UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND
(Baltimore Division)

WYETH
Five Giralda Farms
Madison, New Jersey 07940

Plaintiff,

v.

LUPIN LTD.,
Laxmi Towers "B" Wing, 5th Floor
Bandra Kurla Complex
Mumbai 400 051
India

Serve:

Dr. Desh Bandhu Gupta, Chairman
Lupin Limited
Laxmi Towers "B" Wing, 5th Floor
Bandra Kurla Complex
Mumbai 400 051
India

and

LUPIN PHARMACEUTICALS, INC.
Harborplace Tower, 21st Floor
111 South Calvert Street
Baltimore, Maryland 21202

Serve Registered Agent:

Vinita Gupta
21st Floor
111 S. Calvert Street
Baltimore, Maryland 21202

Defendants.

Civil Action No.: _____

COMPLAINT

Plaintiff, Wyeth, by their attorneys, for their Complaint against Lupin Limited and Lupin Pharmaceuticals, Inc., 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 Lupin Limited is a company organized and existing under the laws of India and has its principal place of business at Laxmi Towers "B" wing, 5th Floor, Bandra Kurla Complex, Mumbai 400 051, India.

3. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation incorporated under the laws of the Commonwealth of Virginia and has its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

4. On information and belief, Lupin Pharmaceuticals, Inc., a wholly-owned subsidiary of Lupin Limited, is Lupin Limited's "representative office" in the United States.

5. On information and belief, the acts of Lupin Limited 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, Lupin Pharmaceuticals, Inc.

6. On information and belief, the acts of Lupin Pharmaceuticals, 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 Lupin Limited.

Nature Of The Action

7. 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 Lupin Limited and Lupin Pharmaceuticals, Inc. with the United States Food and Drug Administration ("FDA") for approval to market a generic copy of Wyeth's highly successful EFFEXOR® XR pharmaceutical products that are sold in the United States ("the Lupin ANDA").

Jurisdiction And Venue

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

9. On information and belief, Lupin Pharmaceuticals, Inc. has its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland, and conducts business in Maryland.

10. On information and belief, Lupin Pharmaceuticals, Inc. participated in the preparation and filing of the Lupin ANDA as the authorized agent of Lupin Limited and/or in its own capacity.

11. This Court has personal jurisdiction over Lupin Pharmaceuticals, Inc.

12. On information and belief, Lupin Limited is in the business of developing, manufacturing, marketing, and selling generic drugs. On information and belief, Lupin Limited established Lupin Pharmaceuticals, Inc. for the purpose of distributing, marketing, and selling its generic drug products in the United States. Lupin Limited maintains an Internet website at the URL www.lupinworld.com at which Lupin Limited represents that it has a representative office at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland, the principal place of business of Lupin Pharmaceuticals, Inc.

13. Lupin Pharmaceuticals, Inc. maintains a website at www.lupinpharmaceuticals.com, and on its website states:

> Lupin Pharmaceuticals, Inc. provides the advanced manufacturing capabilities and processes that create quality specialty and generic products. Lupin is amongst the world's largest manufacturers of products in its chosen therapeutic areas. Lupin has manufacturing operations in five cities in India and also a site in Thailand. Our plants are located in Mandideep, Aurangabad, Tarapur, Ankleshwar, and Goa, in India.

On information and belief, these manufacturing facilities are part of Lupin Limited.

14. Lupin Limited's website located at www.lupinworld.com instructs visitors to "get in touch with a Lupin representative . . . office[] in the U.S." and provides a hyperlink to the address of Lupin Pharmaceuticals, Inc. as that "representative . . . office[] in the U.S."

15. Furthermore, Lupin India's Annual Report for 2005/2006 states the following:

> [W]hatever investments we made over the last two years in the US are now paying off. This is the culmination of two years of solid foundation building. With our Suprax® range gaining rapid market acceptance, we have filed two more line extensions with the US FDA. Demonstrating our commitment and confidence in our strategies for the US, we took the bold

> step of internalising our field force. In an effort to expand our near-term product offering, we entered an alliance with Chester Valley Pharmaceuticals, USA to promote Atopiclar™ non-steroidal cream to Paediatricians. To bolster our positioning further in this segment, we are also actively exploring acquisition opportunities. Furthermore, we also decided to create our own structure for marketing generic products, hitherto partnered with other companies. We aim to play a bigger role through our direct-to-market team in launching products ourselves and with one-to-one interactions with our customers, providing us better appreciation of their needs and therefore, competitive positioning.

