

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

ALLERGAN, INC.,

Plaintiff,

v.

WATSON PHARMACEUTICALS, INC.,
WATSON LABORATORIES, INC., and WATSON
PHARMA INC.

Defendant.

Civil Action No. _____

Jury Trial Demanded

ALLERGAN'S COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Allergan, Inc. ("Allergan" or "Plaintiff") by its attorneys, Stevens Love and Fish & Richardson P.C., for its complaint against Defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. and Watson Pharma, Inc. (collectively "Watson" or "Defendants"), hereby alleges as follows:

The Nature of the Action

1. This is an action for infringement of United States Patents Nos. 7,030,149 ("the '149 patent"), 7,320,976 ("the '976 patent"), 7,323,463 ("the '463 patent"), and 7,642,258 ("the '258 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. On information and belief, Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

4. On information and belief, Watson Laboratories, Inc. (“Watson Laboratories”) is a Nevada corporation having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

5. On information and belief, Watson Laboratories is a wholly-owned subsidiary of Watson Pharmaceuticals, and the two share at least some common officers and directors.

6. On information and belief, Watson Pharma, Inc. (“Watson Pharma”) is a Delaware corporation having a principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07962.

7. On information and belief, Watson Pharma is a wholly-owned subsidiary of Watson Pharmaceuticals, and the two share at least some common officers and directors.

Jurisdiction and Venue

8. 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.

9. This Court has personal jurisdiction over Watson by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein, as well as because of the injury to Allergan, and the cause of action Allergan has raised, as alleged herein.

10. Specifically, this Court has personal jurisdiction over defendants Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma because they, either directly or through an agent, including each other, regularly do or solicit business in this jurisdiction, engage in other persistent courses of conduct in this jurisdiction, and/or derive substantial revenue from services or things used or consumed in this jurisdiction.

11. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the generic brimonidine tartrate/timolol maleate ophthalmic solution, .2%/0.5% described in ANDA No. 201949 (defined below).

12. On information and belief, Watson Pharma is a licensed drug distributor in Texas.

13. On information and belief, drug products of both Watson Pharma and Watson Laboratories are listed on the Texas prescription drug formulary.

14. On information and belief, Watson Pharma markets and sells generic drugs manufactured by Watson Laboratories throughout the United States, including this judicial district.

15. On information and belief, in 2009, Watson Pharma had over \$825 million in sales in Texas alone, and at least \$50 million of these sales were in this judicial district.

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

Background

17. The '149 patent, entitled "Combination of Brimonidine Timolol for Topical Ophthalmic Use," issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh on April 18, 2006. A copy of the '149 patent is attached to this complaint as Exhibit A.

18. Allergan, as assignee, owns the entire right, title, and interest in the '149 patent.

19. The '976 patent, entitled "Combination of Brimonidine and Timolol for Topical Ophthalmic Use," issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L.

Batoosingh on January 22, 2008. A copy of the '976 patent is attached to this complaint as Exhibit B.

20. Allergan, as assignee, owns the entire right, title, and interest in the '976 patent.

21. The '463 patent, entitled "Combination of Brimonidine and Timolol for Topical Ophthalmic Use," issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L.

Batoosingh on January 29, 2008. A copy of the '463 patent is attached to this complaint as Exhibit C.

22. Allergan, as assignee, owns the entire right, title, and interest in the '463 patent.

23. The '258 patent, entitled "Combination of Brimonidine and Timolol for Topical Ophthalmic Use," issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L.

Batoosingh on January 5, 2010. A copy of the '258 patent is attached to this complaint as Exhibit D.

24. Allergan, as assignee, owns the entire right, title, and interest in the '258 patent.

25. Allergan is the holder of an approved New Drug Application ("NDA") No. 21-398 for brimonidine tartrate/timolol maleate ophthalmic solution 0.2%/0.5%, sold under the Combigan® trademark.

26. In conjunction with that NDA, Allergan has listed with the United States Food and Drug Administration ("FDA") four patents (the "Listed Patents") that cover the approved formulation of Combigan®. The Listed Patents are the '149, '976, '463, and '258 patents. The FDA has published the Listed Patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

27. Combigan® is covered by at least one claim of each of the Listed Patents.

28. On July 30, 2010, Allergan received a letter, dated July 26, 2010, signed on behalf of Watson Laboratories by Joyce Anne DelGaudio. The letter stated that Watson Laboratories had filed Abbreviated New Drug Application (“ANDA”) No. 201949 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) seeking approval to market a generic version of Allergan’s Combigan® product before expiration of the Listed Patents.

29. The stated purpose of the July 26, 2010 letter was to notify Allergan that ANDA No. 201949 contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the ’149, ’976, ’463, and ’258 patents. The letter alleged that the claims of the Listed Patents are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of the Watson product.

