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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH LLC, Plaintiff, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Wyeth, LLC ("Wyeth") for its Complaint against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (referred to collectively as "Dr. Reddy's Laboratories") hereby states as follows:

THE PARTIES

1. Plaintiff Wyeth is a Delaware limited liability company with a place of business at Five Giralda Farms, Madison, New Jersey 07940.

2. Plaintiff Wyeth is an indirect wholly owned subsidiary of Pfizer Inc., a Delaware corporation.

3. On information and belief, Defendant Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India, having a place of business at 7-1-27, Ameerpet, Hyderabad 500 016, India.

4. On information and belief, Defendant Dr. Reddy's Laboratories, Ltd., directly and/or through its wholly-owned subsidiaries, develops, manufactures, distributes, sells, and markets generic drug products for sale and use throughout the United States, including within this judicial district.

5. On information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 200 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

6. On information and belief, Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd.

7. On information and belief, Dr. Reddy's Laboratories, Inc. develops, manufactures, distributes, sells, and markets generic drug products for sale and use throughout the United States, including within this judicial district.

8. On information and belief, Dr. Reddy's Laboratories, Ltd. operates through its wholly owned subsidiary and agent, Dr. Reddy's Laboratories, Inc.

9. On information and belief, Dr. Reddy's Laboratories, Inc. is controlled and/or dominated by Dr. Reddy's Laboratories, Ltd.

10. On information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have common officers and directors, and Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have represented to the public that they are a unitary entity.

11. On information and belief, the acts of Dr. Reddy's Laboratories, Ltd. 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 Dr. Reddy's Laboratories, Inc.

12. On information and belief, the acts of Dr. Reddy's Laboratories, 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 Dr. Reddy's Laboratories, Ltd.

NATURE OF THE ACTION

13. 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. 78-421 submitted by Dr. Reddy's Laboratories to 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

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

15. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. are in the business of developing, formulating, manufacturing, marketing, offering to sell, selling and commercializing pharmaceutical products. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. maintain a website at the uniform resource locator (URL) http://www.drreddys.com ("the Dr. Reddy's website"), which serves as the website for Dr. Reddy's Laboratories. According to that website, Dr. Reddy's Laboratories is "an emerging global pharmaceutical company," which produces "branded and unbranded generics." The Dr.

Reddy's website further states that Dr. Reddy's Laboratories' "products are marketed globally, with a focus on India, US, Europe, and Russia."

16. On information and belief, Dr. Reddy's Laboratories, Ltd., either directly or through one or more of its wholly owned subsidiaries and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

17. On information and belief, Dr. Reddy's Laboratories, Inc., with the assistance and/or at the direction of Dr. Reddy's Laboratories, Ltd., develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

18. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. have generated significant revenue from purchases made by Dr. Reddy's Laboratories' prescription drug product customers, who are located throughout the United States, including within this judicial district.

19. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. operate as an integrated, unitary business.

20. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. acted in concert to develop the Dr. Reddy's Laboratories generic copies of Wyeth's EFFEXOR® XR Capsules, and to seek approval from the FDA to sell Dr. Reddy's Laboratories' generic copies of Wyeth's EFFEXOR® XR Capsules throughout the United States and in this judicial district.

21. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. submitted ANDA No. 78-421 to the FDA. On information and belief, Dr.

Reddy's Laboratories, Ltd. has attributed the acts of Dr. Reddy's Laboratories, Inc. to itself. Moreover, on information and belief, Dr. Reddy's Laboratories, Inc. has attributed the acts of Dr. Reddy's Laboratories, Ltd. to itself. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. thus acted as a single entity in connection with preparing and submission of ANDA No. 78-421.

22. By letter dated July 23, 2010, Dr. Reddy's Laboratories notified Wyeth that Dr. Reddy's Laboratories had submitted ANDA No. 78-421, seeking approval to market Dr. Reddy's Laboratories' Venlafaxine Hydrochloride ER Capsules, and that it was providing information to Wyeth pursuant to § 505(j)(2)(B)(ii) of the Food, Drug and Cosmetic Act and § 314.95 of Title 21 of the Code of Federal Regulations.

23. In its July 23, 2010 letter, Dr. Reddy's Laboratories stated that the name and address of its agent in the United States authorized to accept service of process for Dr. Reddy's Laboratories for purposes of an infringement action based upon its July 23, 2010 letter is Lee Banks, Dr. Reddy's Laboratories, Inc., 200 Somerset Corporate Blvd., Floor 7, Bridgewater, NJ 08807.

24. By naming Lee Banks, Dr. Reddy's Laboratories, Inc., 200 Somerset Corporate Blvd., Floor 7, Bridgewater, NJ 08807 as its agent, Dr. Reddy's Laboratories has consented to jurisdiction in the State of New Jersey for this action.

