IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELI LILLY AND COMPANY, ELI LILLY EXPORT S.A. and ACRUX DDS PTY LTD., Plaintiffs, v. CIPLA LIMITED and CIPLA USA, INC., Defendants.	)	C.A. No. _____

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 Cipla Limited and Cipla USA, Inc. ("Cipla USA") (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. Cipla USA is a Delaware corporation with its principal place of business at 9100 S. Dadeland Blvd., Ste. 1500, Miami, FL 33156. On information and belief, Cipla USA is an indirect, wholly owned subsidiary of Cipla Limited.

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

6. Cipla Limited is an Indian corporation with its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400 013.

7. On information and belief, Cipla Limited is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States in concert with its subsidiary Cipla USA.

8. On information and belief, the acts of Cipla Limited complained of herein were done with the cooperation, participation, and assistance of Cipla USA.

NATURE OF THE ACTION

9. This is an action for infringement of U.S. Patent Nos. 8,435,944 ("the '944 patent"), 8,993,520 ("the '520 patent"), and 9,180,194 ("the '194 patent"). This action relates to Abbreviated New Drug Application ("ANDA") No. 209533 ("Cipla's ANDA") submitted in the name of Cipla Limited 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 act 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. On information and belief, this Court has personal jurisdiction over Defendants.

14. On information and belief, Cipla USA is a Delaware corporation. On information and belief, Cipla USA has a registered agent in Delaware (located at Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, DE 19808).

15. On information and belief, Defendants regularly and continuously transact business within the State of Delaware. On information and belief, Defendants develop, manufacture, market, and sell pharmaceutical products throughout the United States, including the State of Delaware. Defendants maintain a broad distributorship network within Delaware. Defendants derive substantial revenue from Delaware drug sales and have availed themselves of the privilege of conducting business within the State of Delaware.

16. According to Cipla Limited's Annual Report for 2015-16, Cipla Limited has over 165 ANDAs filed in the U.S. As a result of the recent acquisition of both InvaGen and Exelan Pharmaceuticals, Cipla Limited obtained manufacturing facilities in the U.S., 32 additional products on the market in the U.S., and 30 additional pipeline products in the U.S. According to Cipla Limited's Annual Report, its "global growth strategy [is] to grow its presence in the US pharmaceutical market and increase its position amongst key pharmaceutical wholesalers and retailers." The Annual Report touts that "Cipla has already established a strong US team which has been deeply involved in Cipla's launch of its own label products in the US as well as in evaluation of inorganic growth opportunities."

17. Cipla USA's website states that "Cipla has been dedicated to providing access to medicines at an affordable price for over 30 years in the US. The company has executed over 20

US partnerships and currently has commercialized products in the US." Cipla USA is also a pharmaceutical vendor for the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP). The MMCAP sells pharmaceuticals in the State of Delaware.

18. On information and belief, Cipla USA, either directly or through distributors, currently sells significant quantities of generic drug products in the State of Delaware. Those products include, for example, generic versions of Wellbutrin SR®, Celebrex®, Vibramycin®, Cymbalta®, Lexapro®, Zoloft®, and Valtrex®. Cipla USA, through its website, solicits customers and potential customers from across the U.S., including in the District of Delaware, who can search and access prescribing information for Cipla's full product line and learn how to return Cipla's products. A list of generic products sold by Cipla USA in the United States can be found at http://www.ciplausa.com/content/products.

19. On information and belief, directors of Cipla USA are employees of Cipla Limited.

20. Cipla Limited and Cipla USA have availed themselves of this forum numerous times previously for the purpose of litigating a patent dispute. For example, Cipla Limited chose the District of Delaware as the forum to file its suit against Sunovion Pharmaceuticals last year. *Cipla Ltd. v. Sunovion Pharms.*, No. 1:15-cv-00424-LPS (D. Del.). As another example, both Cipla Limited and Cipla USA filed counterclaims against Bristol-Myers Squibb Co. this year. *Bristol-Myers Squibb Co. v. Cipla USA, Inc. et al.*, No. 1:16-cv-00074 (D. Del.).

21. Cipla Limited and Cipla USA, either directly or through distributors, sell products to national and regional retail drug, supermarket, and mass merchandise chains in Delaware, and Cipla Limited and Cipla USA derive substantial revenue from these sales.

22. Cipla Limited and Cipla USA develop and manufacture pharmaceutical products for the United States market, including the State of Delaware.

23. Cipla USA acts as the agent and official submitter to the FDA of Cipla Limited's ANDA No. 209533 at issue in this case. Cipla USA participated in the preparation and submission of ANDA No. 209533 and will benefit directly and indirectly from the approval of ANDA No. 209533.

