IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION

WYETH

Plaintiff,

v.

OSMOTICA PHARMACEUTICAL CORPORATION,

Defendant.

Civil Action No.: 7:07-cv-00067

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Wyeth, for its Complaint against Osmotica Pharmaceutical Corporation ("Osmotica"), hereby states as follows:

THE PARTIES

1. Plaintiff Wyeth is a Delaware corporation having its principal place of business at Five Giralda Farms, Madison, New Jersey 07940.

2. On information and belief, Defendant Osmotica is a company incorporated under the laws of the State of Delaware with a place of business at 1205 Culbreth Drive, Suite 200, Wilmington, NC 28405.

NATURE OF THE ACTION

3. 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 a New Drug Application ("NDA") filed by Osmotica with the United States Food and Drug Administration ("FDA") for approval to market a copy of Wyeth's highly successful EFFEXOR® XR pharmaceutical products that are sold in the United States ("the Osmotica NDA").

JURISDICTION AND VENUE

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

5. On information and belief, Osmotica has a place of business at 1205 Culbreth Drive, Suite 200, Wilmington, NC 28405, and conducts business in North Carolina. Osmotica is registered to do business in North Carolina and has appointed United Corporate Services, Inc., 327 Hillsborough Street, Raleigh NC 27603, as its registered agent.

6. This Court has personal jurisdiction over Osmotica.

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

BACKGROUND

8. 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.

9. On information and belief, Osmotica filed with the FDA, in Rockville, Maryland, New Drug Application (NDA) No. 22-104 under 21 U.S.C. § 355(b)(2) (also known as a 505(b)(2) application), to obtain FDA approval for the commercial manufacture, use, and sale of venlafaxine hydrochloride extended release tablets in 37.5 mg, 75 mg, 150 mg, and 225 mg dosage strengths.

10. By letter dated February 23, 2007, Osmotica notified Wyeth that it had filed an NDA seeking FDA approval to market venlafaxine hydrochloride extended release tablets in 37.5 mg, 75 mg, 150 mg, and 225 mg dosage strengths (hereinafter referred to as "the Osmotica venlafaxine hydrochloride extended release tablets"), and that it was providing information to Wyeth pursuant to 21 U.S.C. §§ 355(b)(3) and 355(b)(3)(B). Wyeth received that letter on or about March 8, 2007.

11. As provided by the relevant statute (cited below), Osmotica's February 23, 2007 letter to Wyeth contained the following statement:

> Pursuant to 21 U.S.C. § 355(c)(3)(D)(i)(III), Osmotica offers confidential access to NDA No. 22-104 under appropriate terms and conditions.

12. Promptly after receiving Osmotica's notice letter, on March 16, 2007, Wyeth, through counsel, requested a complete copy of Osmotica's NDA No. 22-104, as well as 10 tablets of each dosage strength of Osmotica's venlafaxine hydrochloride extended release tablets and invited Osmotica to promptly provide a proposed confidential access agreement. Wyeth repeated that request on March 26, 2007.

13. Wyeth received a proposed confidential access agreement from Osmotica's counsel on March 27, 2007. Because the proposed confidential access agreement conditioned confidential access on provisions that are not authorized by the relevant statue, 21 U.S.C. § 355(c)(3)(D)(i)(III), Wyeth could not agree to Osmotica's proposal and so informed Osmotica in letters dated March 29, April 13, and April 16, 2007 from Wyeth counsel to Osmotica counsel.

14. On April 17, 2007, Osmotica offered to drop the unauthorized provisions. By that time, however, it was too late for Wyeth to receive and meaningfully review the contents of Osmotica's NDA prior to bringing this suit.

15. Wyeth was thus deprived of timely and meaningful access to the contents of Osmotica's NDA No. 22-104 and to samples of Osmotica's venlafaxine hydrochloride extended release tablets.

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

16. Wyeth incorporates by reference paragraphs 1-15 of this Complaint as if fully set forth herein.

17. 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 A.

18. On information and belief, Osmotica filed NDA No. 22-104 in order to obtain approval to market the Osmotica venlafaxine hydrochloride extended release tablets in the United States, before the expiration of the '120 patent. On information and belief, Osmotica also filed with the FDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), a certification alleging that the claims of the '120 patent are invalid and not infringed.

19. Under 35 U.S.C. § 271(e)(2)(A), on information and belief, Osmotica's submission to the FDA of NDA No. 22-104 to obtain approval for the commercial manufacture, use, or sale of the Osmotica venlafaxine hydrochloride extended release tablets before the expiration date of the '120 patent constitutes infringement of one or more claims of the '120 patent.

20. Upon FDA approval of Osmotica's NDA No. 22-104, on information and belief, Osmotica will infringe the '120 patent by making, using, offering to sell, selling and/or importing the Osmotica venlafaxine hydrochloride extended release tablets 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 Osmotica's NDA shall be no earlier than the expiration of the '120 patent.

21. By way of example, on information and belief, the Osmotica venlafaxine hydrochloride extended release tablets, 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.

22. On information and belief, the use of the Osmotica venlafaxine hydrochloride extended release tablets constitutes a material part of at least one of the claims of the '120 patent; Osmotica knows that the Osmotica venlafaxine hydrochloride extended release tablets are especially made or adapted for use in infringing at least one of the claims of the '120 patent; and the Osmotica venlafaxine hydrochloride extended release tablets are not staple articles of commerce or commodities of commerce suitable for substantial non-infringing use.

