UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, ELI LILLY EXPORT S.A. AND ACRUX DDS PTY LTD.,

Plaintiffs,

v.

LUPIN PHARMACEUTICALS, INC. AND LUPIN LTD.,

Defendants.

Case No. 1:14-CV-1047

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Eli Lilly and Company ("Lilly"), Eli Lilly Export S.A., and Acrux DDS Pty Ltd. ("Acrux") file this Complaint for patent infringement against Lupin Pharmaceuticals, Inc. ("LPI") and Lupin Ltd. (collectively, "Defendants") under 35 U.S.C. § 271. This patent action concerns the pharmaceutical drug product Axiron®.

THE PARTIES

1. Lilly is an Indiana corporation that has its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. Eli Lilly Export S.A. is a Swiss corporation that has its corporate office at 16 Chemin des Coquelicots, The Air Centre, 1214 Vernier/Geneva, Switzerland. Eli Lilly Export S.A. is a wholly owned subsidiary of Lilly.

3. Acrux is an Australian corporation that has its corporate offices and principal place of business at 103-113 Stanley Street, West Melbourne VIC 3003, Australia. Acrux is

engaged in the development and commercialization of pharmaceutical products for sale throughout the world.

4. LPI is a Virginia corporation with its principal place of business at 111 South Calvert Street, 21st Floor, Baltimore, MD 21202. On information and belief, LPI is a wholly-owned subsidiary of Lupin Ltd.

5. On information and belief, LPI is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Indiana and throughout the United States.

6. Lupin Ltd. is an Indian corporation with its principal place of business at Laxmi Towers, 'B' Wing, Bandra Kurla Complex, Bandra (East), Mumbai, 400 051, India.

7. On information and belief, Lupin Ltd. is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Indiana and throughout the United States in concert with its subsidiary LPI.

8. On information and belief, the acts of Lupin Ltd. complained of herein were done with the cooperation, participation, and assistance of LPI.

NATURE OF THE ACTION

9. This is an action for infringement of U.S. Patent Nos. 8,419,307 ("the '307 patent"), 8,177,449 ("the '449 patent"), 8,435,944 ("the '944 patent"), 8,807,861 ("the '861 patent"), and 8,993,520 ("the '520 patent"). This action relates to Abbreviated New Drug Application ("ANDA") No. 208061 submitted in the name of Lupin Ltd. to the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of Lilly's Axiron® (testosterone) product, which constitutes an action of infringement under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2).

SUBJECT MATTER JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

11. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

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

PERSONAL JURISDICTION

13. The Court has personal jurisdiction over Defendants because they regularly and continuously transact business within the State of Indiana. On information and belief, Defendants develop, manufacture market, and sell pharmaceutical products throughout the United States, including the State of Indiana. Defendants maintain a broad distributorship network within Indiana. Defendants derive substantial revenue from Indiana drug sales and have availed themselves of the privilege of conducting business within the State of Indiana.

14. According to Lupin Ltd.'s website, it is "a fully integrated pharmaceutical company with an unrivaled position in the US, India and Japan," with "US & Europe formulation sales contribut[ing] 47% to the Company's overall consolidated revenues for FY 2014."

15. Lupin Ltd.'s 2014 Annual Report states that "Lupin remains the fifth largest and the fastest growing top 5 generics player in the US." Furthermore, "[a]s of March 2014, 31 of the 63 generic products marketed by LPI in the US ranked No. 1 by market share and 53 of the 63 are in the top 3 by Market share (IMS Health)."

16. On information and belief, Lupin Ltd. and LPI share common officers and directors.

17. LPI is registered corporation in the State of Indiana. LPI has been registered in Indiana as a "for-profit foreign corporation" since at least 2006. LPI maintains a registered agent in the State of Indiana at 150 West Market Street, Suite 800, Indianapolis, IN 46204.

18. LPI has directly entered into distribution agreements with at least six Indiana distributors. According to LPI's website, LPI has at least six authorized distributors in the state of Indiana, including Amerisourcebergen Drug Corp in Mishawaka, CVS Indiana LLC in Indianapolis, Henry Schein Inc. in Indianapolis, Peytons North in Bluffton, The Harvard Drug Group, LLC (DBA Major Pharmaceuticals) in Indianapolis, and Wal-Mart Pharmacy Warehouse in Crawford. A list of LPI's distributors in the United States can be found at http://www.lupinpharmaceuticals.com/adrsub.htm.

