

AUGUST 18, 2008

STEVEN M. LARIMORE
CLERK U.S. DIST. CT.
S.D. OF FLA. - MIAMI

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

CASE NO.

08-22308-Civ-MORENO/TORRES

WYETH,

Plaintiff,

v.

APOTEX INC., and
APOTEX CORP.,

Defendants.

_____ /

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Wyeth, for its Complaint against Defendants, Apotex Incorporated (“Apotex Inc.”) and Apotex Corporation (“Apotex Corp.”) (referred to collectively as “Apotex”), states as follows:

THE PARTIES

1. Wyeth is a Delaware corporation having its principal place of business at Five Giralda Farms, Madison, New Jersey 07940.
2. On information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, Weston, Ontario, Canada, M9L 1T9.
3. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

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

5. On information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc.

6. On information and belief, the acts of Apotex Corp. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Apotex Inc.

7. On information and belief, the acts of Apotex Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Apotex Corp.

NATURE OF THE ACTION

8. This is a civil action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application (“ANDA”) No. 90-436 filed by Apotex with the United States Food and Drug Administration (“FDA”) for approval to market a generic copy of Wyeth’s highly successful EFFEXOR® XR pharmaceutical products that are sold in the United States.

JURISDICTION AND VENUE

9. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

10. On information and belief, and as previously noted, Apotex Corp. has its principal place of business in this district.

11. On information and belief, Apotex Corp. has continuous and systematic business contacts within the State of Florida.

12. On information and belief, this Court has personal jurisdiction over Apotex Corp.

13. Apotex Inc. has designated Tammy McIntire, Apotex Corp., 2400 N. Commerce Parkway, Westin, Florida 33326, as its agent for service of process. Consequently, this Court has personal jurisdiction over Apotex Inc. because it has consented to be sued in this Court.

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and 1400(b).

BACKGROUND

15. Wyeth-Ayerst Laboratories (now known as Wyeth Pharmaceuticals), a division of Wyeth, is the holder of approved New Drug Application (NDA) No. 20-699 for EFFEXOR® XR Capsules, an extended release dosage form containing venlafaxine hydrochloride.

16. On information and belief, Apotex filed with the FDA ANDA No. 90-436 under 21 U.S.C. § 355(j), seeking approval to market Venlafaxine Hydrochloride Extended-Release Capsules in 37.5, 75, and 150 mg dosage strengths (“Apotex’s Venlafaxine Hydrochloride ER Capsules”), which are generic copies of Wyeth’s EFFEXOR® XR Capsules, in 37.5, 75, and 150 mg dosage strengths, respectively.

17. By letter dated July 4, 2008, Apotex Inc. notified Wyeth that it had filed ANDA No. 90-436, seeking approval to market Apotex’s Venlafaxine Hydrochloride ER Capsules, and that it was providing information to Wyeth pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. §§ 314.95(c)(6)(i), (ii). Wyeth received that letter on or about July 10, 2008.

FIRST COUNT FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,274,171 B1

18. United States Patent No. 6,274,171 B1 (“the ’171 patent”), entitled “Extended Release Formulation of Venlafaxine Hydrochloride,” was duly and legally issued by the United

States Patent and Trademark Office on August 14, 2001. Wyeth (formerly known as American Home Products Corporation) is the owner by assignment of the '171 patent and has the right to sue for infringement thereof. A true and correct copy of the '171 patent is attached as Exhibit A.

19. On information and belief, Apotex filed ANDA No. 90-436 in order to obtain approval to market Apotex's Venlafaxine Hydrochloride ER Capsules in the United States before the expiration of the '171 patent. On information and belief, Apotex also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetics Act), a certification alleging that the claims of the '171 patent are invalid, unenforceable, or not infringed.