25. On information and belief, and as previously noted, Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey. By virtue of its incorporation in New Jersey, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc.

26. On information and belief, by virtue of, *inter alia*, Dr. Reddy's Laboratories, Ltd.'s relationship with Dr. Reddy's Laboratories, Inc. in connection with the preparation and/or filing of ANDA No. 78-421, Dr. Reddy's Laboratories, Ltd.'s designation of Lee Banks, Dr. Reddy's Laboratories, Inc., 200 Somerset Corporate Blvd., Floor 7, Bridgewater, NJ 08807 as its agent for service of process, and the sales-related activities of Dr. Reddy's Laboratories in New Jersey, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of New Jersey, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd.

27. On information and belief, Dr. Reddy's Laboratories, Ltd. has continuous and systematic contacts with New Jersey, including, but not limited to, ongoing communications and contacts with Dr. Reddy's Laboratories, Inc. On information and belief, separate and apart from its relationship with Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd. has availed itself of the laws of the State of New Jersey and engaged in a course of conduct in the State of New Jersey, at least by incorporating its U.S. subsidiary, Dr. Reddy's Laboratories, Inc. under New Jersey law.

28. On information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have previously been sued in this district and have not challenged personal jurisdiction. *See, e.g., Albany Molecular Research, Inc. v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.*, Civ. No. 09-04638, (GEB) (MCA) (D.N.J.); *Sepracor, Inc. v. Teva Pharmaceuticals USA, Inc., et al.*, Civ. No. 09-01302 (DMC) (MF) (D.N.J.); *Hoffman-La Roche Inc. v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.*, Civ. No. 08-04055 (SRC) (MAS) (D.N.J.).

29. On information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have availed themselves of the jurisdiction of this court by initiating litigation in this district. *See, e.g., Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc v. Eli Lilly & Co.*, Civ. No. 09-00192 (GHB) (LHG) (filed Jan. 8, 2009).

30. On information and belief, by virtue of, *inter alia,* Dr. Reddy's Laboratories' continuous and systematic contacts with New Jersey, including but not limited to the above-described contacts, and the actions on behalf of Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. in connection with ANDA No. 78-421, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. These activities satisfy due process and confer personal jurisdiction over Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. consistent with the New Jersey long arm statute.

31. 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

32. Wyeth Pharmaceuticals Inc. is the holder of approved New Drug Application ("NDA") No. 20-699 for EFFEXOR® XR Capsules, an extended release dosage form containing venlafaxine hydrochloride. Wyeth Pharmaceuticals Inc. is a wholly owned indirect subsidiary of Pfizer Inc.

33. On information and belief, Dr. Reddy's Laboratories submitted to the FDA ANDA No. 78-421 under 21 U.S.C. § 355(j), seeking approval to market Venlafaxine Hydrochloride 37.5, 75, and 150 mg Extended-Release Capsules ("Dr. Reddy's Laboratories' Venlafaxine Hydrochloride ER Capsules"), which are generic copies of Wyeth's EFFEXOR® XR Capsules, in 37.5, 75, and 150 mg dosage strengths, respectively.

34. By letter dated July 23, 2010, Dr. Reddy's Laboratories notified Wyeth that it had submitted ANDA No.78-421, seeking approval to market Dr. Reddy's Laboratories' Venlafaxine Hydrochloride ER Capsules, and that it was providing information to Wyeth pursuant to § 505(j)(2)(B)(ii) of the Food, Drug and Cosmetic Act, and § 314.95 of Title 21 of the Code of Federal Regulations. Wyeth received that letter on or about July 26, 2010.

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

35. Wyeth incorporates by reference paragraphs 1-35 of this Complaint as if fully set forth herein.

36. 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.

37. On information and belief, Dr. Reddy's Laboratories submitted ANDA No. 78-421 in order to obtain approval to market Dr. Reddy's Laboratories' Venlafaxine Hydrochloride ER Capsules in the United States before the expiration of the '171 Patent. On information and belief, Dr. Reddy's Laboratories 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.

38. Under 35 U.S.C. § 271(e)(2)(A), Dr. Reddy's Laboratories' submission to the FDA of ANDA No. 78-421 to obtain approval for the commercial manufacture, use, or sale of Dr. Reddy's Laboratories' 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.

39. Upon FDA approval of Dr. Reddy's Laboratories ANDA No. 78-421, Dr. Reddy's Laboratories will infringe the '171 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Dr. Reddy's Laboratories' 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 Dr. Reddy's Laboratories' ANDA shall be no earlier than the expiration date of the '171 Patent and any additional periods of exclusivity.

