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. AMNEAL PHARMACEUTICALS LLC, Defendant.	Case No. 1:14-CV-2025

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 Amneal Pharmaceuticals LLC ("Amneal") 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 in P.O. Box 580, 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. Amneal is a Delaware corporation with its principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807-2863. Amneal 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.

NATURE OF THE ACTION

5. This is an action for infringement of U.S. Patent Nos. 8,435,944 ("the '944 patent"), 8,419,307 ("the '307 patent"), 8,177,449 ("the '449 patent"), and 8,807,861 ("the '861 patent"). This action relates to Abbreviated New Drug Application ("ANDA") No. 206998 submitted in the name of Amneal 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

6. 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.

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

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

PERSONAL JURISDICTION

9. The Court has personal jurisdiction over Defendant because it regularly and continuously transacts business within the State of Indiana. Defendant markets and sells

pharmaceutical products throughout the United States, including the State of Indiana. Defendant maintains a broad distributorship network within Indiana. Defendant derives substantial revenue from Indiana drug sales and has availed itself of the privilege of conducting business within the State of Indiana.

10. According to the website for Amneal, "Amneal sells over 12 billion units of medication annually in the U.S. alone." In fact, "Amneal's primary distribution facility allows it to service customers in every corner of the U.S. in an expeditious, accurate and dependable fashion." Amneal boasts on its website that because it is "[s]trategically located in close proximity to the UPS hub and within the Central Time Zone, Amneal is able to provide one-day ground delivery to more than 75% of the American population."

11. Upon information and belief, Amneal Pharmaceuticals currently sells significant quantities of generic drug products in the state of Indiana. Those products include, for example, generic versions of Percocet®, Ultracet®, and Neurontin®. A list of generic products manufactured and sold by Amneal Pharmaceuticals in the United States can be found at http://prd03.apsiva.net/amneal/#/.

12. According to the website for Amneal, "Amneal proudly sells directly to warehousing chains, wholesalers/distributors and mail order operations in order to make its quality products available to all levels of retail pharmacy including independently owned, regional chains and cooperatives."

13. On information and belief, Amneal has directly entered into a distribution agreement with an Indiana wholesale distributor. According to the website for Amneal, Amneal lists A.F. Hauser, Inc. as an authorized distributor of its products. On information and belief, A.F. Hauser, Inc. is located at 4401 East U.S. Hwy. 30, Valparaiso, Indiana 46383.

14. On information and belief Amneal has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Amneal filed counterclaims for declaratory judgment in the Southern District of Indiana. *Eli Lilly and Company et al. v. Accord Healthcare, Inc. USA. et al.*, No. 1:14-cv-389-SEB-TAB (S.D.Ind.).

15. Amneal has engaged in substantial and continuous contacts with Indiana that satisfy due process and confer personal jurisdiction over Amneal in Indiana on the basis of general jurisdiction.

16. Amneal, either directly or through wholesalers, sells products to national and regional retail drug, supermarket, and mass merchandise chains in Indiana, and Amneal derives substantial revenue from these sales.

17. Amneal develops and manufactures pharmaceutical products for the United States market, including the State of Indiana.

18. Amneal prepared and submitted ANDA No. 206998 and will benefit from the approval of ANDA No. 206998.

FACTUAL BACKGROUND

A. Axiron®

19. 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 '944 Patent

20. United States Patent No. 8,435,944 ("the '944 patent"), entitled "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 FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") in connection with Axiron®. A true and correct copy of the '944 patent is attached as Exhibit A. 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.

C. The '307 Patent

21. United States Patent No. 8,419,307 ("the '307 patent"), entitled "Spreading Implement," was duly and legally issued by the PTO on April 16, 2013. The '307 patent claims, *inter alia*, a method 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 Orange Book in connection with Axiron®. A true and correct copy of the '307 patent is attached as Exhibit B. 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.

D. The '449 Patent

22. United States Patent No. 8,177,449 ("the '449 patent") entitled "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 C. 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.

E. The ’861 Patent

23. United States Patent No. 8,807,861 (“the ’861 patent”) entitled “Spreading Implement,” was duly and legally issued by the PTO on August 19, 2014. The ’861 patent claims, *inter alia*, a method of transdermal administration of a physiologically active agent. 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 ’449 patent. Eli Lilly Export S.A. has licensed its rights in the ’861 patent to Lilly.

F. Infringement by Amneal

24. Defendant filed or caused to be filed with the FDA ANDA No. 206998 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of “Testosterone Topical Solution, 30mg/1.5mL” (“Amneal’s Generic Product”) in the United States before the expiration of the ’944, ’307,’449 and ’861 patents.

