

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

ALLERGAN, INC.,

Plaintiff,

v.

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

Defendants.

Civil Action No. 6:12-cv-197

Jury Trial Demanded

ALLERGAN'S INC.'S COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendants Watson Laboratories, Inc., Watson Pharmaceuticals, Inc., and Watson Pharma, Inc. (collectively "Watson" or "Defendants"), 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 Patent No. 7,851,504 B2 ("the '504 patent") and U.S. Patent No. 5,688,819 ("the '819 patent") under 35 U.S.C. §§ 271(a), (b), and (e)(2) that arises out of Watson's filing of Abbreviated New Drug Application ("ANDA") No. 203748 with the U.S. Food and Drug Administration ("FDA").

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, Watson Pharmaceuticals, Inc. (“Watson Pharmaceuticals”) is a corporation organized and existing under the laws of the State of Nevada, with its principal place of business at 311 Bonnie Circle, Corona, California 92880.

5. On information and belief, Watson Pharmaceuticals, both directly and through its subsidiaries, is engaged in the development, marketing, sale, and distribution of brand and generic pharmaceutical products throughout the United States, included Texas.

6. On information and belief, Watson Laboratories, Inc. (“Watson Laboratories”) is a corporation organized and existing under the laws of the State of Nevada, with its principal place of business at 311 Bonnie Circle, Corona, California 92880.

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

8. On information and belief, Watson Pharma, Inc. (“Watson Pharma”) is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 360 Mount Hemble Avenue, Morristown, New Jersey 07962.

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

Jurisdiction and Venue

10. 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, 1338, 2201, and 2202.

11. This Court has personal jurisdiction over Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma by virtue of their systematic and continuous contacts with this

jurisdiction, as alleged herein, and because of the injury to Allergan and the causes of action Allergan raises here, as alleged herein.

12. Specifically, this Court has personal jurisdiction over 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.

13. 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 Bimatoprost Ophthalmic Solution, 0.01% described in ANDA No. 203748.

14. On information and belief, Watson Pharma is a licensed drug distributor in Texas, and sells over 380 products in Texas.

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

16. On information and belief, in 2011, Watson Pharma sold over \$1.06 billion of products in Texas, over \$62.88 million of which were sold in this judicial district.

17. On information and belief, from 2008 to 2010, Watson Pharma sold over \$2.5 billion of products in Texas, over \$151.76 million of which were sold in this judicial district.

18. On information and belief, Watson has entered into contracts with the Texas Department of State Health Service to sell prescription drugs in Texas.

19. On information and belief, Watson's 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.

20. On information and belief, as a Medicaid participant, Watson is required to sell products to Veterans Administration and Public Health Services facilities, of which there are over 200 in Texas. The Department of Veteran Affairs Formulary lists Watson products as being available to its participants.

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

22. On information and belief, Watson Laboratories previously admitted to this Court that it markets and sells products in Texas, including in this judicial district. *See Allergan, Inc. v. Watson Laboratories, Inc.*, Case No. 2:10-cv-00344, D.I. 17 (E.D. Tex.).

23. On information and belief, Watson Laboratories has previously availed itself of this forum for purposes of litigating its patent disputes regarding its ANDA products. For example, Watson Laboratories has submitted to the jurisdiction of this Court and filed counterclaims in *Allergan, Inc. v. Watson Laboratories, Inc.*, Case No. 2:10-cv-00344 (E.D. Tex.).

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

Background

25. 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.

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

27. 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.

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

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

30. In conjunction with that NDA, Allergan has listed with the FDA four patents (the "Listed Patents") that cover the approved 0.01% formulation of Lumigan®. The Listed Patents are the '504 patent, the '819 patent, U.S. Patent No. 6,403,649 ("the '649 patent"), and U.S. Patent No. 8,017,655 ("the '655 patent"). The FDA has published the Listed Patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

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

32. On or about March 1, 2012, Allergan received a letter, dated February 29, 2012, signed on behalf of Watson Laboratories by Joyce Delgaudio, Executive Director, Regulatory Affairs.

33. The February 29, 2012 letter stated that Watson Laboratories had submitted an ANDA to the FDA under 21 U.S.C. §§ 355(j)(1) and (2)(A), seeking approval to engage in the commercial manufacture, use, or sale of Bimatoprost Ophthalmic Solution, 0.01%, a generic version of Allergan's Lumigan® 0.01% product, prior to the expiration of the '504 patent. The ANDA number for Watson's application is 203748.

34. The February 29, 2012 letter stated that the '504 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Watson's proposed Bimatoprost Ophthalmic Solution, 0.01%. The February 29, 2012 letter did not discuss the '819 patent, the '649 patent, or the '655 patent.