16. Lupin India's Annual Report also states:

> This year, [the Company] launched Ceftriaxone through our marketing alliance with Baxter Healthcare Corporation (Baxter). . . . As per IMS MAT May 2005 data, the US market size for Ceftriaxone was US $756 million. In addition to Baxter exclusively distributing Lupin's generic Ceftriaxone for the US hospital segment, the Company also entered into an agreement with Henry Schein, Inc., whereby Henry Schein exclusively distributes Lupin's Ceftriaxone to physician offices. Baxter has already garnered 25% market share.

17. On information and belief, based in part on the representations on their websites and Lupin Limited's Annual Report, Lupin Limited and Lupin Pharmaceuticals, Inc. hold themselves out as a unitary entity and have deliberately disregarded corporate formalities by representing to the public that the activities of Lupin Limited and Lupin Pharmaceuticals, Inc. are directed, controlled, and carried out by a single entity, namely, Lupin Limited, headquartered in India.

18. On information and belief, Lupin Limited maintains and controls a broad distribution network in the United States for Lupin Limited's products that results in the distribution and sale of hundreds of millions of dollars of Lupin Limited products. That distribution network consists of the "field force," "direct-to-market team" and "structure for marketing generic products" referred to in Lupin Limited's 2005/2006 Annual Report, as well as marketing alliances with other companies located in the United States, including but not limited to Baxter and Henry Schein. In a July 21, 2005 press release that currently can be found at Lupin Limited's website, Lupin Limited describes its agreements with Baxter and Schein as "a major milestone in Lupin's advanced markets strategy." On information and belief, Lupin Limited's "advanced market strategy" also includes the distribution of substantial volumes of other Lupin Limited generic drug products in the United States, Maryland, and this judicial

district through its wholly-owned subsidiary, "representative office," and agent, Lupin Pharmaceuticals, Inc. On information and belief, as part of its generic business in the United States, Lupin Limited has entered into an alliance with Watson Pharmaceuticals, Inc. to market generic products in the United States.

19. On information and belief, Lupin Limited has continuous and systematic contacts with Maryland, including, but not limited to, communications and contacts with Lupin Pharmaceuticals, Inc.

20. On information and belief, Lupin Limited exercises considerable control over its wholly-owned subsidiary, Lupin Pharmaceuticals, Inc., including, but not limited to, approving significant decisions of Lupin Pharmaceuticals, Inc. such as allowing Lupin Pharmaceuticals, Inc. to act as the agent for Lupin Limited in connection with preparing and filing the Lupin ANDA, as described elsewhere herein, and acting as Lupin Limited's "representative office" and agent in the United States.

21. On information and belief, Lupin Limited, directly and/or indirectly through Lupin Pharmaceuticals, Inc., develops and manufactures generic drugs that are marketed, distributed, and sold throughout the United States, Maryland, and this judicial district. On further information and belief, the generic drug products manufactured by Lupin Limited and sold throughout the United States, Maryland, and this judicial district indicate that they are manufactured by Lupin Limited.

22. On information and belief, about $240 million worth of Lupin Limited's prescription drug products have been sold in the United States during the three year period from April 1, 2003, to March 31, 2006, and on information and belief significant revenue was generated from purchases made by customers in Maryland and this judicial district.

23. On information and belief, Lupin Limited has generated millions of dollars in profit from the sale of its products in this judicial district and the United States.

24. On information and belief, Lupin Pharmaceuticals, Inc. acted in concert with Lupin Limited to develop Lupin Limited's generic copy of Wyeth's EFFEXOR® XR Capsules, and to seek approval from the U.S. Food and Drug Administration (FDA) to sell Lupin Limited's generic copy of Wyeth's EFFEXOR® XR Capsules throughout the United States, Maryland, and this judicial district.

25. On information and belief, Lupin Pharmaceuticals, Inc. is Lupin Limited's designated agent in Maryland, and acted as Lupin Limited's representative U.S. agent in filing Lupin's ANDA with the FDA for approval to market generic versions of Wyeth's EFFEXOR® XR Capsules. On further information and belief, Lupin Pharmaceuticals, Inc., as Lupin Limited's authorized agent and thus acting as Lupin Limited, participated in Maryland in the preparation and/or submission of Lupin's ANDA, which constitute acts in Maryland that directly give rise to Wyeth's present claims of patent infringement.