19. On information and belief, LPI, either directly or through distributors, currently sells significant quantities of generic drug products in the State of Indiana. Those products include, for example, generic versions of Celebrex®, Cipro®, Clarinex®, and Lunesta®. A list of generic products sold by LPI in the United States can be found at http://www.lupinpharmaceuticals.com/productlist.htm.

20. Lupin Ltd. and LPI have availed themselves of this forum previously for the purpose of litigating a patent dispute. For example, Lupin Ltd. and LPI filed counterclaims for declaratory judgment in two different cases the Southern District of Indiana. *Eli Lilly and Company et al. v. Lupin Ltd. et al.*, No. 1:15-cv-673-SEB-TAB (S.D.Ind.) and *Eli Lilly and Company v. Lupin Ltd. et al.*, No. 1:08-cv-1596-LJM-JMS (S.D.Ind.).

21. Lupin Ltd. and LPI, either directly or through distributors, sell products to national and regional retail drug, supermarket, and mass merchandise chains in Indiana, and Lupin Ltd. and LPI derive substantial revenue from these sales.

22. Lupin Ltd. and LPI develop and manufacture pharmaceutical products for the United States market, including the State of Indiana.

23. LPI acts as the agent and official submitter to the FDA of Lupin Ltd.'s ANDA No. 208061 at issue in this case. LPI participated in the preparation and submission of ANDA No. 208061 and will benefit directly and indirectly from the approval of ANDA No. 208061.

24. This Court has personal jurisdiction over Defendants by virtue of, inter alia: (1) their course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Indiana; (2) their presence in Indiana including having a registered agent in Indiana; and (3) their purposeful availment of this forum previously for the purpose of litigating patent disputes.

FACTUAL BACKGROUND

A. Axiron®

25. Lilly is the holder of approved New Drug Application ("NDA") No. 022504 for the manufacture and sale of testosterone metered transdermal solution, 30mg/1.5mL used to treat males for conditions associated with a deficiency or absence of endogenous testosterone. Lilly markets and sells testosterone metered transdermal solution, 30mg/1.5mL under the trade name Axiron®. Axiron® was approved by the FDA on November 23, 2010.

B. The '307 Patent

26. United States Patent No. 8,419,307 ("the '307 patent"), titled "Spreading Implement," was duly and legally issued by the PTO on April 16, 2013. The '307 patent claims, *inter alia*, methods of increasing the testosterone blood level of a person in need thereof comprising applying a liquid pharmaceutical composition that contains testosterone. The '307 patent is listed in the FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") in connection with Axiron®.

A true and correct copy of the ’307 patent is attached as ***Exhibit A***. Since its date of issue, Acrux has been, and continues to be, the owner of the ’307 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the ’307 patent. Eli Lilly Export S.A. has licensed its rights in the ’307 patent to Lilly.

C. The ’449 Patent

27. United States Patent No. 8,177,449 (“the ’449 patent”), titled “Spreading Implement,” was duly and legally issued by the PTO on May 15, 2012. The ’449 patent claims, *inter alia*, a method of transdermal administration of a physiologically active agent. A true and correct copy of the ’449 patent is attached as ***Exhibit B***. Since its date of issue, Acrux has been, and continues to be, the owner of the ’449 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the ’449 patent. Eli Lilly Export S.A. has licensed its rights in the ’449 patent to Lilly.

D. The ’944 Patent

28. United States Patent No. 8,435,944 (“the ’944 patent”), titled “Method and Composition for Transdermal Drug Delivery,” was duly and legally issued by the United States Patent and Trademark Office (“PTO”) on May 7, 2013. The ’944 patent claims, *inter alia*, methods of increasing the testosterone blood level of an adult male comprising applying a transdermal drug delivery composition that contains testosterone. The ’944 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the ’944 patent is attached as ***Exhibit C***. Since its date of issue, Acrux has been, and continues to be, the owner of the ’944 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the ’944 patent. Eli Lilly Export S.A. has licensed its rights in the ’944 patent to Lilly.

