IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. CADILA HEALTHCARE LIMITED and ZYDUS PHARMACEUTICALS (USA) INC., Defendants.	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Wyeth, for its Complaint against Defendants Cadila Healthcare Limited ("Cadila") and Zydus Pharmaceuticals (USA) Inc. ("Zydus Inc.") (referred to collectively as "Zydus"), 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, Cadila is a company organized and existing under the laws of India, having its principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad – 380015 Gujarat, India.

3. On information and belief, Zydus Inc. is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 210 Carnegie Center, Suite 103, Princeton, NJ 08540.

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

5. On information and belief, Zydus Inc. is a 70%-owned subsidiary of Cadila.

6. On information and belief, the acts of Cadila 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, Zydus Inc.

7. On information and belief, the acts of Zydus 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, Cadila.

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. 90-174 filed by Zydus with the United States Food and Drug Administration ("FDA") for approval to market generic copies 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, Cadila is in the business of formulating, manufacturing, and commercializing pharmaceutical products. On information and belief, Cadila established Zydus Inc. for the purpose of distributing, marketing, and selling its generic drug products in the United States. Cadila maintains a website at the uniform resource locator (URL) http://www.zyduscadila.com/. According to that website, "Zydus Cadila is a global healthcare provider and one of the top five pharma companies in India. . . . In 1995, the group

restructured its operations and now operates as Cadila Healthcare Ltd., under the aegis of the Zydus group." (http://www.zyduscadila.com/keyfacts.html.) "One of the most reputed pharma companies globally, Zydus Cadila aims to be a leading global healthcare provider with a robust product pipeline and sales over $1 billion by 2010. It plans to achieve sales of over $3 billion by 2015 and be a global research-driven company by 2020." *Id.* In a press release dated January 29, 2009, located on the Cadila website, Cadila announced that it recently received three product approvals from the FDA and that it will market those drugs "through its US subsidiary Zydus Pharmaceuticals (USA) Inc. The group now has forty-four approvals . . . . So far, the group has filed eighty ANDAs . . . ." In an investor presentation dated February 2009, located on the Cadila website, Cadila reported that it has launched twenty-two products in the United States, that the market for those products is more than $20 billion annually, that Cadila's market share for those products ranges between 5 and 25%, that its U.S. sales in 2008 totaled about $79 million, that it plans to launch eight to ten new products every year, and that IMS has rated it as one of the fastest growing generic companies in the United States.

11. On information and belief, Zydus Inc. maintains a website at the uniform resource locator (URL) http://www.zydususa.com. According to that website, "Zydus Pharmaceuticals (USA) Inc. is a globally integrated generic pharmaceutical company . . . . [O]ur parent Zydus Cadila has a large presence in the global markets . . . . (*Id.* at Company Overview.) The website further lists authorized distributors of record of Zydus Inc. as of May 22, 2007, including among thirty-five companies such well-known names as Caremark, CVS Pharmacy, Mallinckrodt Pharmaceuticals, Walgreen Co., and Wal-Mart. (*Id.* at Locations.) Cadila's annual report for 2007-08 states, "Remarkable performance in the U.S. market with a launch of seven new products in 2007-08 . . . ." Report at 2. It further reports that Zydus Inc. posted sales of

$64 million, an increase of 105%. *Id.* at 13. It reports further that "[m]ost of the formulations marketed by [Zydus Inc.] have captured market share exceeding 10% in USA." *Id.* at 30. On information and belief, Cadila, either directly or through one or more of its wholly-owned subsidiaries, agents, or distributors, markets, sells, and/or distributes pharmaceutical products throughout the United States, including in this judicial district.

12. On information and belief, Zydus Inc. is in the business of marketing and selling Zydus generic drugs throughout the United States. On information and belief, Zydus Inc. markets and/or sells Cadila drug products in this judicial district. On further information and belief, the generic products manufactured by Cadila and sold throughout the United States, and Delaware, indicate that they are manufactured by Cadila. On further information and belief, significant revenue was generated from purchases made by customers in Delaware of Zydus generic drugs. On further information and belief, one or more of the Zydus Inc. authorized distributors referred to in paragraph 11, above, including Walgreens and CVS Pharmacy, sell Zydus generic drugs in Delaware.