35. Attached to the February 29, 2012 letter was a statement of the factual and legal bases for Watson's certification under 21 C.F.R. § 314.95 that the '504 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of Watson's proposed Bimatoprost Ophthalmic Solution, 0.01%. No such statement was attached to the February 29, 2012 letter regarding the '819 patent, the '649 patent, or the '655 patent.

36. On or around March 9, 2012, Allergan requested confirmation from Watson that Watson had certified under 21 U.S.C. § 355(j)(2)(A)(vii)(III) as to the '819 patent, the '649 patent, or the '655 patent. In response, on March 14, 2012, Watson did not state whether or not it had certified under 21 U.S.C. § 355(j)(2)(A)(vii)(III) as to the '819 patent, the '649 patent, or the '655 patent.

37. In filing its ANDA No. 203748, Watson 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.

38. On information and belief, following FDA approval of its ANDA No. 203748, Watson will sell the approved generic version of Allergan's Lumigan® 0.01% product throughout the United States, including in Texas.

39. On information and belief, Watson has made, and continues to make, substantial preparation in the United States to manufacture, offer for sale, sell, and/or import into the United

States a generic version of Allergan's Lumigan® 0.01% product, prior to expiration of the '504 patent and the '819 patent.

40. Watson's actions, including, but not limited to, the development its proposed generic Bimatoprost Ophthalmic Solution, 0.01% and the filing of its ANDA No. 203748 with a Paragraph IV certification, indicate a refusal to change the course of its actions in the face of acts by Allergan.

41. Watson continues to seek approval of ANDA No. 203748 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of its proposed generic Bimatoprost Ophthalmic Solution, 0.01%.

Count I

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

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

43. Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma, acting jointly, submitted ANDA No. 203748 to the FDA under 21 U.S.C. §§ 355(j)(1) and (2)(A) for approval to engage in the commercial manufacture, use, or sale of their proposed generic Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma have committed an act of infringement of the '504 patent under 35 U.S.C. § 271(e)(2)(A).

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

45. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma became aware of the '504 patent no later than the date on which they jointly

submitted ANDA No. 203748 to the FDA, in which they identified the '504 patent as one of the patents covering the approved 0.01% formulation of Lumigan®.

46. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma know or should know that their commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '504 patent.

47. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson'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

(Declaratory Judgment of Infringement of the '504 Patent Under 35 U.S.C. §§ 271(a) and/or (b) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

48. Paragraphs 1 through 47 are incorporated herein as set forth above.

49. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic Bimatoprost Ophthalmic Solution, 0.01% immediately and imminently upon approval of ANDA No. 203748.

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

51. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma intend to, and will, actively induce infringement of the '504 patent when ANDA No. 203748 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

52. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma became aware of the '504 patent no later than the date on which they jointly submitted ANDA No. 203748 to the FDA, in which they identified the '504 patent as one of the patents covering the approved 0.01% formulation of Lumigan®.

53. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma know or should know that their commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '504 patent.

54. The foregoing actions by Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma constitute and/or will constitute infringement of the '504 patent and active inducement of infringement of the '504 patent.

55. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Allergan on the one hand and Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma on the other hand regarding Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma's infringement of the '504 patent and active inducement of infringement of the '504 patent.

56. Allergan is entitled to a judgment declaring that the foregoing actions by Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma constitute and/or will constitute infringement of the '504 patent and active inducement of infringement of the '504 patent.

57. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma have acted with full knowledge of the '504 patent and without a reasonable basis for believing that they would not be liable for infringing the '504 patent and actively inducing the infringement of the '504 patent.

58. Unless Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma are enjoined from infringing the '504 patent and actively inducing infringement of the '504 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

Count III

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

59. Paragraphs 1 to 58 are incorporated herein as set forth above.

60. Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma jointly submitted ANDA No. 203748 to the FDA under 21 U.S.C. §§ 355(j)(1) and (2)(A) for approval to engage in the commercial manufacture, use, or sale of their proposed generic Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma have committed an act of infringement of the '819 patent under 35 U.S.C. § 271(e)(2)(A).

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

62. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma became aware of the '819 patent no later than the date on which they jointly submitted ANDA No. 203748 to the FDA, in which they identified at least one of the Listed Patents covering the approved 0.01% formulation of Lumigan®. The '819 patent is one of the four Listed Patents.

63. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma know or should know that their commercial manufacture, use, offer for sale,

sale, and/or importation of their proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '819 patent.