E. The ’861 Patent

29. United States Patent No. 8,807,861 (“the ’861 patent”), titled “Spreading Implement,” was duly and legally issued by the PTO on August 19, 2014. The ’861 patent claims, *inter alia*, methods of transdermal administration of a physiologically active agent. The ’861 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the ’861 patent is attached as ***Exhibit D***. Since its date of issue, Acrux has been, and continues to be, the owner of the ’861 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the ’861 patent. Eli Lilly Export S.A. has licensed its rights in the ’861 patent to Lilly.

F. The ’520 Patent

30. United States Patent No. 8,993,520 (“the ‘520 patent”), titled “Method and Composition for Transdermal Drug Delivery,” was duly and legally issued by the PTO on March 31, 2015. The ’520 patent claims, *inter alia*, methods of increasing the testosterone blood level of an adult male subject comprising applying a transdermal drug delivery composition. The ’520 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the ’520 patent is attached as ***Exhibit E***. Since its date of issue, Acrux has been, and continues to be, the owner of the ’520 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the ’520 patent. Eli Lilly Export S.A. has licensed its rights in the ’520 patent to Lilly.

G. Infringement by Lupin Ltd. and LPI

31. Lupin Ltd. and/or LPI filed or caused to be filed with the FDA ANDA No. 208061 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of “Testosterone Topical Solution, 30mg/1.5mL” (“Lupin’s Generic Product”) in the United States before the expiration of the ’307, ’449, ’944, ’861, and ’520 patents.

32. Defendants' ANDA No. 208061 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the '307, '944,'861, and '520 patents are invalid, unenforceable, and/or would not be infringed by Lupin's Generic Product.

33. Lupin Ltd. and/or LPI sent or caused to be sent to Plaintiffs a letter dated May 26, 2015 ("Notice Letter"), notifying Plaintiffs that Lupin's ANDA No. 208061 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Lupin's Generic Product before the expiration of the '307, '944, '861, and '520 patents, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Lupin's Notice Letter states that: "Lupin Limited ("Lupin"), through its agent Lupin Pharmaceuticals, Inc., has submitted to the United States Food and Drug Administration ("FDA") Abbreviated New Drug Application No. 208061 ("the Lupin ANDA") under 21 U.S.C. § 355(j), which contains data from bioavailability or bioequivalence studies to obtain approval to engage in the commercial manufacture, use or sale of testosterone topical solution-in a 30 mg/1.5 ml actuation ("the Lupin ANDA Product")."

34. Lupin's Notice Letter further states: "The Lupin ANDA identifies AXIRON® (30 mg/1.5 ml actuation testosterone topical solution) (NDA No. 22-504) as the Reference Listed Drug and includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ('Paragraph IV Certification') with respect to U.S. Patent Nos. 8,419,307 ('the '307 patent'), 8,807,861 ('the '861 patent'), 8,435,944 ('the '944 patent'), . . . 8,993,520 ('the '520 patent'), which are listed in the FDA's Electronic Orange Book, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the 'Orange Book') for AXIRON® 30 mg/1.5 ml actuation topical solution."

35. The submission of ANDA No. 208061 to the FDA constitutes infringement by Defendants of the '307, '449, '944, '861, and '520 patents under 35 U.S.C. § 271(e)(2).

Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Lupin's Generic Product would infringe the '307, '449, '944, '861, and '520 patents under 35 U.S.C. § 271(a), (b), and/or (c).

36. Defendants know and intend that physicians will prescribe and patients will take Lupin's Generic Product for which approval is sought in ANDA No. 208061 and therefore, will infringe at least one claim of the patents-in-suit.

37. Defendants had knowledge of the patents-in-suit and by their promotional activities and proposed Generic Product, knew or should know that they will aid and abet another's direct infringement of at least one of the claims of the patents-in-suit either literally or under the doctrine of equivalents.

38. Defendants plan to make, use, sell, offer to sell and/or import their Generic Product for uses that will infringe the patents-in-suit. Lupin's Generic Product is a material part of these infringing uses and has no substantial non-infringing uses.

39. Plaintiffs commenced this action within 45 days of receiving Lupin's May 26, 2015, Notice Letter.

COUNT I FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 8,419,307)

40. Plaintiffs incorporate by reference and reallege Paragraphs 1-39 above as though fully restated herein.

41. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 208061 to the FDA seeking approval of Lupin's Generic Product before expiration of the '307 patent was an act of infringement of the '307 patent by Defendants.