13. On information and belief, Cadila and Zydus Inc. operate as an integrated, unitary business. For example, Cadila states in its 2006-07 Annual Report that Zydus Inc. is a 70%- owned subsidiary of Cadila and that those entities, together with other subsidiaries of Cadila, are collectively referred to as "the Group."

14. On information and belief, Cadila developed the Zydus generic copies of Wyeth's EFFEXOR® XR Capsules, prepared ANDA 90-174, and instructed Zydus Inc. to sign the ANDA as the applicant and to seek approval from the FDA to sell Zydus's generic copies of Wyeth's EFFEXOR® XR Capsules throughout the United States and in this judicial district.

15. On information and belief, Zydus Inc., as instructed by Cadila, filed ANDA No. 90-174 with the FDA.

16. On information and belief, Zydus Inc. stated in its Paragraph IV Notice letter to Wyeth that *it* (Zydus Inc.) had submitted ANDA No. 90-174, even though it was acting at the behest, and under the control, of Cadila. On information and belief, Zydus Inc. thus attributed the acts of Cadila to itself. On information and belief, Cadila and Zydus Inc. thus acted jointly as a single entity in connection with preparing and filing ANDA No. 90-174. On further information and belief, Zydus Inc. acted as an agent of Cadila.

17. On information and belief, by virtue of, *inter alia*, Cadila's relationship with Zydus Inc. in connection with the preparation and/or filing of ANDA No. 90-174, and their sales-related activities in Delaware, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of Delaware, this Court has personal jurisdiction over Cadila and Zydus Inc.

18. On information and belief, separate and apart from its relationship with Zydus Inc., Cadila has availed itself of the laws of the State of Delaware and engaged in a course of conduct in the State of Delaware, at least by incorporating its wholly-owned U.S. subsidiary, Zydus Healthcare (USA) LLC under Delaware law.

19. On information and belief, by virtue of, *inter alia*, the revenue derived from the sales of Zydus's drug products throughout the United States, including Delaware, Zydus's continuous and systematic contacts with Delaware, including but not limited to the above-described contacts, and the actions on behalf of Cadila in connection with ANDA No. 90-174 undertaken by its agent Zydus Inc., this Court has personal jurisdiction over Cadila and

Zydus Inc. These activities satisfy due process and confer personal jurisdiction over Cadila and Zydus Inc. consistent with the Delaware Long Arm Statute.

20. On information and belief, Cadila directly and/or through its agent, Zydus Inc., caused tortious injury in Delaware to Wyeth, a Delaware corporation, by filing ANDA No. 90-174, further supporting jurisdiction over Cadila and Zydus Inc.

21. On information and belief, if Cadila were not subject to the jurisdiction of the courts of general jurisdiction of the State of Delaware, it likewise would not be subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to personal jurisdiction and service of process based on its aggregate contacts with the United States, including but not limited to the above-described contacts, as authorized by Federal Rule of Civil Procedure 4(k)(2).

22. Venue is proper in this judicial district under 28 U.S.C. § 1391(b), (c), and (d) and/or 28 U.S.C. § 1400(b).

BACKGROUND

23. 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.

24. On information and belief, Zydus filed with the FDA ANDA No. 90-174 under 21 U.S.C. § 355(j), seeking approval to market Venlafaxine Hydrochloride 37.5, 75, and 150 mg Extended-Release Capsules ("Zydus'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.

25. By letter dated February 25, 2009, Zydus Inc. notified Wyeth that it had filed ANDA No. 90-174, seeking approval to market Zydus's Venlafaxine Hydrochloride ER Capsules, and that it was providing information to Wyeth pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Wyeth received that letter on or about February 27, 2009.

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

26. Wyeth incorporates by reference paragraphs 1 through 25 of this Complaint as if fully set forth herein.

27. 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.