64. The commercial manufacture, use, offer for sale, sale and/or importation of Watson'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 IV

(Declaratory Judgment of Infringement of the '819 Patent Under 35 U.S.C. §§ 271(a) and/or (b) by Watson's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

65. Paragraphs 1 through 64 are incorporated herein as set forth above.

66. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic Bimatoprost Ophthalmic Solution, 0.01% immediately and imminently upon approval of ANDA No. 203748.

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

68. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma intend to, and will, actively induce infringement of the '819 patent when ANDA No. 203748 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

69. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma became aware of the '819 patent no later than the date on which they jointly submitted ANDA No. 203748 to the FDA, in which they identified at least one of the Listed

Patents covering the approved 0.01% formulation of Lumigan®. The '819 patent is one of the four Listed Patents.

70. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma know or should know that their commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '819 patent.

71. The foregoing actions by Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma constitute and/or will constitute infringement of the '819 patent and active inducement of infringement of the '819 patent.

72. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Allergan on the one hand and Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma on the other hand regarding Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma's infringement of the '819 patent and active inducement of infringement of the '819 patent.

73. Allergan is entitled to a judgment declaring that the foregoing actions by Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma constitute and/or will constitute infringement of the '819 patent and active inducement of infringement of the '819 patent.

74. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma have acted with full knowledge of the '819 patent and without a reasonable basis for believing that they would not be liable for infringing the '819 patent and actively inducing the infringement of the '819 patent.

75. Unless Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma are enjoined from infringing the '819 patent and actively inducing infringement of the '819 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

Jury Trial Demand

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff hereby demands 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 Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma have infringed the '504 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203748 under 21 U.S.C. §§ 355(j)(1) and (2)(A), and that the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Watson's generic product disclosed in ANDA No. 203748 will constitute an act of infringement of the '504 patent;
- 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 No. 203748 shall be a date which is not earlier than the expiration date of the '504 patent, 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 Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of any drug product covered by the '504 patent;

d. If Watson Pharmaceuticals, Watson Laboratories, or Watson Pharma attempts to engage in the commercial manufacture, use, offer for sale, sale, or importation of Watson's generic product disclosed in ANDA No. 203748 prior to the expiration of the '504 patent, as extended by any applicable period of exclusivity, that a preliminary injunction be issued enjoining such conduct;

e. If Watson Pharmaceuticals, Watson Laboratories, or Watson Pharma attempts to engage in the commercial manufacture, use, offer for sale, sale, or importation of Watson's generic product disclosed in ANDA No. 203748 prior to the expiration of the '504 patent, as extended by any applicable period of exclusivity, that judgment be entered 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 judgment be entered declaring that Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma will infringe the '504 patent and will actively induce infringement of the '504 patent if and when they engage in the commercial manufacture, use, offer for sale, sale, or importation of Watson's generic product disclosed in ANDA No. 203748 prior to the expiration of the '504 patent, as extended by any applicable period of exclusivity;

g. That judgment be entered that Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma have infringed the '819 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203748 under 21 U.S.C. §§ 355(j)(1) and (2)(A), and that the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Watson's generic product disclosed in ANDA No. 203748 will constitute an act of infringement of the '819 patent;

h. 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 No. 203748 shall be a date which is not earlier than the expiration date of the '819 patent, as extended by any applicable period of exclusivity;

i. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of any drug product covered by the '819 patent;

j. If Watson Pharmaceuticals, Watson Laboratories, or Watson Pharma attempts to engage in the commercial manufacture, use, offer for sale, sale, or importation of Watson's generic product disclosed in ANDA No. 203748 prior to the expiration of the '819 patent, as extended by any applicable period of exclusivity, that a preliminary injunction be issued enjoining such conduct;

k. If Watson Pharmaceuticals, Watson Laboratories, or Watson Pharma attempts to engage in the commercial manufacture, use, offer sale, sale, or importation of Watson's generic product disclosed in ANDA No. 203748 prior to the expiration of the '819 patent, as extended by any applicable period of exclusivity, that judgment be entered 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;

l. That judgment be entered declaring that Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma will infringe the '819 patent and will actively induce infringement of the '819 patent if and when they engage in the commercial manufacture, use,

offer for sale, sale, or importation of Watson's generic product disclosed in ANDA No. 203748 prior to the expiration of the '819 patent, as extended by any applicable period of exclusivity;

m. That this is an exceptional case under 35 U.S.C. § 285, and that Allergan be awarded reasonable attorneys' fees and costs;

n. That an accounting be entered for infringing sales not presented at trial and that an award be issued by the Court of additional damages for any such infringing sales; and

o. That this Court award such other and further relief as it may deem just and proper.

Dated: March 23, 2012

Respectfully submitted,

By: /s/ Wesley Hill (w/permission of lead attorney)

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