42. If ANDA No. 208061 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of

Lupin's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '307 patent under 35 U.S.C. § 271.

43. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '307 patent. Plaintiffs do not have an adequate remedy at law.

COUNT II FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 8,419,307)

44. Plaintiffs incorporate by reference and reallege Paragraphs 1-43 above as though fully restated herein.

45. Defendants have knowledge of the '307 patent.

46. Upon FDA approval of ANDA No. 208061, Defendants will intentionally encourage acts of direct infringement of the '307 patent by others, with knowledge that their acts are encouraging infringement.

COUNT III FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 8,419,307)

47. Plaintiffs incorporate by reference and reallege Paragraphs 1-46 above as though fully restated herein.

48. If ANDA No. 208061 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Lupin's Generic Product.

49. On information and belief, Defendants have had and continue to have knowledge that Lupin's Generic Product is especially adapted for a use that infringes the '307 patent.

50. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Lupin's Generic Product.

COUNT IV FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 8,177,449)

51. Plaintiffs incorporate by reference and reallege Paragraphs 1-50 above as though fully restated herein.

52. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 208061 to the FDA seeking approval of Lupin's Generic Product before expiration of the '449 patent was an act of infringement of the '449 patent by Defendants.

53. If ANDA No. 208061 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Lupin's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '449 patent under 35 U.S.C. § 271.

54. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '449 patent. Plaintiffs do not have an adequate remedy at law.

COUNT V FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 8,177,449)

55. Plaintiffs incorporate by reference and reallege Paragraphs 1-54 above as though fully restated herein.

56. Defendants have knowledge of the '449 patent.

57. Upon FDA approval of ANDA No. 208061, Defendants will intentionally encourage acts of direct infringement of the '449 patent by others, with knowledge that their acts are encouraging infringement.

COUNT VI FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 8,177,449)

58. Plaintiffs incorporate by reference and reallege Paragraphs 1-57 above as though fully restated herein.

59. If ANDA No. 208061 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Lupin's Generic Product.

60. On information and belief, Defendants have had and continue to have knowledge that Lupin's Generic Product is especially adapted for a use that infringes the '449 patent.

61. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Lupin's Generic Product.

COUNT VII FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 8,435,944)

62. Plaintiffs incorporate by reference and reallege Paragraphs 1-61 above as though fully restated herein.

63. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 208061 to the FDA seeking approval of Lupin's Generic Product before expiration of the '944 patent was an act of infringement of the '944 patent by Defendants.

64. If ANDA No. 208061 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Lupin's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '944 patent under 35 U.S.C. § 271.

65. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '944 patent. Plaintiffs do not have an adequate remedy at law.

COUNT VIII FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 8,435,944)

66. Plaintiffs incorporate by reference and reallege Paragraphs 1-65 above as though fully restated herein.

67. Defendants have knowledge of the '944 patent.

68. Upon FDA approval of ANDA No. 208061, Defendants will intentionally encourage acts of direct infringement of the '944 patent by others, with knowledge that their acts are encouraging infringement.

COUNT IX FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 8,435,944)

69. Plaintiffs incorporate by reference and reallege Paragraphs 1-68 above as though fully restated herein.

70. If ANDA No. 208061 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Lupin's Generic Product.

71. On information and belief, Defendants have had and continue to have knowledge that Lupin's Generic Product is especially adapted for a use that infringes the '944 patent.

72. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Lupin's Generic Product.

COUNT X FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 8,807,861)

73. Plaintiffs incorporate by reference and reallege Paragraphs 1-72 above as though fully restated herein.

74. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 208061 to the FDA seeking approval of Lupin's Generic Product before expiration of the '861 patent was an act of infringement of the '861 patent by Defendants.

75. If ANDA No. 208061 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Lupin's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '861 patent under 35 U.S.C. § 271.

76. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '861 patent. Plaintiffs do not have an adequate remedy at law.

COUNT XI FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 8,807,861)

77. Plaintiffs incorporate by reference and reallege Paragraphs 1-76 above as though fully restated herein.

78. Defendants have knowledge of the '861 patent.

79. Upon FDA approval of ANDA No. 208061, Defendants will intentionally encourage acts of direct infringement of the '861 patent by others, with knowledge that their acts are encouraging infringement.