26. On information and belief, by virtue of, *inter alia*, Lupin Limited's relationship with and/or control over Lupin Pharmaceuticals, Inc., the sale of Lupin Limited's generic drug products throughout the United States and Maryland, and Lupin Limited's coordination with Lupin Pharmaceuticals, Inc. to prepare and/or file the Lupin ANDA with the FDA, as well as Lupin Limited's own actions in Maryland through its authorized agent, Lupin Pharmaceuticals, Inc., including but not limited to those actions in connection with preparing and/or filing the Lupin ANDA, this Court has both specific personal jurisdiction and general personal jurisdiction over Lupin Limited. Lupin Limited's continuous and systematic contacts with Maryland and the United States, including but not limited to the above described contacts, satisfy due process and confer personal jurisdiction over Lupin Limited, consistent with the Maryland Long Arm statute (Md. Code Ann., Cts. & Jud. Proc. § 6-103). On information and belief, and in the alternative, Wyeth alleges that to the extent Lupin Limited is not subject to the jurisdiction of the courts of general jurisdiction of the state of Maryland, Lupin Limited likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

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

Background

28. 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.

29. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. filed with the FDA, in Rockville, Maryland, Abbreviated New Drug Application (ANDA) No. 78-543 under 21 U.S.C. § 355(j), to obtain 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® XR Capsules in 37.5 mg, 75 mg, and 150 mg dosage strengths, respectively.

30. By letter dated January 26, 2007, Lupin Limited notified Wyeth that it had filed an ANDA seeking approval to market Venlafaxine HCl Extended-Release Capsules in 37.5 mg, 75 mg, and 150 mg dosage strengths (hereinafter referred to as "the Lupin Venlafaxine HCl Extended-Release Capsules"), and that it was providing information to Wyeth pursuant to 21 U.S.C. § 355(j)(2)(B)(i) and (ii) and 21 C.F.R. § 314.95. Wyeth received that letter on or about January 29, 2007.

First Count For Infringement By Lupin Limited And Lupin Pharmaceuticals, Inc. Of United States Patent No. 6,274,171 B1

31. Wyeth incorporates by reference paragraphs 1-30 of this Complaint as if fully set forth herein.

32. 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.

33. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. filed ANDA No. 78-543 in order to obtain approval to market the Lupin Venlafaxine HCl Extended-Release Capsules in the United States before the expiration of the '171 patent. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. 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 not infringed and/or invalid.

34. Under 35 U.S.C. § 271(e)(2)(A), the submission by Lupin Limited and Lupin Pharmaceuticals, Inc. to the FDA of ANDA No. 78-543 to obtain approval for the commercial manufacture, use, or sale of the Lupin 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.

35. Upon FDA approval of ANDA No. 78-543, Lupin Limited and Lupin Pharmaceuticals, Inc. will infringe the '171 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing the Lupin Venlafaxine HCl Extended-Release Capsules in the United States, and by actively inducing and contributing to infringement by each other and others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of Lupin Limited's and Lupin Pharmaceuticals, Inc.'s ANDA shall be no earlier than the expiration date of the '171 patent.

36. By way of example, on information and belief, the Lupin 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.

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

38. On information and belief, the offering to sell, sale and/or importation of the Lupin 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.

39. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. had knowledge of the '171 patent and, by their promotional activities and package insert for the Lupin Venlafaxine HCl Extended-Release Capsules, will know or should know that they 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.

40. On information and belief, the offering to sell, sale, and/or importation of the Lupin 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.

41. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. have intentionally and willfully infringed the '171 patent.

42. 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 By Lupin Limited And Lupin Pharmaceuticals, Inc. Of United States Patent No. 6,403,120 B1

43. Wyeth incorporates by reference paragraphs 1-30 of this Complaint as if fully set forth herein.

44. 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.

45. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. filed ANDA No. 78-543 in order to obtain approval to market the Lupin Venlafaxine HCl Extended-Release Capsules in the United States, before the expiration of the '120 patent. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. 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 not infringed and/or invalid.

46. Under 35 U.S.C. § 271(e)(2)(A), the submission by Lupin Limited and Lupin Pharmaceuticals, Inc. to the FDA of ANDA No. 78-543 to obtain approval for the commercial manufacture, use, or sale of the Lupin 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.