20. Under 35 U.S.C. § 271(e)(2)(A), Apotex's submission to the FDA of ANDA No. 90-436 to obtain approval for the commercial manufacture, use, or sale of Apotex's Venlafaxine Hydrochloride ER Capsules before the expiration date of the '171 patent constitutes infringement of one or more claims of the '171 patent, either literally or under the doctrine of equivalents.

21. Upon FDA approval of Apotex's ANDA No. 90-436, Apotex will infringe the '171 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Apotex's Venlafaxine Hydrochloride ER Capsules in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of Apotex's ANDA shall be no earlier than the expiration date of the '171 patent and any additional periods of exclusivity.

22. On information and belief, Apotex's Venlafaxine Hydrochloride ER Capsules, when offered for sale, sold, and/or imported, and when used as directed, would be used in a

manner that would directly infringe at least one of the claims of the '171 patent, either literally or under the doctrine of equivalents.

23. On information and belief, the use of Apotex's Venlafaxine Hydrochloride ER Capsules constitutes a material part of at least one of the claims of the '171 patent; Apotex knows that its Venlafaxine Hydrochloride ER Capsules are especially made or adapted for use in infringing at least one of the claims of the '171 patent, either literally or under the doctrine of equivalents; and Apotex's Venlafaxine Hydrochloride ER Capsules are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

24. On information and belief, the offering to sell, sale, and/or importation of Apotex's Venlafaxine Hydrochloride ER Capsules would contributorily infringe at least one of the claims of the '171 patent, either literally or under the doctrine of equivalents.

25. On information and belief, Apotex had knowledge of the '171 patent and, by its promotional activities and package insert for Apotex's Venlafaxine Hydrochloride ER Capsules, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '171 patent, either literally or under the doctrine of equivalents.

26. On information and belief, the offering to sell, sale, and/or importation of Apotex's Venlafaxine Hydrochloride ER Capsules would actively induce infringement of at least one of the claims of the '171 patent, either literally or under the doctrine of equivalents.

27. Wyeth will be substantially and irreparably harmed by Apotex's infringing activities unless those activities are enjoined by this Court. Wyeth has no adequate remedy at law.

**SECOND COUNT FOR INFRINGEMENT
OF UNITED STATES PATENT NO. 6,403,120 B1**

28. United States Patent No. 6,403,120 B1 (“the ’120 patent”), entitled “Extended Release Formulation of Venlafaxine Hydrochloride,” was duly and legally issued by the United States Patent and Trademark Office on June 11, 2002. Wyeth is the owner by assignment of the ’120 patent and has the right to sue for infringement thereof. A true and correct copy of the ’120 patent is attached as Exhibit B.

29. On information and belief, Apotex filed ANDA No. 90-436 in order to obtain approval to market Apotex’s Venlafaxine Hydrochloride ER Capsules in the United States, before the expiration of the ’120 patent. On information and belief, Apotex also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the ’120 patent are invalid, unenforceable, or not infringed.

30. Under 35 U.S.C. § 271(e)(2)(A), Apotex’s submission to the FDA of ANDA No. 90-436 to obtain approval for the commercial manufacture, use, or sale of Apotex’s Venlafaxine Hydrochloride ER Capsules before the expiration date of the ’120 patent constitutes infringement of one or more claims of the ’120 patent, either literally or under the doctrine of equivalents.

31. Upon FDA approval of Apotex’s ANDA No. 90-436, Apotex will infringe the ’120 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Apotex’s Venlafaxine Hydrochloride ER Capsules in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of Apotex’s ANDA shall be no earlier than the expiration of the ’120 patent and any additional periods of exclusivity.

32. On information and belief, Apotex's Venlafaxine Hydrochloride ER Capsules, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '120 patent, either literally or under the doctrine of equivalents.

