

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

**FILED**  
JUL - 6 2007  
U.S. DISTRICT COURT  
WHEELING, WV 26003

WYETH

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Civil Action No.:

1:07-CV-91

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff, Wyeth, for its Complaint against Mylan Pharmaceuticals Inc. ("Mylan"), 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 Mylan is a West Virginia corporation, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia, 26504.

**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 an Abbreviated New Drug Application ("ANDA") filed by Mylan with the United

States Food and Drug Administration ("FDA") for approval to market a copy of Wyeth's highly successful EFFEXOR<sup>®</sup> XR pharmaceutical products that are sold in the United States ("the Mylan ANDA").

#### **JURISDICTION AND VENUE**

4. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).
5. This Court has personal jurisdiction over Mylan.
6. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and 1400(b).

#### **BACKGROUND**

7. 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<sup>®</sup> XR Capsules, an extended release dosage form containing venlafaxine hydrochloride.

8. On information and belief, Mylan filed with the FDA, in Rockville, Maryland, ANDA No. 78-789 under 21 U.S.C. § 355(j), to obtain FDA approval for the commercial manufacture, use, and sale of Venlafaxine HCl Extended-Release Capsules in 37.5 mg, 75 mg, and 150 mg dosage strengths, which are generic copies of Wyeth's EFFEXOR<sup>®</sup> XR Capsules, in 37.5, 75, and 150 mg dosage strengths, respectively.

9. By letter dated May 22, 2007, Mylan notified Wyeth that it had filed an ANDA seeking FDA approval to market Venlafaxine HCl Extended-Release Capsules in 37.5 mg, 75 mg, and 150 mg dosage strengths (hereinafter referred to as "the Mylan Venlafaxine HCl Extended-Release Capsules"), and that it was providing information to Wyeth pursuant to §

505(j)(2)(B)(i) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95(a). Wyeth received that letter on or about May 23, 2007.

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

10. 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.

11. On information and belief, Mylan filed ANDA No. 78-789 in order to obtain approval to market the Mylan Venlafaxine HCl Extended-Release Capsules in the United States before the expiration of the ’171 patent. On information and belief, Mylan also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the ’171 patent are invalid and not infringed.

12. Under 35 U.S.C. § 271(e)(2)(A), Mylan’s submission to the FDA of ANDA No. 78-789 to obtain approval for the commercial manufacture, use, or sale of the Mylan Venlafaxine HCl Extended-Release 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.

13. Upon FDA approval of ANDA No. 78-789, Mylan will infringe the ’171 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Mylan Venlafaxine HCl Extended-Release 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 Mylan's ANDA shall be no earlier than the expiration date of the '171 patent.

14. By way of example, on information and belief, the Mylan Venlafaxine HCl Extended-Release Capsules, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe, either literally or under the doctrine of equivalents, at least one of the claims of the '171 patent.

15. On information and belief, the use of the Mylan Venlafaxine HCl Extended-Release Capsules constitutes a material part of at least one of the claims of the '171 patent; Mylan knows that the Mylan Venlafaxine HCl Extended-Release 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 the Mylan Venlafaxine HCl Extended-Release Capsules are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

16. On information and belief, the offering to sell, sale, and/or importation of the Mylan Venlafaxine HCl Extended-Release Capsules would contributorily infringe at least one of the claims of the '171 patent, either literally or under the doctrine of equivalents.

17. On information and belief, Mylan had knowledge of the '171 patent and, by its promotional activities and package insert for the Mylan Venlafaxine HCl Extended-Release 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 '171 patent, either literally or under the doctrine of equivalents.

18. On information and belief, the offering to sell, sale, and/or importation of the Mylan Venlafaxine HCl Extended-Release Capsules would actively induce infringement of at least one of the claims of the '171 patent, either literally or under the doctrine of equivalents.

19. On information and belief, Mylan has intentionally and willfully infringed the '171 patent.

20. Wyeth will be substantially and irreparably harmed by the infringing activities described above 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**

21. 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.

22. On information and belief, Mylan filed ANDA No. 78-789 in order to obtain approval to market the Mylan Venlafaxine HCl Extended-Release Capsules in the United States before the expiration of the '120 patent. On information and belief, Mylan also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '120 patent are invalid and not infringed.

23. Under 35 U.S.C. § 271(e)(2)(A), Mylan's submission to the FDA of ANDA No. 78-789 to obtain approval for the commercial manufacture, use, or sale of the Mylan Venlafaxine HCl Extended-Release 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.

24. Upon FDA approval of Mylan's ANDA No. 78-789, Mylan will infringe the '120 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Mylan Venlafaxine HCl Extended-Release 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 Mylan's ANDA shall be no earlier than the expiration of the '120 patent.

25. By way of example, on information and belief, the Mylan Venlafaxine HCl Extended-Release Capsules, when offered for sale, sold, and/or imported and when used as directed, would be used in a manner that would directly infringe, either literally or under the doctrine of equivalents, at least one of the claims of the '120 patent.

26. On information and belief, the use of the Mylan Venlafaxine HCl Extended-Release Capsules constitutes a material part of at least one of the claims of the '120 patent; Mylan knows that the Mylan Venlafaxine HCl Extended-Release Capsules are especially made or adapted for use in infringing at least one of the claims of the '120 patent; and the Mylan Venlafaxine HCl Extended-Release Capsules are not staple articles of commerce or commodities of commerce suitable for substantial non-infringing use.

27. On information and belief, the offering to sell, sale, and/or importation of the Mylan Venlafaxine HCl Extended-Release Capsules would contributorily infringe at least one of the claims of the '120 patent, either literally or under the doctrine of equivalents.

