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

ALLERGAN, INC., Plaintiff, v. ALCON LABORATORIES, INC., ALCON RESEARCH, LTD., ALCON, INC. AND FALCON PHARMACEUTICALS, LTD., Defendants.	Civil Action No. 2:09-cv-348 **Jury Trial Demanded**

PLAINTIFF ALLERGAN, INC.'S COMPLAINT AGAINST ALCON RESEARCH, LTD., ALCON LABORATORIES, INC., ALCON, INC. AND FALCON PHARMACEUTICALS, LTD.

Plaintiff Allergan, Inc. ("Allergan" or "Plaintiff") by its attorneys, Ireland, Carroll & Kelley, P.C. and Fish & Richardson P.C., for its complaint against Defendants Alcon Research, Ltd., Alcon Laboratories, Inc., Alcon, Inc. and Falcon Pharmaceuticals, Ltd. (collectively "Alcon" or "Defendants") 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") and 7,323,463 ("the '463 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, defendant Alcon Research, Ltd. is a limited partnership organized under the laws of Texas. On information and belief, defendant Alcon

Laboratories, Inc. is a corporation incorporated under the laws of the State of Delaware, and is headquartered in Fort Worth, Texas. On information and belief, Alcon Laboratories is the general partner of the Alcon Research, Ltd. limited partnership. On information and belief, Alcon, Inc. is headquartered in Hünenberg, Switzerland and is related to Alcon Laboratories, Inc. and/or Alcon Research, Ltd. On information and belief, Falcon Pharmaceuticals, Ltd. is a generic pharmaceutical subsidiary of Alcon, Inc.

4. On information and belief, Alcon is in the business of manufacturing, distributing and selling generic drugs throughout the United States, including in this judicial jurisdiction.

Jurisdiction and Venue

5. 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.

6. This Court has personal jurisdiction over Alcon by virtue of its systematic and continuous contacts with this jurisdiction.

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

Background

8. 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.

9. Allergan, as assignee, owns the entire right, title, and interest in the ’149 patent.

10. 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.

11. Allergan, as assignee, owns the entire right, title, and interest in the ’976 patent.

12. 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.

13. Allergan, as assignee, owns the entire right, title, and interest in the ’463 patent.

14. Allegan 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.

15. In conjunction with that NDA, Allergan has listed with the United States Food and Drug Administration (“FDA”) three patents that cover the approved formulation of Combigan®. The listed patents are the ’149, ’976 and ’463 patents (collectively, “the Listed Patents”). The FDA has published these three patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book.”

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

17. On September 29, 2009, Allergan received a letter from outside counsel for Alcon Research, Ltd. dated September 25, 2009. The letter stated that pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), Alcon Research, Ltd. was providing notice that it had filed Abbreviated New Drug Application (“ANDA”) No. 91-574 with the FDA.

18. The September 25, 2009 letter stated that the ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A) and contained a paragraph IV certification to obtain approval to

engage in the commercial manufacture, use or sale of a generic version of Allergan's Combigan® product before expiration of the Listed Patents.

19. The September 25, 2009 letter alleged that the claims of the '149, '976 and '463 patents were invalid, unenforceable and/or would not be infringed by the commercial manufacture, use or sale of Alcon's proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%.

20. Attached to the September 25, 2009 letter was a document describing the factual and legal bases for Alcon's opinion that the Listed Patents were invalid, unenforceable and/or would not be infringed by the Alcon product described in ANDA No. 91-574.

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

22. On information and belief, following FDA approval of its ANDA, Alcon 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 Alcon's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

23. Paragraphs 1 to 22 are incorporated herein as set forth above.

24. Alcon submitted ANDA No. 91-574 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 and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% throughout the United States. By submitting this application, Alcon has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

25. The commercial manufacture, use, offer for sale, sale and/or importation of Alcon's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will constitute an act of infringement of the '149 patent.

26. On information and belief, Alcon's commercial manufacture, use, offer for sale, sale and/or importation of Alcon's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce and/or contribute to the infringement of the '149 patent.

27. The commercial manufacture, use, offer for sale, sale and/or importation of Alcon's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% 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 '149 Patent Under 35 U.S.C. § 271(a-c))

28. Paragraphs 1 to 22 are incorporated herein as set forth above.

29. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

30. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

31. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%.