33. On information and belief, the use of Apotex's Venlafaxine Hydrochloride ER Capsules constitutes a material part of at least one of the claims of the '120 patent; Apotex knows that Apotex's Venlafaxine Hydrochloride ER Capsules are especially made or adapted for use in infringing at least one of the claims of the '120 patent, either literally or under the doctrine of equivalents; and Apotex's Venlafaxine Hydrochloride ER Capsules are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

34. On information and belief, the offering to sell, sale, and/or importation of Apotex's Venlafaxine Hydrochloride ER Capsules would contributorily infringe at least one of the claims of the '120 patent, either literally or under the doctrine of equivalents.

35. On information and belief, Apotex had knowledge of the '120 patent and, by its promotional activities and package insert for Apotex's Venlafaxine Hydrochloride ER Capsules, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '120 patent, either literally or under the doctrine of equivalents.

36. On information and belief, the offering to sell, sale, and/or importation of Apotex's Venlafaxine Hydrochloride ER Capsules would actively induce infringement of at least one of the claims of the '120 patent, either literally or under the doctrine of equivalents.

37. Wyeth will be substantially and irreparably harmed by Apotex's infringing activities unless those activities are enjoined by this Court. Wyeth has no adequate remedy at law.

**THIRD COUNT FOR INFRINGEMENT
OF UNITED STATES PATENT NO. 6,419,958 B2**

38. United States Patent No. 6,419,958 B2 (“the ’958 patent”), entitled “Extended Release Formulation of Venlafaxine Hydrochloride,” was duly and legally issued by the United States Patent and Trademark Office on July 16, 2002. Wyeth is the owner by assignment of the ’958 patent and has the right to sue for infringement thereof. A true and correct copy of the ’958 patent is attached as Exhibit C.

39. On information and belief, Apotex filed ANDA No. 90-436 in order to obtain approval to market Apotex’s Venlafaxine Hydrochloride ER Capsules in the United States, before the expiration of the ’958 patent. On information and belief, Apotex also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the ’958 patent are invalid, unenforceable, or not infringed.

40. Under 35 U.S.C. § 271(e)(2)(A), Apotex’s submission to the FDA of ANDA No. 90-436 to obtain approval for the commercial manufacture, use, or sale of Apotex’s Venlafaxine Hydrochloride ER Capsules before the expiration date of the ’958 patent constitutes infringement of one or more claims of the ’958 patent, either literally or under the doctrine of equivalents.

41. Upon FDA approval of Apotex’s ANDA No. 90-436, Apotex will infringe the ’958 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Apotex’s Venlafaxine Hydrochloride ER Capsules in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of Apotex’s ANDA shall be no earlier than the expiration date of the ’958 patent and any additional periods of exclusivity.

42. On information and belief, Apotex's Venlafaxine Hydrochloride ER Capsules, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '958 patent, either literally or under the doctrine of equivalents.

43. On information and belief, the use of Apotex's Venlafaxine Hydrochloride ER Capsules constitutes a material part of at least one of the claims of the '958 patent; Apotex knows that its Venlafaxine Hydrochloride ER Capsules are especially made or adapted for use in infringing at least one of the claims of the '958 patent, either literally or under the doctrine of equivalents; and Apotex's Venlafaxine Hydrochloride ER Capsules are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

44. On information and belief, the offering to sell, sale, and/or importation of Apotex's Venlafaxine Hydrochloride ER Capsules would contributorily infringe at least one of the claims of the '958 patent, either literally or under the doctrine of equivalents.

45. On information and belief, Apotex had knowledge of the '958 patent and, by its promotional activities and package insert for Apotex's Venlafaxine Hydrochloride ER Capsules, will know or should know that it will aid and abet another's direct infringement of at least one of the claims of the '958 patent, either literally or under the doctrine of equivalents.

46. On information and belief, the offering to sell, sale, and/or importation of Apotex's Venlafaxine Hydrochloride ER Capsules would actively induce infringement of at least one of the claims of the '958 patent, either literally or under the doctrine of equivalents.

47. Wyeth will be substantially and irreparably harmed by Apotex's infringing activities unless those activities are enjoined by this Court. Wyeth has no adequate remedy at law.

