

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC.,

Plaintiff,

v.

APOTEX, INC. and APOTEX CORP.,

Defendants.

Civil Action No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Allergan, Inc. (“Allergan” or “Plaintiff”), by its attorneys, Fish & Richardson P.C., for its 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. 5,424,078, (“the ’078 patent”), 6,562,873 (“the ’873 patent”), 6,627,210 (“the ’210 patent”), 6,673,337 (“the ’337 patent”), and 6,641,834 (“the ’834 patent”) under 35 U.S.C. § 271(e)(2).

The Parties

2. Plaintiff Allergan, Inc. 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 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, Apotex Corp. sells numerous generic drugs manufactured and supplied by Apotex, Inc. throughout the United States, including this judicial district.

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. Based on the facts and causes alleged herein, this Court has personal jurisdiction over Defendants.

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

Background

10. The '078 patent, entitled "Aqueous Ophthalmic Formulations and Methods for Preserving Same," issued to Anthony Dziabo and Paul Ripley on June 13, 1995. A copy of the '078 patent is attached to this complaint as Exhibit A.

11. Allergan, Inc., as the assignee, owns the entire right, title, and interest in the '078 patent.

12. The '873 patent, entitled "Compositions Containing Therapeutically Active Components Having Enhanced Solubility," issued to Orest Olejnik and Edward D.S. Kerslake on May 13, 2003. A copy of the '873 patent is attached to this complaint as Exhibit B.

13. Allergan, Inc., as the assignee, owns the entire right, title, and interest in the '873 patent.

14. The '210 patent, entitled "Compositions Containing α -2-Adrenergic Agonist Components," issued to Orest Olejnik and Edward D.S. Kerslake on September 30, 2003. A copy of the '210 patent is attached to this complaint as Exhibit C.

15. Allergan, Inc., as the assignee, owns the entire right, title, and interest in the '210 patent.

16. The '337 patent, entitled "Compositions Containing Alpha-2-Adrenergic Agonist Components," issued to Orest Olejnik and Edward D.S. Kerslake on January 6, 2004. A copy of the '337 patent is attached to this complaint as Exhibit D.

17. Allergan, Inc., as the assignee, owns the entire right, title, and interest in the '337 patent.

18. The '834 patent, entitled "Compositions Containing Alpha-2-Adrenergic Agonist Components," issued to Orest Olejnik and Edward D.S. Kerslake on November 4, 2003. A copy of the '834 patent is attached to this complaint as Exhibit E.

19. Allergan, Inc., as the assignee, owns the entire right, title, and interest in the '834 patent.

20. Allergan is the holder of approved New Drug Applications ("NDAs") No. 21-262 and 21-770 for 0.15% and 0.10% brimonidine tartrate ophthalmic solutions, respectively, sold under the ALPHAGAN® P trademark.

21. In conjunction with those NDAs, Allergan has listed with the FDA five patents (the "Listed Patents") that cover various aspects of the approved formulations of ALPHAGAN® P 0.15% and 0.10%. The Listed Patents are the '078, '873, '210, '337, and '834 patents.

22. ALPHAGAN® P 0.15% and 0.10% are covered by at least one claim of each of the Listed Patents.

23. On April 30, 2007, Allergan received a letter, dated April 26, 2007, signed on behalf of Apotex, Inc. The letter stated that Apotex had filed Abbreviated New Drug Application Nos. 78-479 and 78-480 ("ANDAs") with the United States Food and Drug

Administration (“FDA”) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) seeking approval to market generic versions of Allergan’s ALPHAGAN® P products, both the 0.15% and 0.10% formulations, before the expiration of the Listed Patents.

24. The purpose of the April 26, 2007 letter was to notify Allergan that Apotex had filed a certification with the FDA under 21 C.F.R. § 314.50(i)(1)(i)(A)(4) (“Paragraph IV certification”) in conjunction with its ANDAs. The letter alleged: (1) that the Listed Patents were invalid or unenforceable and (2) that, even if valid and enforceable, some claims of the Listed Patents would not be infringed by Apotex’s generic versions of Allergan’s ALPHAGAN® P products.

