff,

v.

SANDOZ INC.,

Defendant.

Civil Action No. _____

Jury Trial Demanded

ALLERGAN'S COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendant Sandoz Inc. ("Sandoz" or "Defendant"), Plaintiff Allergan, Inc. ("Allergan" or "Plaintiff"), by its attorneys, alleges as follows:

The Nature of the Action

1. This is an action for infringement of United States Patents Nos. 7,851,504 B2 ("the '504 patent") and 5,688,819 ("the '819 patent") under 35 U.S.C. § 271(e)(2).

The Parties

2. Allergan is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

3. Allergan operates a facility in Waco, Texas where it manufactures and distributes numerous pharmaceutical products, including Lumigan®. Allergan employs approximately 600 individuals in Texas, more than in any other U.S. state except California.

4. On information and belief, Sandoz is a corporation incorporated under the laws of the State of Colorado, with a place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

5. On information and belief, Sandoz is in the business of manufacturing, distributing and selling generic drugs throughout the United States, including in this judicial district.

Jurisdiction and Venue

6. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.* This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338.

7. This Court has personal jurisdiction over Defendant Sandoz by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein.

8. Specifically, this Court has personal jurisdiction over Sandoz because it, either directly or through an agent, regularly does or solicits business in this jurisdiction, engages in other persistent courses of conduct in this jurisdiction, and/or derives substantial revenue from services or things used or consumed in this jurisdiction.

9. On information and belief, Sandoz has indicated that it is subject to personal jurisdiction in any judicial district in which it conducts business.

10. On information and belief, Sandoz is a licensed wholesale distributor of prescription drugs in Texas, and sells over 180 products in Texas.

11. On information and belief, in 2010 Sandoz sold over \$1 billion of products in Texas, over \$70 million of which were sold in this judicial district.

12. On information and belief, from 2007-2010 Sandoz sold over \$3 billion of products in Texas, over \$230 million of which were sold in this judicial district. On information and belief, Sandoz's sales in Texas during this period were higher than its sales in any other U.S. state except California.

13. On information and belief, numerous Sandoz over-the-counter products are available for purchase at pharmacies throughout Texas and in this judicial district.

14. On information and belief, Sandoz has entered into contracts with the State of Texas related to sales of prescription drugs. For example, on information and belief Sandoz has signed a Supplemental Rebate Agreement with the State of Texas and is classified as a “Preferred Generic Manufacturer” in the Texas Medicaid program.

15. On information and belief, Sandoz products appear on the Preferred Drug List for the Texas Medicaid program, and are available to the millions of Texans in this judicial district and throughout the State who participate in the Texas Medicaid program.

16. On information and belief, Sandoz sells products to hundreds of Veterans Administration and Public Health Services facilities throughout Texas through the Texas Medicaid program.

17. On information and belief, Sandoz has entered into arrangements with Texas entities to have its products appear on the formulary lists of major managed care and health plan companies in Texas, including Blue Cross Blue Shield Texas and the Scott and White formulary list.

18. On information and belief, Sandoz has entered into arrangements with Novation, LLC, a 25,000 member contracting services organization based in Irving, Texas, to make Sandoz products available to Novation’s member network.

19. On information and belief, Sandoz has entered into arrangements with pharmaceutical wholesalers, including AmeriSource Bergen Co., Cardinal Health, and McKesson Co., which distribute Sandoz products to pharmacies throughout Texas, including in this judicial district.

20. On information and belief, AmeriSource Bergen Co. operates a large distribution center in this judicial district in Roanoke, Texas, where Sandoz products bound for this district and locations throughout Texas are warehoused prior to distribution.

21. On information and belief, Sandoz has previously availed itself of this forum for purposes of litigating its patent disputes. For example, Sandoz has submitted to the jurisdiction of this Court and filed counterclaims in *Allergan, Inc. v. Sandoz Inc.*, Case No. 09-cv-00097 (E.D. Tex.).

22. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

Background

23. The '504 patent, entitled "Enhanced Bimatoprost Ophthalmic Solution," issued to Chin-Ming Chang, James N. Chang, Rhett M. Schiffman, R. Scott Jordan, and Joan-En Chang-Lin on December 14, 2010. A copy of the '504 patent is attached to this complaint as Exhibit A.

24. Allergan, as assignee, owns the entire right, title, and interest in the '504 patent.

25. The '819 patent, entitled "Cyclopentane Heptanoic Acid, 2-Cycloalkyl or Arylalkyl Derivatives as Therapeutic Agents," issued to David F. Woodward, Steven W. Andrews, Robert M. Burk, and Michael E. Garst on November 18, 1997. A copy of the '819 patent is attached to this complaint as Exhibit B.

26. Allergan, as assignee, owns the entire right, title, and interest in the '819 patent.

27. Allegan is the holder of an approved New Drug Application ("NDA") No. 22-184 for bimatoprost ophthalmic solution 0.01% sold under the Lumigan® trademark.

28. In conjunction with that NDA, Allergan has listed with the United States Food and Drug Administration ("FDA") three patents (the "Listed Patents") that cover the approved 0.01% formulation of Lumigan®. The Listed Patents are the '504 patent, the '819 patent, and

U.S. Patent No. 6,403,649 (“the ’649 patent”). The FDA has published the Listed Patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book.”