**FOURTH COUNT FOR INFRINGEMENT OF
UNITED STATES PATENT NOS. 6,274,171 B1, 6,403,120 B1, AND 6,419,958 B2**

48. Wyeth incorporates by reference paragraphs 1 through 47 of this Complaint as if fully set forth herein.

49. On information and belief, Apotex Corp. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 90-436 to the FDA. On information and belief, Apotex Corp. was aware of the '171 patent, the '120 patent, and the '958 patent when it engaged in these knowing and purposeful activities referred to above.

50. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Apotex Corp. induced the infringement of the '171 patent, the '120 patent, and the '958 patent by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 90-436. The filing of the ANDA by Apotex Inc. and/or Apotex Corp. constitutes direct infringement under 35 U.S.C. § 271(e). Apotex Corp.'s active and knowing aiding and abetting Apotex Inc. in the filing of ANDA No. 90-436 constitute induced infringement.

51. Wyeth will be substantially and irreparably harmed by Apotex Corp.'s infringing activities unless those activities are enjoined by this Court. Wyeth has no adequate remedy at law.

**FIFTH COUNT FOR INFRINGEMENT OF
UNITED STATES PATENT NOS. 6,274,171 B1, 6,403,120 B1, AND 6,419,958 B2**

52. Wyeth incorporates by reference paragraphs 1 through 47 of this Complaint as if fully set forth herein.

53. On information and belief, Apotex Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA

No. 90-436 to the FDA. On information and belief, Apotex Inc. was aware of the '171 patent, the '120 patent, and the '958 patent when it engaged in these knowing and purposeful activities referred to above.

54. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Apotex Inc. induced the infringement of the '171 patent, the '120 patent, and the '958 patent by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 90-436. The filing of the ANDA by Apotex Inc. and/or Apotex Corp. constitutes direct infringement under 35 U.S.C. § 271(e). Apotex Inc.'s active and knowing aiding and abetting Apotex Corp. in the filing of ANDA No. 90-436 constitute induced infringement.

55. Wyeth will be substantially and irreparably harmed by Apotex Inc.'s infringing activities unless those activities are enjoined by this Court. Wyeth has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Wyeth respectfully requests that this Court enter judgment in its favor as follows:

(1) declaring that, under 35 U.S.C. § 271(e)(2)(A), Apotex's submission to the FDA of ANDA No. 90-436 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Apotex's Venlafaxine Hydrochloride ER Capsules before the expiration of the '171 patent was an act of infringement of the '171 patent;

(2) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Apotex Corp.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 90-436 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation

into the United States of Apotex's Venlafaxine Hydrochloride ER Capsules before the expiration of the '171 patent was an act of induced infringement of the '171 patent;

(3) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Apotex Inc.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 90-436 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Apotex's Venlafaxine Hydrochloride ER Capsules before the expiration of the '171 patent was an act of induced infringement of the '171 patent;

(4) declaring that Apotex's commercial manufacture, use, offer for sale, or sale in, or importation into the United States by Apotex of Apotex's Venlafaxine Hydrochloride ER Capsules would constitute infringement of the '171 patent;

(5) declaring that, under 35 U.S.C. § 271(e)(2)(A), Apotex's submission to the FDA of ANDA No. 90-436 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Apotex's Venlafaxine Hydrochloride ER Capsules before the expiration of the '120 patent was an act of infringement of the '120 patent;

(6) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Apotex Corp.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 90-436 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Apotex's Venlafaxine Hydrochloride ER Capsules before the expiration of the '120 patent was an act of induced infringement of the '120 patent;

(7) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Apotex Inc.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 90-436 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the

United States of Apotex's Venlafaxine Hydrochloride ER Capsules before the expiration of the '120 patent was an act of induced infringement of the '120 patent;

(8) declaring that Apotex's commercial manufacture, use, offer for sale or sale in, or importation into the United States by Apotex of Apotex's Venlafaxine Hydrochloride ER Capsules would constitute infringement of the '120 patent;