28. On information and belief, Mylan had knowledge of the '120 patent and, by its promotional activities and package insert for its Venlafaxine HCl Extended-Release 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 '120 patent, either literally or under the doctrine of equivalents.

29. On information and belief, the offering to sell, sale, and/or importation of the Mylan Venlafaxine HCl Extended-Release Capsules would actively induce infringement of at least one of the claims of the '120 patent, either literally or under the doctrine of equivalents.

30. On information and belief, Mylan has intentionally and willfully infringed the '120 patent.

31. Wyeth will be substantially and irreparably harmed by Mylan'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**

32. 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.

33. On information and belief, Mylan filed ANDA No. 78-789 in order to obtain approval to market the Mylan Venlafaxine HCl Extended-Release Capsules in the United States before the expiration of the '958 patent. On information and belief, Mylan also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '958 patent are invalid and not infringed.

34. Under 35 U.S.C. § 271(e)(2)(A), Mylan's submission to the FDA of ANDA No. 78-789 to obtain approval for the commercial manufacture, use, or sale of the Mylan Venlafaxine HCl Extended-Release 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.

35. Upon FDA approval of Mylan's ANDA No. 78-789, Mylan will infringe the '958 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Mylan Venlafaxine HCl Extended-Release 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 Mylan's ANDA shall be no earlier than the expiration date of the '958 patent.

36. By way of example, on information and belief, the Mylan Venlafaxine HCl Extended-Release Capsules, when offered for sale, sold, and/or imported and when used as directed, would be used in a manner that would directly infringe, either literally or under the doctrine of equivalents, at least one of the claims of the '958 patent.

37. On information and belief, the use of the Mylan Venlafaxine HCl Extended-Release Capsules constitutes a material part of at least one of the claims of the '958 patent;

Mylan knows that the Mylan Venlafaxine HCl Extended-Release 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 the Mylan Venlafaxine HCl Extended-Release Capsules are not staple articles of commerce or commodities of commerce suitable for substantial non-infringing use.

38. On information and belief, the offering to sell, sale, and/or importation of the Mylan Venlafaxine HCl Extended-Release Capsules would contributorily infringe at least one of the claims of the '958 patent, either literally or under the doctrine of equivalents.

39. On information and belief, Mylan had knowledge of the '958 patent and, by its promotional activities and package insert for the Mylan Venlafaxine HCl Extended-Release 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.

40. On information and belief, the offering to sell, sale, and/or importation of the Mylan Venlafaxine HCl Extended-Release Capsules would actively induce infringement of at least one of the claims of the '958 patent, either literally or under the doctrine of equivalents.

41. On information and belief, Mylan has intentionally and willfully infringed the '958 patent.

42. Wyeth will be substantially and irreparably harmed by Mylan'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), Mylan's submission to the FDA of ANDA No. 78-789 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Mylan Venlafaxine HCl Extended-Release Capsules before the expiration of the '171 patent was an act of infringement of the '171 patent;

(2) declaring that Mylan's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Mylan Venlafaxine HCl Extended-Release Capsules would constitute infringement of the '171 patent;

(3) declaring that, under 35 U.S.C. § 271(e)(2)(A), Mylan's submission to the FDA of ANDA No. 78-789 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Mylan Venlafaxine HCl Extended-Release Capsules before the expiration of the '120 patent was an act of infringement of the '120 patent;

(4) declaring that Mylan's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Mylan Venlafaxine HCl Extended-Release Capsules would constitute infringement of the '120 patent;

(5) declaring that, under 35 U.S.C. § 271(e)(2)(A), Mylan's submission to the FDA of ANDA No. 78-789 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Mylan Venlafaxine HCl Extended-Release Capsules before the expiration of the '958 patent was an act of infringement of the '958 patent;

(6) declaring that Mylan's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Mylan Venlafaxine HCl Extended-Release Capsules would constitute infringement of the '958 patent;

(7) ordering that the effective date of any FDA approval of the Mylan Venlafaxine HCl Extended-Release Capsules shall be no earlier than the expiration date of the '171 patent, in accordance with 35 U.S.C. § 271(e)(4)(A);

(8) ordering that the effective date of any FDA approval of the Mylan Venlafaxine HCl Extended-Release Capsules shall be no earlier than the expiration date of the '120 patent, in accordance with 35 U.S.C. § 271(e)(4)(A);

(9) ordering that the effective date of any FDA approval of the Mylan Venlafaxine HCl Extended-Release Capsules shall be no earlier than the expiration date of the '958 patent, in accordance with 35 U.S.C. § 271(e)(4)(A);

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

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

(12) enjoining Mylan and all persons acting in concert with Mylan, from commercially manufacturing, using, offering for sale, or selling the Mylan Venlafaxine HCl Extended-Release Capsules within the United States or importing into the United States the Mylan Venlafaxine HCl Extended-Release Capsules, until the expiration of the '958 patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

(13) enjoining Mylan and all persons acting in concert with Mylan, from seeking, obtaining, or maintaining approval of ANDA No. 78-789 until the expiration of the '171 patent;

(14) enjoining Mylan and all persons acting in concert with Mylan, from seeking, obtaining, or maintaining approval of ANDA No. 78-789 until the expiration of the '120 patent;

(15) enjoining Mylan and all persons acting in concert with Mylan, from seeking, obtaining, or maintaining approval of ANDA No. 78-789 until the expiration of the '958 patent;

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

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

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

This 6th day of July 2007.

Respectfully submitted,

SCHRADER BYRD & COMPANION PLLC

*James F. Companion*

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