29. Lumigan® 0.01% is covered by at least one claim of each of the Listed Patents.

30. On or about July 15, 2011, Plaintiffs received a letter, dated July 11, 2011, signed on behalf of Sandoz by Bernadette Attinger, Regulatory Affairs.

31. The July 11, 2011 letter stated that Sandoz had submitted, and the FDA had received, an Abbreviated New Drug Application (“ANDA”) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), seeking approval to engage in the commercial manufacture, use, importation, sale or offer for sale of Bimatoprost Ophthalmic Solution, 0.01%, a generic version of Allergan’s Lumigan® 0.01% product, prior to expiration of the ’504 and ’819 patents. The ANDA Number for Sandoz’s application is 203056.

32. The July 11, 2011 letter stated that the ’504 and ’819 patents are invalid and/or will not be infringed by the commercial manufacture, use, importation, sale or offer for sale of Sandoz’s proposed Bimatoprost Ophthalmic Solution, 0.01%. The July 11, 2011 letter did not discuss the ’649 patent. Allergan believes that Sandoz has filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) as to the ’649 patent, and has no intention of selling a product made under ANDA No. 203056 prior to the expiration of the ’649 patent.

33. Attached to the July 11, 2011 letter was a statement of the factual and legal bases for Sandoz’s certifications under 21 CFR § 314.95 that the ’504 and ’819 patents are invalid, or will not be infringed by the manufacture, use, importation, sale or offer for sale of Sandoz’s proposed Bimatoprost Ophthalmic Solution, 0.01%.

34. In filing its ANDA No. 203056, Sandoz has requested the FDA's approval to market a generic version of Allergan's Lumigan® 0.01% product throughout the United States, including in Texas.

35. On information and belief, following FDA approval of its ANDA No. 203056, Sandoz will sell the approved generic version of Allergan's Lumigan® 0.01% product throughout the United States, including in Texas.

Count I

(Infringement of the '504 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

36. Paragraphs 1 to 35 are incorporated herein as set forth above.

37. Sandoz submitted ANDA No. 203056 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Sandoz has committed an act of infringement of the '504 patent under 35 U.S.C. § 271(e)(2)(A).

38. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of the '504 patent.

39. On information and belief, Sandoz became aware of the '504 patent no later than when it submitted ANDA No. 203056 to the FDA, in which it identified the '504 patent as one of the patents covering the approved 0.01% formulation of Lumigan®.

40. On information and belief, Sandoz knew or should have known that its commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic

Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '504 patent.

41. On information and belief, Sandoz knew or should have known that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '504 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '504 patent.

42. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count II

(Infringement of the '819 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

43. Paragraphs 1 to 42 are incorporated herein as set forth above.

44. Sandoz submitted ANDA No. 203056 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Sandoz has committed an act of infringement of the '819 patent under 35 U.S.C. § 271(e)(2)(A).

45. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of the '819 patent.

46. On information and belief, Sandoz became aware of the '819 patent no later than when it submitted ANDA No. 203056 to the FDA, in which it identified the '819 patent as one of the patents covering the approved 0.01% formulation of Lumigan®.

47. On information and belief, Sandoz knew or should have known that its commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '819 patent.

48. On information and belief, Sandoz knew or should have known that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted for use in an infringement of the '819 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '819 patent.

49. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Jury Trial Demand

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury of all issues so triable.

Prayer for Relief

Allergan respectfully prays for the following relief:

a. That judgment be entered that Sandoz has infringed the '504 and '819 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203056 under section 505(j) of the

Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Sandoz's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '504 and '819 patents;

b. That an Order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Sandoz's ANDA No. 203056 shall be a date which is not earlier than the expiration date of the '504 and '819 patents, as extended by any applicable period of exclusivity;

c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Sandoz, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '504 and/or '819 patents;

d. If Sandoz attempts to engage in the commercial manufacture, use, offer to sell, sale or importation of Sandoz's generic product disclosed in its ANDA No. 203056 prior to the expiration of the '504 and '819 patents, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

e. If Sandoz attempts to engage in the commercial manufacture, use, offer to sell, sale or importation of Sandoz's generic product disclosed in its ANDA No. 203056 prior to the expiration of the '504 and '819 patents, as extended by any applicable period of exclusivity, judgment awarding Allergan damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

- f. That this is an exceptional case under 35 U.S.C. § 285, and that Allergan be awarded reasonable attorneys' fees and costs;
- g. An accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales; and
- h. That this Court award such other and further relief as it may deem just and proper.

Dated: August 26, 2011

Respectfully submitted,

By: /s/ W. Chad Shear

W. Chad Shear
Texas Bar No. 24013493
shear@fr.com
Douglas E. McCann
dmccann@fr.com
FISH & RICHARDSON P.C.
222 Delaware Avenue, 17th Floor
Wilmington, DE 19801
Telephone: (302) 652-5070
Facsimile: (302) 652-0607

Jonathan E. Singer
singer@fr.com
FISH & RICHARDSON P.C.
60 South Sixth St., #3200
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

Juanita R. Brooks
brooks@fr.com
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070
Facsimile: (858) 678-5099

Jeffrey T. Thomas
jtthomas@gibsondunn.com
GIBSON DUNN & CRUTCHER
3161 Michelson Drive
Irvine, CA 92612
Telephone: (949) 451-3800
Facsimile: (949) 475-4670

Attorneys for Plaintiff Allergan, Inc.