30. Attached to the July 26, 2010 letter was a “Detailed Statement” of the factual and legal basis for Watson Laboratories’ opinion that the Listed Patents are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of the Watson product. The Detailed Statement alleged only that the Listed Patents were invalid, and therefore would not be infringed by the manufacture, use, importation, sale or offer for sale of the Watson product.

31. In filing its ANDA, Watson has requested the FDA’s approval to market a generic version of Allergan’s Combigan® product throughout the United States, including in Texas.

32. On information and belief, following FDA approval of its ANDA, Watson will sell the approved generic version of Allergan’s Combigan® product throughout the United States, including in Texas.

Count I

(Infringement of the '149 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Brimonidine tartrate/Timolol maleate Ophthalmic Solution 0.2%, 0.5%)

33. Paragraphs 1 to 32 are incorporated herein as set forth above.

34. Watson submitted ANDA No. 201949 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 brimonidine tartrate/timolol maleate ophthalmic solution 0.2%, 0.5% product throughout the United States. By submitting this application, Watson has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

35. The commercial manufacture, use, offer for sale, sale and/or importation of Watson's proposed generic brimonidine tartrate/timolol maleate ophthalmic solution 0.2%, 0.5% product will constitute an act of infringement of the '149 patent.

36. The commercial manufacture, use, offer for sale, sale and/or importation of Watson's proposed generic brimonidine tartrate/timolol maleate ophthalmic solution 0.2%, 0.5% product in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count II

(Infringement of the '976 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Brimonidine tartrate/Timolol maleate Ophthalmic Solution 0.2%, 0.5%)

37. Paragraphs 1 to 32 are incorporated herein as set forth above.

38. Watson submitted ANDA No. 201949 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 brimonidine tartrate/timolol maleate ophthalmic solution 0.2%, 0.5% product throughout the United States. By submitting this application, Watson has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

39. The commercial manufacture, use, offer for sale, sale and/or importation of Watson's proposed generic brimonidine tartrate/timolol maleate ophthalmic solution 0.2%, 0.5% product will constitute an act of infringement of the '976 patent.

40. The commercial manufacture, use, offer for sale, sale and/or importation of Watson's proposed generic brimonidine tartrate/timolol maleate ophthalmic solution 0.2%, 0.5% product in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count III

(Infringement of the '463 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Brimonidine tartrate/Timolol maleate Ophthalmic Solution 0.2%, 0.5%)

41. Paragraphs 1 to 32 are incorporated herein as set forth above.

42. Watson submitted ANDA No. 201949 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 brimonidine tartrate/timolol maleate ophthalmic solution 0.2%, 0.5% product throughout the United States. By submitting this application, Watson has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

43. The commercial manufacture, use, offer for sale, sale and/or importation of Watson's proposed generic brimonidine tartrate/timolol maleate ophthalmic solution 0.2%, 0.5% product will constitute an act of infringement of the '463 patent.

44. The commercial manufacture, use, offer for sale, sale and/or importation of Watson's proposed generic brimonidine tartrate/timolol maleate ophthalmic solution 0.2%, 0.5% product in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count IV

(Infringement of the '258 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Brimonidine tartrate/Timolol maleate Ophthalmic Solution 0.2%, 0.5%)

45. Paragraphs 1 to 32 are incorporated herein as set forth above.

46. Watson submitted ANDA No. 201949 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 brimonidine tartrate/timolol maleate ophthalmic solution 0.2%, 0.5% product throughout the United States. By submitting this application, Watson has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

47. The commercial manufacture, use, offer for sale, sale and/or importation of Watson's proposed generic brimonidine tartrate/timolol maleate ophthalmic solution 0.2%, 0.5% product will constitute an act of infringement of the '258 patent.

48. The commercial manufacture, use, offer for sale, sale and/or importation of Watson's proposed generic brimonidine tartrate/timolol maleate ophthalmic solution 0.2%, 0.5% product 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

Plaintiffs respectfully pray for the following relief:

a. That judgment be entered that Watson has infringed the '149, '976, '463, and '258 patents under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale,

sale and/or importation of Watson's proposed brimonidine tartrate/timolol maleate ophthalmic solution 0.2%, 0.5% product will constitute an act of infringement of the '149, '976, '463, and '258 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 Watson's ANDA shall be a date which is not earlier than the expiration date of the '149, '976, '463, and '258 patents;

c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Watson, 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 '149, '976, '463, and '258 patents;

d. If Watson attempts to engage in the commercial manufacture, use, offer to sell, sale or importation of Watson's generic product disclosed in its ANDA prior to the expiration of the '149, '976, '463, and '258 patents, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

e. If Watson attempts to engage in the commercial manufacture, use, offer to sell, sale or importation of Watson's generic product disclosed in its ANDA prior to the expiration of the '149, '976, '463, and '258 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: September 2, 2010

Respectfully submitted,

By: /s/ Gregory P. Love

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