28. On information and belief, Zydus filed ANDA No. 90-174 to obtain approval to market Zydus's Venlafaxine Hydrochloride ER Capsules in the United States before the expiration of the '171 Patent. On information and belief, Zydus 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 and/or not infringed.

29. Under 35 U.S.C. § 271(e)(2)(A), Zydus's submission to the FDA of ANDA No. 90-174 to obtain approval for the commercial manufacture, use, or sale of Zydus'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.

30. Upon FDA approval of Zydus's ANDA No. 90-174, Zydus will infringe the '171 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Zydus'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 Zydus's ANDA shall be no earlier than the expiration date of the '171 Patent and any additional periods of exclusivity.

31. On information and belief, Zydus'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.

32. On information and belief, the use of Zydus's Venlafaxine Hydrochloride ER Capsules constitutes a material part of at least one of the claims of the '171 Patent; Zydus 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 Zydus's Venlafaxine Hydrochloride ER Capsules are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

33. On information and belief, the offering to sell, sale, and/or importation of Zydus'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.

34. On information and belief, Zydus had knowledge of the '171 Patent and, by its promotional activities and package insert for Zydus'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.

35. On information and belief, the offering to sell, sale, and/or importation of Zydus'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.

36. Wyeth will be substantially and irreparably harmed by Zydus'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

37. Wyeth incorporates by reference paragraphs 1 through 36 of this Complaint as if fully set forth herein.

38. 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.

39. On information and belief, Zydus filed ANDA No. 90-174 to obtain approval to market Zydus's Venlafaxine Hydrochloride ER Capsules in the United States before the expiration of the '120 Patent. On information and belief, Zydus 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 and/or not infringed.

40. Under 35 U.S.C. § 271(e)(2)(A), Zydus's submission to the FDA of ANDA No. 90-174 to obtain approval for the commercial manufacture, use, or sale of Zydus'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.

41. Upon FDA approval of Zydus's ANDA No. 90-174, Zydus will infringe the '120 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Zydus'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 Zydus's ANDA shall be no earlier than the expiration of the '120 Patent and any additional periods of exclusivity.

42. On information and belief, Zydus'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.

43. On information and belief, the use of Zydus's Venlafaxine Hydrochloride ER Capsules constitutes a material part of at least one of the claims of the '120 Patent; Zydus knows that Zydus'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 Zydus'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 Zydus'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.

45. On information and belief, Zydus had knowledge of the '120 Patent and, by its promotional activities and package insert for Zydus'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.

46. On information and belief, the offering to sell, sale, and/or importation of Zydus'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.

47. Wyeth will be substantially and irreparably harmed by Zydus'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

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

49. 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.

50. On information and belief, Zydus filed ANDA No. 90-174 to obtain approval to market Zydus's Venlafaxine Hydrochloride ER Capsules in the United States before

the expiration of the '958 Patent. On information and belief, Zydus 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 and/or not infringed.

51. Under 35 U.S.C. § 271(e)(2)(A), Zydus's submission to the FDA of ANDA No. 90-174 to obtain approval for the commercial manufacture, use, or sale of Zydus'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.

52. Upon FDA approval of Zydus's ANDA No. 90-174, Zydus will infringe the '958 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Zydus'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 Zydus's ANDA shall be no earlier than the expiration date of the '958 Patent and any additional periods of exclusivity.

53. On information and belief, Zydus'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.

54. On information and belief, the use of Zydus's Venlafaxine Hydrochloride ER Capsules constitutes a material part of at least one of the claims of the '958 Patent; Zydus 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 Zydus's Venlafaxine Hydrochloride ER Capsules are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

55. On information and belief, the offering to sell, sale, and/or importation of Zydus'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.

56. On information and belief, Zydus had knowledge of the '958 Patent and, by its promotional activities and package insert for Zydus'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.

57. On information and belief, the offering to sell, sale, and/or importation of Zydus'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.