47. Upon FDA approval of ANDA No. 78-543, Lupin Limited and Lupin Pharmaceuticals, Inc. will infringe the '120 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing the Lupin Venlafaxine HCl Extended-Release Capsules in the United States, and by actively inducing and contributing to infringement by each other and others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of Lupin Limited's and Lupin Pharmaceuticals, Inc.'s ANDA shall be no earlier than the expiration of the '120 patent.

48. By way of example, on information and belief, the Lupin 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.

49. On information and belief, the use of the Lupin Venlafaxine HCl Extended-Release Capsules constitutes a material part of at least one of the claims of the '120 patent; Lupin Limited and Lupin Pharmaceuticals, Inc. know that the Lupin Venlafaxine HCl Extended-Release 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 the Lupin Venlafaxine HCl Extended-Release Capsules are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

50. On information and belief, the offering to sell, sale and/or importation of the Lupin 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.

51. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. had knowledge of the '120 patent and, by their promotional activities and package insert for the Lupin Venlafaxine HCl Extended-Release Capsules, will know or should know that they 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.

52. On information and belief, the offering to sell, sale, and/or importation of the Lupin 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.

53. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. have intentionally and willfully infringed the '120 patent.

54. 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.

Third Count For Infringement By Lupin Limited And Lupin Pharmaceuticals, Inc. Of United States Patent No. 6,419,958 B2

55. Wyeth incorporates by reference paragraphs 1-30 of this Complaint as if fully set forth herein.

56. 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.

57. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. filed ANDA No. 78-543 in order to obtain approval to market the Lupin Venlafaxine HCl Extended-Release Capsules in the United States, before the expiration of the '958 patent. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. 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 not infringed and/or invalid.

58. Under 35 U.S.C. § 271(e)(2)(A), the submission by Lupin Limited and Lupin Pharmaceuticals, Inc. to the FDA of ANDA No. 78-543 to obtain approval for the commercial manufacture, use, or sale of the Lupin 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.

59. Upon FDA approval of ANDA No. 78-543, Lupin Limited and Lupin Pharmaceuticals, Inc. will infringe the '958 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing the Lupin Venlafaxine HCl Extended-Release Capsules in the United States, and by actively inducing and contributing to infringement by each other and others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of Lupin Limited's and Lupin Pharmaceuticals, Inc.'s ANDA shall be no earlier than the expiration date of the '958 patent.

60. By way of example, on information and belief, the Lupin 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.

61. On information and belief, the use of the Lupin Venlafaxine HCl Extended-Release Capsules constitutes a material part of at least one of the claims of the '958 patent; Lupin Limited and Lupin Pharmaceuticals, Inc. knows that the Lupin 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 Lupin Venlafaxine HCl Extended-Release Capsules are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

62. On information and belief, the offering to sell, sale and/or importation of the Lupin 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.

63. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. had knowledge of the '958 patent and, by their promotional activities and package insert for the Lupin Venlafaxine HCl Extended-Release Capsules, will know or should know that they 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.

64. On information and belief, the offering to sell, sale, and/or importation of the Lupin 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.

65. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. have intentionally and willfully infringed the '958 patent.

66. 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.

Fourth Count For Infringement By Lupin Pharmaceuticals, Inc. Of United States Patent Nos. 6,274,171 B1, 6,403,120 B1 And 6,419,958 B2

67. Wyeth incorporates by reference paragraphs 1-66 and 71-73 of this Complaint as if fully set forth herein.

68. On information and belief, Lupin Pharmaceuticals, Inc., actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 78-543 to the FDA. On information and belief, Lupin Pharmaceuticals, 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.

69. Under 35 U.S.C. § § 271(b) and 271(e)(2)(A), Lupin Pharmaceuticals, 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. 78-543. The filing of the ANDA by Lupin

Limited and Lupin Pharmaceuticals, Inc. constitutes direct infringement under 35 U.S.C. § 271(e). Lupin Pharmaceuticals, Inc.'s active and knowing aiding and abetting Lupin Limited in the filing of ANDA No. 78-543 constitutes induced infringement.

70. On information and belief, Lupin Pharmaceuticals, Inc. has intentionally and willfully infringed the '171 patent, the '120 patent, and the '958 patent.

