

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

ALLERGAN, INC.,

Plaintiff,

v.

APOTEX, INC. and APOTEX CORP.,

Defendants.

Civil Action No. 2:10-cv-00200

Jury Trial Demanded

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Allergan, Inc. (“Allergan” or “Plaintiff”) by its attorneys, Fish & Richardson P.C. and Stevens Love, for its amended complaint against Defendants Apotex, Inc. and Apotex Corp. (collectively “Apotex” 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”), 7,323,463 (“the ’463 patent”) and 7,642,258 (“the ’258 patent”) under 35 U.S.C. § 271(e)(2) relating to Allergan’s commercially successful glaucoma treatment, Combigan®.

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. Combigan® is manufactured in the state of Texas, and is distributed out of this judicial district.

3. On information and belief, defendant Apotex, Inc. is a corporation organized and existing under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

4. On information and belief, defendant Apotex, Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

5. On information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

6. On information and belief, defendant Apotex Corp. is a subsidiary of Apotex, Inc.

Jurisdiction and Venue

7. 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.

8. This Court has personal jurisdiction over Apotex 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.

9. Specifically, this Court has personal jurisdiction over defendants Apotex Inc. and Apotex Corp. 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.

10. On information and belief, Apotex Inc. and Apotex Corp. 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. 91-442 (defined below).

11. Further demonstrating the close interconnections between the two entities is the fact that both Apotex Inc. and Apotex Corp. provided Allergan with notice (via a single letter) that the two entities had submitted a new drug application for brimonidine tartrate/timolol maleate ophthalmic solution, .2%/0.5% to the United States Food and Drug Administration (“FDA”).

12. On information and belief, defendant Apotex Corp. is a licensed drug distributor in Texas.

13. On information and belief, Apotex, Inc. drug products are listed on the Texas prescription drug formulary.

14. On information and belief, Apotex Corp. sells numerous generic drugs, manufactured and supplied by Apotex, Inc., throughout the United States, including this judicial district.

15. On information and belief, in 2009 Apotex Corp. sold nearly \$700 million worth of Apotex, Inc.’s products in Texas, over \$50 million of which were sold 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 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 or about May 4, 2010, Allergan received a letter, dated April 29, 2010, signed on behalf of Apotex Inc. and Apotex Corp. by Stephen Benson of Katten Muchin Rosenman LLP. The letter stated that Apotex Inc. and Apotex Corp. had filed Abbreviated New Drug Application (“ANDA”) No. 91-442 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of a generic version of Allergan’s Combigan® product before the expiration of the ’149, ’976, ’463 and ’258 patents.

29. The April 29, 2010 letter stated that the ’149, ’976, ’463 and ’258 patents were invalid, unenforceable, and/or would not be infringed by the manufacture, use, or sale of Apotex’s proposed Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution, 0.2%/0.5%.

30. Attached to the April 29, 2010 letter was a statement of the factual and legal bases for Apotex’s Paragraph IV certifications that U.S. Patent Nos. 7,030,149, 7,323,463, 7,320,976, and 7,642,258 are invalid and/or will not be infringed.

31. In filing its ANDA, Apotex 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, Apotex 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 Apotex’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. Apotex submitted ANDA No. 91-442 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 Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution, 0.2%/0.5% throughout the United States. By submitting this application, Apotex 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 Apotex's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will constitute an act of infringement of the '149 patent.

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

37. The commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Brimonidine Tartrate/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

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

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

39. Apotex submitted ANDA No. 91-442 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 Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution, 0.2%/0.5% throughout the United States. By submitting this application, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

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

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

42. The commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Brimonidine Tartrate/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 III

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

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

44. Apotex submitted ANDA No. 91-442 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 Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution, 0.2%/0.5% throughout the United States. By submitting this application, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

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

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

47. The commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Brimonidine Tartrate/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

(Infringement of the '258 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution, 0.2%/ 0.5%)

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

49. Apotex submitted ANDA No. 91-442 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 Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution, 0.2%/0.5% throughout the United States. By submitting this application, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

50. The commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will constitute an act of infringement of the '258 patent.

51. On information and belief, Apotex's commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce and/or contribute to the infringement of the '258 patent.

52. The commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Brimonidine Tartrate/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.

Jury Trial Demand

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff hereby requests 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 Apotex 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 Apotex's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution, 0.2%/0.5% 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 Apotex's ANDA shall be a date which is not earlier than the expiration date of the '149, '976, '463 and '258 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 Apotex, 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 Apotex attempts to engage in the commercial manufacture, use, offer to sell, sale or importation of Apotex'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 Apotex attempts to engage in the commercial manufacture, use, offer to sell, sale or importation of Apotex'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: June 23, 2010

Respectfully submitted,

By: /s/ Gregory P. Love

Gregory P. Love
greg@stevenslove.com
STEVENS LOVE
P.O. Drawer 3427
Longview, TX 75606
Phone: (903) 753-6760
Facsimile: (903) 753-6761

W. Chad Shear
Texas Bar No. 24013493
shear@fr.com
FISH & RICHARDSON P.C.
1717 Main Street, Suite 5000
Dallas, TX 75201
Telephone: (214) 747-5070
Facsimile: (214) 747-2091

Juanita Brooks – *to be admitted pro hac*
brooks@fr.com
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070
Facsimile: (858) 678-5099

Jonathan E. Singer – *to be admitted pro hac*
singer@fr.com
Deanna J. Reichel – *to be admitted pro hac*
reichel@fr.com
Áine M. Skow – *to be admitted pro hac*
skow@fr.com
FISH & RICHARDSON P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

Susan M. Coletti – *to be admitted pro hac*
coletti@fr.com
FISH & RICHARDSON P.C.
222 Delaware Avenue, 17th Floor
Wilmington, DE 19899
Telephone: (302) 652-5070
Facsimile: (302) 652-0607

Counsel for Plaintiff
ALLERGAN, INC.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served on June 23, 2010, to all counsel of record who are deemed to have consented to electronic service via the Court's CM/ECF system per Local Rule CV-5(a)(3).

/s/ Gregory P. Love _____

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