58. Wyeth will be substantially and irreparably harmed by Zydus'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

59. Wyeth incorporates by reference paragraphs 1 through 58 of this Complaint as if fully set forth herein.

60. On information and belief, Cadila actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 90-174 to the FDA. On information and belief, Cadila 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.

61. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Cadila 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. 90-174. The filing of the ANDA by Cadila and/or Zydus Inc. constitutes direct infringement under 35 U.S.C. § 271(e). Cadila's active and knowing aiding and abetting Zydus Inc. in the filing of ANDA No. 90-174 constitutes induced infringement.

62. Wyeth will be substantially and irreparably harmed by Cadila'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

63. Wyeth incorporates by reference paragraphs 1 through 62 of this Complaint as if fully set forth herein.

64. On information and belief, Zydus Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 90-174 to the FDA. On information and belief, Zydus 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.

65. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Zydus 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. 90-174. The filing of the ANDA by Zydus Inc. and/or Cadila constitutes direct infringement under 35 U.S.C. § 271(e). Zydus Inc.'s active and knowing aiding and abetting Cadila in the filing of ANDA No. 90-174 constitute induced infringement.

66. Wyeth will be substantially and irreparably harmed by Zydus 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), Zydus's submission to the FDA of ANDA No. 90-174 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Zydus'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), Cadila's active and knowing aiding and abetting of the submission to the FDA of ANDA No. 90-174 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Zydus'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), Zydus Inc.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 90-174 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Zydus'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 Zydus's commercial manufacture, use, offer for sale, or sale in, or importation into the United States by Zydus of Zydus's Venlafaxine Hydrochloride ER Capsules would constitute infringement of the '171 Patent;

(5) declaring that, under 35 U.S.C. § 271(e)(2)(A), Zydus's submission to the FDA of ANDA No. 90-174 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Zydus'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), Cadila's active and knowing aiding and abetting of the submission to the FDA of ANDA No. 90-174 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Zydus'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), Zydus Inc.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 90-174 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Zydus'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 Zydus's commercial manufacture, use, offer for sale or sale in, or importation into the United States by Zydus of Zydus's Venlafaxine Hydrochloride ER Capsules would constitute infringement of the '120 Patent;

(9) declaring that, under 35 U.S.C. § 271(e)(2)(A), Zydus's submission to the FDA of ANDA No. 90-174 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Zydus'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), Cadila's active and knowing aiding and abetting of the submission to the FDA of ANDA No. 90-174 to

obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Zydus'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), Zydus Inc.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 90-174 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Zydus'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 Zydus's commercial manufacture, use, offer for sale, or sale in, or importation into the United States by Zydus of Zydus's Venlafaxine Hydrochloride ER Capsules would constitute infringement of the '958 Patent;

(13) ordering that the effective date of any FDA approval of Zydus'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(e)(4)(A);

(14) ordering that the effective date of any FDA approval of Zydus'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 Zydus'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 Zydus and all persons acting in concert with Zydus, from commercially manufacturing, using, offering for sale, or selling Zydus's Venlafaxine Hydrochloride ER Capsules within the United States or importing into the United States Zydus'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 Zydus and all persons acting in concert with Zydus from commercially manufacturing, using, offering for sale or selling Zydus's Venlafaxine Hydrochloride ER Capsules within the United States or importing into the United States Zydus'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 Zydus and all persons acting in concert with Zydus from commercially manufacturing, using, offering for sale, or selling Zydus's Venlafaxine Hydrochloride ER Capsules within the United States or importing into the United States Zydus'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 Zydus and all persons acting in concert with Zydus from seeking, obtaining, or maintaining approval of Zydus's ANDA No. 90-174 until the expiration of the '171 Patent;

(20) enjoining Zydus and all persons acting in concert with Zydus from seeking, obtaining, or maintaining approval of Zydus's ANDA No. 90-174 until the expiration of the '120 Patent;

(21) enjoining Zydus and all persons acting in concert with Zydus from seeking, obtaining, or maintaining approval of Zydus's ANDA No. 90-174 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.

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