23. On information and belief, the offering to sell, sale and/or importation of the Osmotica venlafaxine hydrochloride extended release tablets would contributorily infringe at least one of the claims of the '120 patent.

24. On information and belief, Osmotica had knowledge of the '120 patent and, by its promotional activities and package insert for its venlafaxine hydrochloride extended release tablets, will know or should know that it will aid and abet another's direct infringement of at least one of the claims of the '120 patent.

25. On information and belief, the offering to sell, sale, and/or importation of the Osmotica venlafaxine hydrochloride extended release tablets would actively induce infringement of at least one of the claims of the '120 patent.

26. On information and belief, Osmotica has intentionally and willfully infringed the '120 patent.

27. Wyeth will be substantially and irreparably harmed by Osmotica'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. 6,419,958 B2

28. Wyeth incorporates by reference paragraphs 1-15 of this Complaint as if fully set forth herein.

29. 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 B.

30. On information and belief, Osmotica filed NDA No. 22-104 in order to obtain approval to market the Osmotica venlafaxine hydrochloride extended release tablets in the United States, before the expiration of the '958 patent. On information and belief, Osmotica also filed with the FDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), a certification alleging that the claims of the '958 patent are invalid and not infringed.

31. Under 35 U.S.C. § 271(e)(2)(A), on information and belief, Osmotica's submission to the FDA of NDA No. 22-104 to obtain approval for the commercial manufacture, use, or sale of the Osmotica venlafaxine hydrochloride extended release tablets before the expiration date of the '958 patent constitutes infringement of one or more claims of the '958 patent.

32. Upon FDA approval of Osmotica's NDA No. 22-104, on information and belief, Osmotica will infringe the '958 patent by making, using, offering to sell, selling and/or importing the Osmotica venlafaxine hydrochloride extended release tablets 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 Osmotica's NDA shall be no earlier than the expiration date of the '958 patent.

33. By way of example, on information and belief, the Osmotica venlafaxine hydrochloride extended release tablets, 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.

34. On information and belief, the use of the Osmotica venlafaxine hydrochloride extended release tablets constitutes a material part of at least one of the claims of the '958 patent; Osmotica knows that the Osmotica venlafaxine hydrochloride extended release tablets are especially made or adapted for use in infringing at least one of the claims of the '958 patent; and the Osmotica venlafaxine hydrochloride extended release tablets are not staple articles of commerce or commodities of commerce suitable for substantial non-infringing use.

35. On information and belief, the offering to sell, sale and/or importation of the Osmotica venlafaxine hydrochloride extended release tablets would contributorily infringe at least one of the claims of the '958 patent.

36. On information and belief, Osmotica had knowledge of the '958 patent and, by its promotional activities and package insert for the Osmotica venlafaxine hydrochloride extended release tablets, 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.

37. On information and belief, the offering to sell, sale, and/or importation of the Osmotica venlafaxine hydrochloride extended release tablets would actively induce infringement of at least one of the claims of the '958 patent.

38. On information and belief, Osmotica has intentionally and willfully infringed the '958 patent.

39. Wyeth will be substantially and irreparably harmed by Osmotica'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), Osmotica's submission to the FDA of NDA No. 22-104 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Osmotica venlafaxine hydrochloride extended release tablets before the expiration of the '120 patent was an act of infringement of the '120 patent;

(2) declaring that Osmotica's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Osmotica venlafaxine hydrochloride extended release tablets would constitute infringement of the '120 patent;

(3) declaring that, under 35 U.S.C. § 271(e)(2)(A), Osmotica's submission to the FDA of NDA No. 22-104 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Osmotica venlafaxine hydrochloride extended release tablets before the expiration of the '958 patent was an act of infringement of the '958 patent;

(4) declaring that Osmotica's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Osmotica venlafaxine hydrochloride extended release tablets would constitute infringement of the '958 patent;

(5) ordering that the effective date of any FDA approval of the Osmotica venlafaxine hydrochloride extended release tablets shall be no earlier than the expiration date of the '120 patent, in accordance with 35 U.S.C. § 271(e)(4)(A);

(6) ordering that the effective date of any FDA approval of the Osmotica venlafaxine hydrochloride extended release tablets shall be no earlier than the expiration date of the '958 patent, in accordance with 35 U.S.C. § 271(e)(4)(A);

(7) enjoining Osmotica and all persons acting in concert with Osmotica, from commercially manufacturing, using, offering for sale, or selling the Osmotica venlafaxine hydrochloride extended release tablets within the United States or importing into the United States the Osmotica venlafaxine hydrochloride extended release tablets, until the expiration of the '120 patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

(8) enjoining Osmotica and all persons acting in concert with Osmotica, from commercially manufacturing, using, offering for sale, or selling the Osmotica venlafaxine hydrochloride extended release tablets within the United States or importing into the United States the Osmotica venlafaxine hydrochloride extended release tablets, until the expiration of the '958 patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

(9) enjoining Osmotica and all persons acting in concert with Osmotica, from seeking, obtaining, or maintaining approval of NDA No. 22-104 until the expiration of the '120 patent;

(10) enjoining Osmotica and all persons acting in concert with Osmotica, from seeking, obtaining, or maintaining approval of NDA No. 22-104 until the expiration of the '958 patent;

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

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

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

This 20th day of April 2007.

Respectfully submitted,

/s/ James L. Gale
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