COUNT XII FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 8,807,861)

80. Plaintiffs incorporate by reference and reallege Paragraphs 1-79 above as though fully restated herein.

81. If ANDA No. 208061 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Lupin's Generic Product.

82. On information and belief, Defendants have had and continue to have knowledge that Lupin's Generic Product is especially adapted for a use that infringes the '861 patent.

83. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Lupin's Generic Product.

COUNT XIII FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 8,993,520)

84. Plaintiffs incorporate by reference and reallege Paragraphs 1-83 above as though fully restated herein.

85. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 208061 to the FDA seeking approval of Lupin's Generic Product before expiration of the '520 patent was an act of infringement of the '520 patent by Defendants.

86. If ANDA No. 208061 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Lupin's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '520 patent under 35 U.S.C. § 271.

87. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '520 patent. Plaintiffs do not have an adequate remedy at law.

COUNT XIV FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 8,993,520)

88. Plaintiffs incorporate by reference and reallege Paragraphs 1-87 above as though fully restated herein.

89. Defendants have knowledge of the '520 patent.

90. Upon FDA approval of ANDA No. 208061, Defendants will intentionally encourage acts of direct infringement of the '520 patent by others, with knowledge that their acts are encouraging infringement.

COUNT XV FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 8,993,520)

91. Plaintiffs incorporate by reference and reallege Paragraphs 1-90 above as though fully restated herein.

92. If ANDA No. 208061 is approved, Defendants intends to and will offer to sell, sell, or import into the United States Lupin's Generic Product.

93. On information and belief, Defendants have had and continue to have knowledge that Lupin's Generic Product is especially adapted for a use that infringes the '520 patent.

94. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Lupin's Generic Product.

COUNT XVI FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 8,419,307)

95. Plaintiffs incorporate by reference and reallege Paragraphs 1-94 above as though fully restated herein.

96. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

97. Defendants submitted ANDA No. 208061, seeking authorization to commercially manufacture, use, offer for sale, and sell Lupin's Generic Product in the United States. Lupin's Generic Product has no substantial non-infringing uses.

98. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Lupin's Generic Product prior to expiration of the '307 patent.

99. Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Lupin's Generic Product upon receipt of final FDA approval of ANDA No. 208061, unless enjoined by the Court.

100. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Lupin's Generic Product would infringe one or more claims of the '307 patent under 35 U.S.C. § 271(a), (b), and/or (c).

101. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Lupin's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '307 patent.

102. On information and belief, Defendants have had and continue to have knowledge that Lupin's Generic Product is especially adapted for a use that infringes the '307 patent.

103. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Lupin's Generic Product.

104. There is a justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's Generic Product according to ANDA No. 208061 would infringe one or more claims of the '307 patent.

105. If Defendants' infringement of the '307 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

COUNT XVII FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 8,177,449)

106. Plaintiffs incorporate by reference and reallege Paragraphs 1-105 above as though fully restated herein.

107. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

108. Defendants submitted ANDA No. 208061, seeking authorization to commercially manufacture, use, offer for sale, and sell Lupin's Generic Product in the United States. Lupin's Generic Product has no substantial non-infringing uses.

109. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Lupin's Generic Product prior to expiration of the '449 patent.

110. Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Lupin's Generic Product upon receipt of final FDA approval of ANDA No. 208061, unless enjoined by the Court.

111. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Lupin's Generic Product would infringe one or more claims of the '449 patent under 35 U.S.C. § 271(a), (b), and/or (c).

112. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Lupin's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '449 patent.

113. On information and belief, Defendants have had and continue to have knowledge that Lupin's Generic Product is especially adapted for a use that infringes the '449 patent.

114. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Lupin's Generic Product.

115. There is a justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's Generic Product according to ANDA No. 208061 would infringe one or more claims of the '449 patent.

116. If Defendants' infringement of the '449 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

COUNT XVIII FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 8,435,944)

117. Plaintiffs incorporate by reference and reallege Paragraphs 1-116 above as though fully restated herein.

118. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

119. Defendants submitted ANDA No. 208061, seeking authorization to commercially manufacture, use, offer for sale, and sell Lupin's Generic Product in the United States. Lupin's Generic Product has no substantial non-infringing uses.

120. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Lupin's Generic Product prior to expiration of the '944 patent.

121. Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Lupin's Generic Product upon receipt of final FDA approval of ANDA No. 208061, unless enjoined by the Court.

122. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Lupin's Generic Product would infringe one or more claims of the '944 patent under 35 U.S.C. § 271(a), (b), and/or (c).

123. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Lupin's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '944 patent.

124. On information and belief, Defendants have had and continue to have knowledge that Lupin's Generic Product is especially adapted for a use that infringes the '944 patent.

125. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Lupin's Generic Product.

126. There is a justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's Generic Product according to ANDA No. 208061 would infringe one or more claims of the '944 patent.

127. If Defendants' infringement of the '944 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

COUNT XIX FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 8,807,861)

128. Plaintiffs incorporate by reference and reallege Paragraphs 1-127 above as though fully restated herein.

129. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

130. Defendants submitted ANDA No. 208061, seeking authorization to commercially manufacture, use, offer for sale, and sell Lupin's Generic Product in the United States. Lupin's Generic Product has no substantial non-infringing uses.

131. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Lupin's Generic Product prior to expiration of the '861 patent.

132. Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Lupin's Generic Product upon receipt of final FDA approval of ANDA No. 208061, unless enjoined by the Court.

133. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Lupin's Generic Product would infringe one or more claims of the '861 patent under 35 U.S.C. § 271(a), (b), and/or (c).

134. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Lupin's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '861 patent.

135. On information and belief, Defendants have had and continue to have knowledge that Lupin's Generic Product is especially adapted for a use that infringes the '861 patent.

136. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Lupin's Generic Product.

137. There is a justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's Generic Product according to ANDA No. 208061 would infringe one or more claims of the '861 patent.

138. If Defendants' infringement of the '861 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

COUNT XX FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 8,993,520)

139. Plaintiffs incorporate by reference and reallege Paragraphs 1-138 above as though fully restated herein.

140. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

141. Defendants submitted ANDA No. 208061, seeking authorization to commercially manufacture, use, offer for sale, and sell Lupin's Generic Product in the United States. Lupin's Generic Product has no substantial non-infringing uses.

142. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Lupin's Generic Product prior to expiration of the '520 patent.

143. Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Lupin's Generic Product upon receipt of final FDA approval of ANDA No. 208061, unless enjoined by the Court.

144. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Lupin's Generic Product would infringe one or more claims of the '520 patent under 35 U.S.C. § 271(a), (b), and/or (c).

145. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Lupin's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '520 patent.

146. On information and belief, Defendants have had and continue to have knowledge that Lupin's Generic Product is especially adapted for a use that infringes the '520 patent.

147. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Lupin's Generic Product.

148. There is a justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's Generic Product according to ANDA No. 208061 would infringe one or more claims of the '520 patent.

149. If Defendants' infringement of the '520 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor as follows:

a) United States Patent Nos. 8,419,307; 8,177,449; 8,435,944; 8,807,861; and 8,993,520 are valid and enforceable;

b) Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed United States Patent Nos. 8,419,307; 8,177,449; 8,435,944; 8,807,861; and 8,993,520 by submitting ANDA No. 208061 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Lupin's Generic Product prior to expiration of said patents;

c) Defendants' threatened acts of commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Lupin's Generic Product prior to the expiration of United States Patent Nos. 8,419,307; 8,177,449; 8,435,944; 8,807,861; and 8,993,520 would constitute infringement of said patents;

d) The effective date of any FDA approval of Lupin's Generic Product shall be no earlier than the latest of the expiration date of United States Patent Nos.

8,419,307; 8,177,449; 8,435,944; 8,807,861; and 8,993,520 and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) Defendants, and all persons acting in concert with Defendants, shall be enjoined from commercially manufacturing, using, offering for sale, or selling Lupin's Generic Product within the United States, or importing Lupin's Generic Product into the United States, until the expiration of United States Patent Nos. 8,419,307; 8,177,449; 8,435,944; 8,807,861; and 8,993,520 in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

f) This is an exceptional case and Plaintiffs should be awarded their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

g) Plaintiffs are entitled to any further appropriate relief under 35 U.S.C. § 271(e)(4); and

h) Plaintiffs are entitled to any further and additional relief that this Court deems just and proper.

Respectfully submitted,

Dated: July 6, 2015

/s/ Jan M. Carroll

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