25. In filing its ANDAs, Apotex has requested the FDA’s approval to market generic versions of Allergan’s ALPHAGAN® P products throughout the United States, including Delaware.

26. On information and belief, following FDA approval of its ANDAs, Apotex, Inc., through Apotex Corp., will sell the approved generic versions of Allergan’s ALPHAGAN® P products throughout the United States, including Delaware.

Count I

(Infringement of the ’078 Patent Under 35 U.S.C. § 271(e)(2) by Apotex’s proposed generic 0.15% brimonidine tartrate ophthalmic solution product)

27. Paragraphs 1 to 26 are incorporated herein as set forth above.

28. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.15% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

29. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '078 patent.

Count II

(Infringement of the '873 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product)

30. Paragraphs 1 to 26 are incorporated herein as set forth above.

31. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.15% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

32. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '873 patent.

Count III

(Infringement of the '210 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product)

33. Paragraphs 1 to 26 are incorporated herein as set forth above.

34. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.15% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the 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 0.15% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '210 patent.

Count IV

(Infringement of the '337 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product)

36. Paragraphs 1 to 26 are incorporated herein as set forth above.

37. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.15% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex 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 Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '337 patent.

Count V

(Infringement of the '834 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product)

39. Paragraphs 1 to 26 are incorporated herein as set forth above.

40. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.15% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

41. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '834 patent.

Count VI

(Infringement of the '078 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product)

42. Paragraphs 1 to 26 are incorporated herein as set forth above.

43. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.1% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

44. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '078 patent.

Count VII

(Infringement of the '873 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product)

45. Paragraphs 1 to 26 are incorporated herein as set forth above.

46. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.1% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex 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 Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '873 patent.

Count VIII

(Infringement of the '210 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product)

48. Paragraphs 1 to 26 are incorporated herein as set forth above.

49. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.1% brimonidine tartrate ophthalmic solution product throughout the United States. By

submitting the 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 0.1% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '210 patent.

Count IX

(Infringement of the '337 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product)

51. Paragraphs 1 to 26 are incorporated herein as set forth above.

52. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.1% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

53. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '337 patent.

Count X

(Infringement of the '834 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product)

54. Paragraphs 1 to 26 are incorporated herein as set forth above.

55. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.1% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

56. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.1% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '834 patent.

Prayer For Relief

Plaintiffs respectfully pray for the following relief:

a. That judgment be entered that Apotex has infringed the '078, '873, '210, '337, and '834 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 0.15% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '078, '873, '210, '337, and '834 patents;

b. That judgment be entered that Apotex has infringed the '078, '873, '210, '337, and '834 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 0.1% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '078, '873, '210, '337, and '834 patents;

c. 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 ANDAs shall be a date which is not earlier than the expiration date of the '078, '873, '210, '337, and '834 patents;

d. 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 '078, '873, '210, '337, and '834 patents;

- e. That damages or other monetary relief be awarded to Allergan under 35 U.S.C. § 271(e)(4)(C) as appropriate;
- f. That this is an exceptional case under 35 U.S.C. § 285, and that Allergan be awarded reasonable attorneys' fees and costs; and
- g. That this Court award such other and further relief as it may deem just and proper.

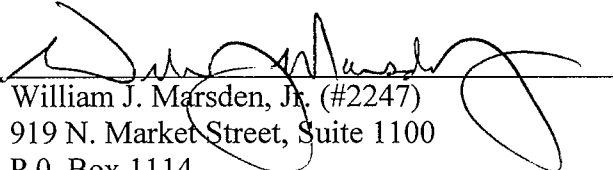
Demand for Jury Trial

Allergan demands a trial by jury on all issues appropriately tried to a jury.

Dated: May 21, 2007

FISH & RICHARDSON P.C.

By:



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