32. Defendants' actions indicate a refusal to change the course of their actions in the face of acts by Allergan.

33. While Defendants denied infringement of the '149 patent in their paragraph IV letter, they did not state their formulation in that letter, and have, to date, failed to provide their ANDA to Allergan. In the absence of such information, Allergan resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their allegations of infringement and to present to the Court evidence that Defendants' proposed product falls within the scope of one or more claims of the '149 patent. *See Hoffman La-Roche v. Invamed*, 213 F.3d 1359 (Fed. Cir. 2000).

34. The commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will infringe, contribute to, and/or induce infringement of the '149 patent.

35. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% by any or all of Defendants will infringe the '149 patent.

Count III

(Infringement of the '976 Patent Under 35 U.S.C. § 271(e)(2) by Alcon's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

36. Paragraphs 1 to 22 are incorporated herein as set forth above.

37. Alcon submitted ANDA No. 91-574 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 and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% throughout the

United States. By submitting this application, Alcon has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

38. The commercial manufacture, use, offer for sale, sale and/or importation of Alcon's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will constitute an act of infringement of the '976 patent.

39. On information and belief, Alcon's commercial manufacture, use, offer for sale, sale and/or importation of Alcon's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce and/or contribute to the infringement of the '976 patent.

40. The commercial manufacture, use, offer for sale, sale and/or importation of Alcon's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% 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 '976 Patent Under 35 U.S.C. § 271(a-c))

41. Paragraphs 1 to 22 are incorporated herein as set forth above.

42. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

43. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

44. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import

Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%.

45. Defendants' actions indicate a refusal to change the course of their actions in the face of acts by Allergan.

46. While Defendants denied infringement of the '976 patent in their paragraph IV letter, they did not state their formulation in that letter, and have, to date, failed to provide their ANDA to Allergan. In the absence of such information, Allergan resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their allegations of infringement and to present to the Court evidence that Defendants' proposed product falls within the scope of one or more claims of the '976 patent. *See Hoffman La-Roche v. Invamed*, 213 F.3d 1359 (Fed. Cir. 2000).

47. The commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will infringe the '976 patent.

48. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% by any or all of Defendants will infringe, contribute to, and/or induce infringement of the '976 patent.

Count V

(Infringement of the '463 Patent Under 35 U.S.C. § 271(e)(2) by Alcon's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

49. Paragraphs 1 to 22 are incorporated herein as set forth above.

50. Alcon submitted ANDA No. 91-574 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 and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% throughout the United States. By submitting this application, Alcon has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

51. The commercial manufacture, use, offer for sale, sale and/or importation of Alcon's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will constitute an act of infringement of the '463 patent.

52. On information and belief, Alcon's commercial manufacture, use, offer for sale, sale and/or importation of Alcon's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce and/or contribute to the infringement of the '463 patent.

53. The commercial manufacture, use, offer for sale, sale and/or importation of Alcon's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count VI

(Declaratory Judgment of Infringement of the '463 Patent Under 35 U.S.C. § 271(a-c))

54. Paragraphs 1 to 22 are incorporated herein as set forth above.

55. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

56. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

57. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import

Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%.

58. Defendants' actions indicate a refusal to change the course of their actions in the face of acts by Allergan.

59. While Defendants denied infringement of the '463 patent in their paragraph IV letter, they did not state their formulation in that letter, and have, to date, failed to provide their ANDA to Allergan. In the absence of such information, Allergan resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their allegations of infringement and to present to the Court evidence that Defendants' proposed product falls within the scope of one or more claims of the '463 patent. *See Hoffman La-Roche v. Invamed*, 213 F.3d 1359 (Fed. Cir. 2000).

60. The commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will infringe, contribute to, and/or induce infringement of the '463 patent.

61. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% by any or all of Defendants will infringe the '463 patent.

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 Alcon has infringed the ’149, ’976 and ’463 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 Alcon’s proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% product will constitute an act of infringement of the ’149, ’976 and ’463 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 Alcon’s ANDA shall be a date which is not earlier than the expiration date of the ’149, ’976 and ’463 patents, as extended by any applicable period of exclusivity;

c. Than an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Alcon, 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 and ’463 patents;

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

e. If Alcon attempts to engage in the commercial manufacture, use, offer to sell, sale or importation of Alcon’s generic product disclosed in its ANDA prior to the expiration of the

’149, ’976 and ’463 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 a declaration be issued under 28 U.S.C. § 2201 that if Alcon, its 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 engage in the commercial manufacture, use, offer for sale, sale and/or importation of Defendants’ proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, it will constitute an act of infringement of the ’149, ’976 and ’463 patents;

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

h. An accounting for infringing sales not presented at trial and an award by the court of additional damages for any such infringing sales; and

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

Dated: November 6, 2009

Respectfully submitted,

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