25. Defendant’s ANDA No. 206998 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“paragraph IV certifications”), alleging that the claims of the ’944, ’307, and ’861 patents are invalid, unenforceable, and/or would not be infringed by Amneal’s Generic Product.

26. Defendant sent to Plaintiffs a letter dated October 29, 2014 (“Notice Letter”), notifying Plaintiffs that Defendant’s ANDA No. 206998 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Amneal’s Generic Product before the expiration of the ’944, ’307, and ’861 patents, and providing information

pursuant to 21 U.S.C. § 355(j)(2)(B). Amneal's Notice Letter states that it: "submitted to the U.S. Food and Drug Administration ("FDA"), and the FDA has received, an Abbreviated New Drug Application ("ANDA") that contains data from bioavailability or bioequivalence studies for, and which seeks approval to engage in the commercial manufacture, use, and/or sale of, Testosterone Topical Solution, 30mg/1.5mL, before the expiration of the Orange Book Listed Patents."

27. The submission of ANDA No. 206998 to the FDA constitutes infringement by Defendant of the '944, '307,'449, and '861 patents under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Amneal's Generic Product would infringe the '944, '307, '449, and '861 patents under 35 U.S.C. § 271(a), (b), and/or (c).

28. Defendant knows and intends that physicians will prescribe and patients will take Amneal's Generic Product for which approval is sought in ANDA No. 206998 and therefore, will infringe at least one claim of the patents-in-suit.

29. Defendant had knowledge of the patents-in-suit and by its promotional activities and proposed Generic product, knew or should know that it 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.

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

31. Plaintiffs commenced this action within 45 days of receiving Amneal's October 29, 2014, Notice Letter.

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

32. Plaintiffs incorporate by reference and reallege Paragraphs 1-31 above as though fully restated herein.

33. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 206998 to the FDA seeking approval of Amneal's Generic Product before expiration of the '944 patent was an act of infringement of the '944 patent by Defendant.

34. If ANDA No. 206998 is approved by the FDA, Defendant's commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Amneal'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.

35. Unless Defendant is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendant's infringement of the '944 patent. Plaintiffs do not have an adequate remedy at law.

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

36. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 35 above as though fully restated herein.

37. Defendant has knowledge of the '944 patent.

38. Upon FDA approval of ANDA No. 206998, Defendant will intentionally encourage acts of direct infringement of the '944 patent by others, with knowledge that its acts are encouraging infringement.

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

39. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 38 above as though fully restated herein.

40. If ANDA No. 206998 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Amneal's Generic Product.

41. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '944 patent.

42. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

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

43. Plaintiffs incorporate by reference and reallege Paragraphs 1-42 above as though fully restated herein.

44. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 206998 to the FDA seeking approval of Amneal's Generic Product before expiration of the '307 patent was an act of infringement of the '307 patent by Defendant.

45. If ANDA No. 206998 is approved by the FDA, Defendant's commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Amneal'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.

46. Unless Defendant is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendant's infringement of the '307 patent. Plaintiffs do not have an adequate remedy at law.

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

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

48. Defendant has knowledge of the '307 patent.

49. Upon FDA approval of ANDA No. 206998, Defendant will intentionally encourage acts of direct infringement of the '307 patent by others, with knowledge that its acts are encouraging infringement.

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

50. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 49 above as though fully restated herein.

51. If ANDA No. 206998 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Amneal's Generic Product.

52. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '307 patent.

53. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

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

54. Plaintiffs incorporate by reference and reallege Paragraphs 1-53 above as though fully restated herein.

55. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 206998 to the FDA seeking approval of Amneal's Generic Product before expiration of the '449 patent was an act of infringement of the '449 patent by Defendant.

56. If ANDA No. 206998 is approved by the FDA, Defendant's commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Amneal'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.

57. Unless Defendant is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendant's infringement of the '449 patent. Plaintiffs do not have an adequate remedy at law.

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

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

59. Defendant has knowledge of the '449 patent.

60. Upon FDA approval of ANDA No. 206998, Defendant will intentionally encourage acts of direct infringement of the '449 patent by others, with knowledge that its acts are encouraging infringement.

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

61. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 60 above as though fully restated herein.

62. If ANDA No. 206998 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Amneal's Generic Product.

63. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '449 patent.

64. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

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

65. Plaintiffs incorporate by reference and reallege Paragraphs 1-64 above as though fully restated herein.

66. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 206998 to the FDA seeking approval of Amneal's Generic Product before expiration of the '861 patent was an act of infringement of the '861 patent by Defendant.

67. If ANDA No. 206998 is approved by the FDA, Defendant's commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Amneal'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.

68. Unless Defendant is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendant's 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)

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

70. Defendant has knowledge of the '861 patent.

71. Upon FDA approval of ANDA No. 206998, Defendant will intentionally encourage acts of direct infringement of the '861 patent by others, with knowledge that its acts are encouraging infringement.