(9) declaring that, under 35 U.S.C. § 271(e)(2)(A), Apotex's submission to the FDA of ANDA No. 90-436 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Apotex's Venlafaxine Hydrochloride ER Capsules before the expiration of the '958 patent was an act of infringement of the '958 patent;

(10) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Apotex Corp.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 90-436 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Apotex's Venlafaxine Hydrochloride ER Capsules before the expiration of the '958 patent was an act of induced infringement of the '958 patent;

(11) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Apotex Inc.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 90-436 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Apotex's Venlafaxine Hydrochloride ER Capsules before the expiration of the '958 patent was an act of induced infringement of the '958 patent;

(12) declaring that Apotex's commercial manufacture, use, offer for sale, or sale in, or importation into the United States by Apotex of Apotex's Venlafaxine Hydrochloride ER Capsules would constitute infringement of the '958 patent;

(13) ordering that the effective date of any FDA approval of Apotex's Venlafaxine Hydrochloride ER Capsules shall be no earlier than the expiration date of the '171 patent and any additional dates of exclusivity, in accordance with 35 U. S. C. § 271(3)(4)(A);

(14) ordering that the effective date of any FDA approval of Apotex's Venlafaxine Hydrochloride ER Capsules shall be no earlier than the expiration date of the '120 patent and any additional dates of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

(15) ordering that the effective date of any FDA approval of Apotex's Venlafaxine Hydrochloride ER Capsules shall be no earlier than the expiration date of the '958 patent and any additional dates of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

(16) enjoining Apotex and all persons acting in concert with Apotex, from commercially manufacturing, using, offering for sale, or selling Apotex's Venlafaxine Hydrochloride ER Capsules within the United States or importing into the United States Apotex's Venlafaxine Hydrochloride ER Capsules, until the expiration of the '171 patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

(17) enjoining Apotex and all persons acting in concert with Apotex from commercially manufacturing, using, offering for sale or selling Apotex's Venlafaxine Hydrochloride ER Capsules within the United States or importing into the United States Apotex's Venlafaxine Hydrochloride ER Capsules until the expiration of the '120 patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

(18) enjoining Apotex and all persons acting in concert with Apotex from commercially manufacturing, using, offering for sale, or selling Apotex's Venlafaxine Hydrochloride ER Capsules within the United States or importing into the United States

Apotex's Venlafaxine Hydrochloride ER Capsules, until the expiration of the '958 patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

(19) enjoining Apotex and all persons acting in concert with Apotex from seeking, obtaining, or maintaining approval of Apotex's ANDA No. 90-436 until the expiration of the '171 patent;

(20) enjoining Apotex and all persons acting in concert with Apotex from seeking, obtaining, or maintaining approval of Apotex's ANDA No. 90-436 until the expiration of the '120 patent;

(21) enjoining Apotex and all persons acting in concert with Apotex from seeking, obtaining, or maintaining approval of Apotex's ANDA No. 90-436 until the expiration of the '958 patent;

(22) declaring this to be an exceptional case and awarding Wyeth its attorney fees under 35 U.S.C. § 285;

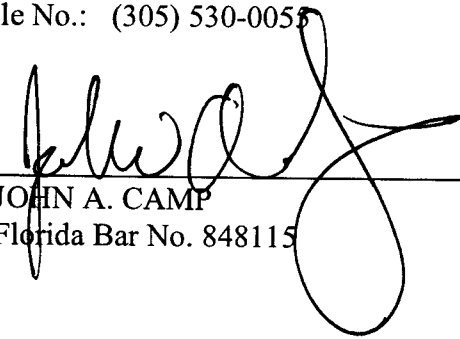
(23) awarding Wyeth its costs and expenses in this action; and

(24) awarding Wyeth any further and additional relief as this Court deems just and proper.

Dated: August 12, 2008

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