40. On information and belief, Dr. Reddy's Laboratories' 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.

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

42. On information and belief, the offering to sell, sale, and/or importation of Dr. Reddy's Laboratories' 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.

43. On information and belief, Dr. Reddy's Laboratories had knowledge of the '171 Patent and, by its promotional activities and package insert for Dr. Reddy's Laboratories' 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.

44. On information and belief, the offering to sell, sale, and/or importation of Dr. Reddy's Laboratories' 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.

45. Wyeth will be substantially and irreparably harmed by Dr. Reddy's Laboratories' 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

46. Wyeth incorporates by reference paragraphs 1-35 of this Complaint as if fully set forth herein.

47. 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.

48. On information and belief, Dr. Reddy's Laboratories submitted ANDA No. 78-421 in order to obtain approval to market Dr. Reddy's Laboratories' Venlafaxine Hydrochloride ER Capsules in the United States before the expiration of the '120 Patent. On information and belief, Dr. Reddy's Laboratories 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.

49. Under 35 U.S.C. § 271(e)(2)(A), Dr. Reddy's Laboratories' submission to the FDA of ANDA No. 78-421 to obtain approval for the commercial manufacture, use, or sale of Dr. Reddy's Laboratories' 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.

50. Upon FDA approval of Dr. Reddy's Laboratories' ANDA No. 78-421, Dr. Reddy's Laboratories will infringe the '120 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Dr. Reddy's Laboratories' 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 Dr. Reddy's Laboratories' ANDA shall be no earlier than the expiration of the '120 Patent and any additional periods of exclusivity.

51. On information and belief, Dr. Reddy's Laboratories' 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.

52. On information and belief, the use of Dr. Reddy's Laboratories' Venlafaxine Hydrochloride ER Capsules constitutes a material part of at least one of the claims of the '120 Patent; Dr. Reddy's Laboratories knows that Dr. Reddy's Laboratories' 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 Dr. Reddy's Laboratories' Venlafaxine Hydrochloride ER Capsules are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

53. On information and belief, the offering to sell, sale, and/or importation of Dr. Reddy's Laboratories' 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.

54. On information and belief, Dr. Reddy's Laboratories had knowledge of the '120 Patent and, by its promotional activities and package insert for Dr. Reddy's Laboratories' 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.

55. On information and belief, the offering to sell, sale, and/or importation of Dr. Reddy's Laboratories' 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.

56. Wyeth will be substantially and irreparably harmed by Dr. Reddy's Laboratories' 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

57. Wyeth incorporates by reference paragraphs 1-35 of this Complaint as if fully set forth herein.

58. 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.

59. On information and belief, Dr. Reddy's Laboratories submitted ANDA No. 78-421 in order to obtain approval to market Dr. Reddy's Laboratories' Venlafaxine Hydrochloride ER Capsules in the United States before the expiration of the '958 Patent. On information and belief, Dr. Reddy's Laboratories 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.

60. Under 35 U.S.C. § 271(e)(2)(A), Dr. Reddy's Laboratories' submission to the FDA of ANDA No. 78-421 to obtain approval for the commercial manufacture, use, or sale of Dr. Reddy's Laboratories' 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.

61. Upon FDA approval of Dr. Reddy's Laboratories' ANDA No. 78-421, Dr. Reddy's Laboratories will infringe the '958 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Dr. Reddy's Laboratories' 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 Dr. Reddy's Laboratories' ANDA shall be no earlier than the expiration date of the '958 Patent and any additional periods of exclusivity.

62. On information and belief, Dr. Reddy's Laboratories' 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.

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

64. On information and belief, the offering to sell, sale, and/or importation of Dr. Reddy's Laboratories' 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.

65. On information and belief, Dr. Reddy's Laboratories had knowledge of the '958 Patent and, by its promotional activities and package insert for Dr. Reddy's Laboratories' 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.

66. On information and belief, the offering to sell, sale, and/or importation of Dr. Reddy's Laboratories' 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.

67. Wyeth will be substantially and irreparably harmed by Dr. Reddy's Laboratories' 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

(By Dr. Reddy's Laboratories, Ltd.)

68. Wyeth incorporates by reference paragraphs 1 through 68 and 73 to 76 of this Complaint as if fully set forth herein.

69. On information and belief, Dr. Reddy's Laboratories, Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 78-421 to the FDA. On information and belief, Dr. Reddy's Laboratories, Ltd. 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.

70. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Dr. Reddy's Laboratories, Ltd. 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. 78-421. The filing of the ANDA by Dr. Reddy's Laboratories, Ltd. and/or Dr. Reddy's Laboratories, Inc. constitutes direct infringement under 35 U.S.C. § 271(e). Dr. Reddy's Laboratories, Ltd.'s active and knowing aiding and abetting Dr. Reddy's Laboratories, Inc. in the filing of ANDA No. 78-421 constitute induced infringement.