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

72. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 71 above as though fully restated herein.

73. If ANDA No. 206998 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Amneal's Generic Product.

74. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '861 patent.

75. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

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

76. Plaintiffs incorporate by reference and reallege Paragraphs 1-75 above as though fully restated herein.

77. 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).

78. Defendant submitted ANDA No. 206998, seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Generic Product in the United States. Defendant's Generic Product has no substantial non-infringing uses.

79. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Amneal's Generic Product prior to expiration of the '944 patent.

80. Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Amneal's Generic Product upon receipt of final FDA approval of ANDA No. 206998, unless enjoined by the Court.

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

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

83. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '944 patent.

84. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

85. There is a justiciable case or controversy between Plaintiffs and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Generic Product according to ANDA No. 206998 would infringe one or more claims of the '944 patent.

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

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

87. Plaintiffs incorporate by reference and reallege Paragraphs 1-86 above as though fully restated herein.

88. 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).

89. Defendant submitted ANDA No. 206998, seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Generic Product in the United States. Defendant's Generic Product has no substantial non-infringing uses.

90. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Amneal's Generic Product prior to expiration of the '307 patent.

91. Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Amneal's Generic Product upon receipt of final FDA approval of ANDA No. 206998, unless enjoined by the Court.

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

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

94. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '307 patent.

95. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

96. There is a justiciable case or controversy between Plaintiffs and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Generic Product according to ANDA No. 206998 would infringe one or more claims of the '307 patent.

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

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

98. Plaintiffs incorporate by reference and reallege Paragraphs 1-97 above as though fully restated herein.

99. 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).

100. Defendant submitted ANDA No. 206998, seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Generic Product in the United States. Defendant's Generic Product has no substantial non-infringing uses.

101. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Amneal's Generic Product prior to expiration of the '449 patent.

102. Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Amneal's Generic Product upon receipt of final FDA approval of ANDA No. 206998, unless enjoined by the Court.

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

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

105. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '449 patent.

106. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

107. There is a justiciable case or controversy between Plaintiffs and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Generic Product according to ANDA No. 206998 would infringe one or more claims of the '449 patent.

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

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

109. Plaintiffs incorporate by reference and reallege Paragraphs 1-108 above as though fully restated herein.

110. 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).

111. Defendant submitted ANDA No. 206998, seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Generic Product in the United States. Defendant's Generic Product has no substantial non-infringing uses.

112. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Amneal's Generic Product prior to expiration of the '861 patent.

113. Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Amneal's Generic Product upon receipt of final FDA approval of ANDA No. 206998, unless enjoined by the Court.

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

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

116. On information and belief, Defendant has had and continues to have knowledge that Amneal's Generic Product is especially adapted for a use that infringes the '861 patent.

117. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Amneal's Generic Product.

118. There is a justiciable case or controversy between Plaintiffs and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Generic Product according to ANDA No. 206998 would infringe one or more claims of the '861 patent.

119. If Defendant's infringement of the '861 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. 8,435,944; 8,419,307; 8,177,449; and 8,807,861 are valid and enforceable;

b) Under 35 U.S.C. § 271(e)(2)(A), Defendant infringed United States Patent Nos. 8,435,944; 8,419,307; 8,177,449; and 8,807,861 by submitting ANDA No. 206998 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Amneal's Generic Product prior to expiration of said patents;

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

d) The effective date of any FDA approval of Amneal's Generic Product shall be no earlier than the latest of the expiration date of United States Patent Nos. 8,435,944; 8,419,307; 8,177,449; and 8,807,861 and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) Defendant, and all persons acting in concert with Defendant shall be enjoined from commercially manufacturing, using, offering for sale, or selling Amneal's Generic Product within the United States, or importing Amneal's Generic Product into the United States, until the expiration of United States Patent Nos. 8,435,944; 8,419,307; 8,177,449; and 8,807,861, 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: December 10, 2014 By: */s/ Jan M. Carroll*
Jan M. Carroll, No. 4187-49

BARNES & THORNBURG LLP
11 South Meridian Street
Indianapolis, Indiana 46204-3535
(317) 236-1313

Of counsel:

Charles E. Lipsey
L. Scott Burwell
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
Two Freedom Square
11955 Freedom Drive
Reston, VA 20190-5675
(571) 203-2700

Laura P. Masurovsky
Danielle A. Duszczyszyn
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

Alissa Lipton
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
Two Seaport Lane
Boston, MA 02210-2001
(617) 646-1600

Attorneys for Plaintiffs,
Eli Lilly and Company, Eli Lilly Export S.A. and
Acrux DDS Pty Ltd.