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

Fifth Count For Infringement By Lupin Limited Of United States Patent Nos. 6,274,171 B1, 6,403,120 B1 And 6,419,958 B2

72. Wyeth incorporates by reference paragraphs 1-71 of this Complaint as if fully set forth herein.

73. Under 35 U.S.C. § § 271(b) and 271(e)(2)(A), Lupin Limited 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. 78-543 by Lupin Pharmaceuticals, Inc.. The filing of the ANDA by Lupin Limited and Lupin Pharmaceuticals, Inc. constitutes direct infringement under 35 U.S.C. § 271(e). Lupin Limited's active and knowing aiding and abetting Lupin Pharmaceuticals, Inc. in the filing of ANDA No. 78-543 constitutes induced infringement.

74. On information and belief, Lupin Limited has intentionally and willfully infringed the '171 patent, the '120 patent, and the '958 patent.

75. Wyeth will be substantially and irreparably harmed by Lupin Limited'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), the submission to the FDA of ANDA No. 78-543 by Lupin Limited and/or Lupin Pharmaceuticals, Inc. to obtain approval for the commercial

manufacture, use, offer for sale, or sale in, or importation into, the United States of the Lupin Venlafaxine HCl Extended-Release 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), Lupin Pharmaceuticals, Inc.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 78-543 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Lupin Venlafaxine HCl Extended-Release 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), Lupin Limited's active and knowing aiding and abetting of Lupin Pharmaceuticals, Inc.'s submission to the FDA of ANDA No. 78-543 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Lupin Venlafaxine HCl Extended-Release Capsules before the expiration of the '171 patent was an act of induced infringement of the '171 patent;

(4) declaring that the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Lupin Venlafaxine HCl Extended-Release Capsules by Lupin Limited and/or Lupin Pharmaceuticals, Inc. would constitute infringement of the '171 patent;

(5) declaring that, under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 78-543 by Lupin Limited and/or Lupin Pharmaceuticals, Inc. to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Lupin Venlafaxine HCl Extended-Release 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), Lupin Pharmaceuticals, Inc.'s active and knowing aiding and abetting of Lupin Limited's submission to the FDA of ANDA No. 78-543 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Lupin Venlafaxine HCl Extended-Release 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), Lupin Limited's active and knowing aiding and abetting of Lupin Pharmaceuticals, Inc.'s submission to the FDA of ANDA No. 78-543 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Lupin Venlafaxine HCl Extended-Release Capsules before the expiration of the '120 patent was an act of induced infringement of the '120 patent;

(8) declaring that the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Lupin Venlafaxine HCl Extended-Release Capsules by Lupin Limited and/or Lupin Pharmaceuticals, Inc. would constitute infringement of the '120 patent;

(9) declaring that, under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 78-543 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Lupin Venlafaxine HCl Extended-Release Capsules by Lupin Limited and/or Lupin Pharmaceuticals, Inc. 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), Lupin Pharmaceuticals, Inc.'s active and knowing aiding and abetting of Lupin Limited's submission to the FDA of the ANDA No. 78-543 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Lupin Venlafaxine HCl Extended-Release 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), Lupin Limited's active and knowing aiding and abetting of Lupin Pharmaceuticals, Inc.'s submission to the FDA of ANDA No. 78-543 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Lupin Venlafaxine HCl Extended-Release Capsules before the expiration of the '958 patent was an act of induced infringement of the '958 patent;

12) declaring that the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Lupin Venlafaxine HCl Extended-Release Capsules by Lupin Limited and/or Lupin Pharmaceuticals, Inc. would constitute infringement of the '958 patent;

(13) ordering that the effective date of any FDA approval of the Lupin 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);

(14) ordering that the effective date of any FDA approval of the Lupin 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);

(15) ordering that the effective date of any FDA approval of the Lupin 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);

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

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

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

(19) enjoining Lupin Limited, Lupin Pharmaceuticals, Inc., and all persons acting in concert with them, from seeking, obtaining, or maintaining approval of ANDA No. 78-543 until the expiration of the '171 patent;

(20) enjoining Lupin Limited, Lupin Pharmaceuticals, Inc., and all persons acting in concert with them, from seeking, obtaining, or maintaining approval of ANDA No. 78-543 until the expiration of the '120 patent;

(21) enjoining Lupin Limited, Lupin Pharmaceuticals, Inc., and all persons acting in concert with them, from seeking, obtaining, or maintaining approval of ANDA No. 78-543 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: March 12, 2007

Respectfully submitted,

/s/

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