71. Wyeth will be substantially and irreparably harmed by Dr. Reddy's Laboratories, Ltd.'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

(By Dr. Reddy's Laboratories, Inc.)

72. Wyeth incorporates by reference paragraphs 1 through 72 of this Complaint as if fully set forth herein.

73. On information and belief, Dr. Reddy's Laboratories, Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 78-421 to the FDA. On information and belief, Dr. Reddy's Laboratories, 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.

74. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Dr. Reddy's Laboratories, 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. 78-421. The filing of the ANDA by Dr. Reddy's Laboratories, Inc. and/or Dr. Reddy's Laboratories, Ltd. constitutes direct infringement under 35 U.S.C. § 271(e). Dr. Reddy's Laboratories, Inc.'s active and knowing aiding and abetting Dr. Reddy's Laboratories, Ltd. in the filing of ANDA No. 78-421 constitute induced infringement.

75. Wyeth will be substantially and irreparably harmed by Dr. Reddy's Laboratories, 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), Dr. Reddy's Laboratories' submission to the FDA of ANDA No. 78-421 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Dr. Reddy's Laboratories' 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), Dr. Reddy's Laboratories, Ltd's. active and knowing aiding and abetting of the submission to the FDA of ANDA No. 78-421 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Dr. Reddy's Laboratories' 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), Dr. Reddy's Laboratories, Inc.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 78-421 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Dr. Reddy's Laboratories' Venlafaxine Hydrochloride ER Capsules before the expiration of the '171 Patent was an act of induced infringement of the '171 Patent;

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

(5) declaring that, under 35 U.S.C. § 271(e)(2)(A), Dr. Reddy's Laboratories' submission to the FDA of ANDA No. 78-421 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Dr. Reddy's Laboratories' 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), Dr. Reddy's Laboratories, Ltd.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 78-421 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Dr. Reddy's Laboratories' 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), Dr. Reddy's Laboratories, Inc.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 78-421 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Dr. Reddy's Laboratories' Venlafaxine Hydrochloride ER Capsules before the expiration of the '120 Patent was an act of induced infringement of the '120 Patent;

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

(9) declaring that, under 35 U.S.C. § 271(e)(2)(A), Dr. Reddy's Laboratories' submission to the FDA of ANDA No. 78-421 to obtain approval for the commercial

manufacture, use, offer for sale, or sale in, or importation into the United States of Dr. Reddy's Laboratories' 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), Dr. Reddy's Laboratories, Ltd.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 78-421 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Dr. Reddy's Laboratories' 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), Dr. Reddy's Laboratories, Inc.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 78-421 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Dr. Reddy's Laboratories' Venlafaxine Hydrochloride ER Capsules before the expiration of the '958 Patent was an act of induced infringement of the '958 Patent;

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

(13) ordering that the effective date of any FDA approval of Dr. Reddy's Laboratories' 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 Dr. Reddy's Laboratories' 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 Dr. Reddy's Laboratories' 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 Dr. Reddy's Laboratories and all persons acting in concert with Dr. Reddy's Laboratories, from commercially manufacturing, using, offering for sale, or selling Dr. Reddy's Laboratories' Venlafaxine Hydrochloride ER Capsules within the United States or importing into the United States Dr. Reddy's Laboratories' Venlafaxine Hydrochloride ER Capsules, until the expiration of the '171 Patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

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

(18) enjoining Dr. Reddy's Laboratories and all persons acting in concert with Dr. Reddy's Laboratories from commercially manufacturing, using, offering for sale, or selling Dr. Reddy's Laboratories' Venlafaxine Hydrochloride ER Capsules within the United States or importing into the United States Dr. Reddy's Laboratories' Venlafaxine Hydrochloride ER Capsules, until the expiration of the '958 Patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

(19) enjoining Dr. Reddy's Laboratories and all persons acting in concert with Dr. Reddy's Laboratories from seeking, obtaining, or maintaining approval of Dr. Reddy's Laboratories' ANDA No. 78-421 until the expiration of the '171 Patent;

(20) enjoining Dr. Reddy's Laboratories and all persons acting in concert with Dr. Reddy's Laboratories from seeking, obtaining, or maintaining approval of Dr. Reddy's Laboratories' ANDA No. 78-421 until the expiration of the '120 Patent;

(21) enjoining Dr. Reddy's Laboratories and all persons acting in concert with Dr. Reddy's Laboratories from seeking, obtaining, or maintaining approval of Dr. Reddy's Laboratories' ANDA No. 78-421 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: September 3, 2010

By: */s Liza M. Walsh*

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