24. This Court has personal jurisdiction over Defendants by virtue of, inter alia: (1) Cipla USA's incorporation in this state; (2) their course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware; and (3) their purposeful availment of this forum previously for the purpose of litigating patent disputes. Cipla "has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at," on information and belief, the District of Delaware and elsewhere. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 759 (Fed. Cir. 2016). Cipla's "ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." *Id.* at 760. On information and belief, Cipla "intends to direct sales of its drugs into [Delaware], among other places, once it has the requested FDA approval to market them." *Id.* at 758. On information and belief, Cipla will engage in marketing of its proposed ANDA product in Delaware upon approval of its ANDA.

25. Cipla's ANDA filing, including its Paragraph IV certifications regarding the '944, '520, and '194 patents, is suit-related and has a substantial connection with this District because it reliably, non-speculatively predicts activities by Cipla in this District. "[T]he minimum-contacts standard is satisfied by the particular actions [Cipla] has already taken—its ANDA

filing[]—for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in" this District. *Id.* at 760. Exercising personal jurisdiction over Cipla in this District would not be unreasonable given Cipla's contacts in this District, and the interest in this District of resolving disputes related to products to be sold herein.

FACTUAL BACKGROUND

A. Axiron®

26. 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

27. 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 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 '520 Patent

28. 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 B. 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.

D. The '194 Patent

United States Patent No. 9,180,194 ("the '194 patent"), titled "Method and Composition for Transdermal Drug Delivery," was duly and legally issued by the PTO on November 10, 2015. The '194 patent claims, *inter alia*, methods of increasing the testosterone blood level of an adult male subject comprising applying a transdermal drug delivery composition. The '194 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the '194 patent is attached as Exhibit C. Since its date of issue, Acrux has been, and continues to be, the owner of the '194 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the '194 patent. Eli Lilly Export S.A. has licensed its rights in the '194 patent to Lilly.

E. Infringement by Cipla Limited and Cipla USA

29. Cipla Limited and/or Cipla USA filed or caused to be filed with the FDA ANDA No. 209533 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of a transdermal "Testosterone solution, metered 30 mg/1.5mL actuation" ("Cipla's Generic Product") in the United States before the expiration of the '944, '520, and '194 patents.

30. Defendants' ANDA No. 209533 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the '944, '520,

and ’194 patents are invalid, unenforceable, and/or would not be infringed by Cipla’s Generic Product.

31. Cipla Limited and/or Cipla USA sent or caused to be sent to Plaintiffs a letter dated September 16, 2016 (“Notice Letter”), notifying Plaintiffs that Cipla’s ANDA No. 209533 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Cipla’s Generic Product before the expiration of the ’944, ’520, and ’194 patents, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Cipla’s Notice Letter states that: “Cipla Limited (“Cipla”), owner of Abbreviated New Drug Application No. 209533 (“Cipla’s ANDA”), hereby provides notice to you, as a representative of Eli Lilly And Company (“Lilly”), that Cipla has filed a certification of invalidity, unenforceability, and/or non-infringement of . . . U.S. Patent No. 8.435,944 (“the ‘944 Patent”), . . . U.S. Patent No. 8,993,520 (“the ‘520 patent”), [and] U.S. Patent No. 9, 180,194 (“the ‘194 patent”), . . . in connection with Cipla’s ANDA seeking approval for Testosterone solution, metered 30mg/1.5mL actuation which contains Testosterone as the active ingredient, related to Lilly’s Axiron®.”

32. Cipla’s Notice Letter further states: “Pursuant to 21 U.S.C. § 355 (j)(2)(B)(ii) and C.F.R § 314.95(c), we advise you that the FDA has received an ANDA from Cipla for Testosterone solution, metered 30mg/1.5 mL actuation (“Cipla’s ANDA Product”). Cipla’s ANDA contains the required bioavailability and/or bioequivalence data from studies on Cipla’s ANDA Product that is the subject of Cipla’s ANDA. Cipla’s ANDA was submitted under 21 U.S.C. § 355(j)(1) and (2)(A). with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, or sale of Cipla’s ANDA Product before the expiration of . . . the ‘944 patent, . . . the ‘520 patent, [and] the ‘194 patent.”

33. The submission of ANDA No. 209533 to the FDA constitutes infringement by Defendants of the '944, '520, and '194 patents under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Cipla's Generic Product would infringe the '944, '520, and '194 patents under 35 U.S.C. § 271(a), (b), and/or (c).

34. Defendants know and intend that physicians will prescribe and patients will take Cipla's Generic Product for which approval is sought in ANDA No. 209533 and therefore, will infringe at least one claim of the patents-in-suit.

35. 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.

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

37. Plaintiffs commenced this action within 45 days of receiving Cipla's September 16, 2016, Notice Letter.

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

38. Plaintiffs incorporate by reference and reallege Paragraphs 1-37 above as though fully restated herein.

39. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209533 to the FDA seeking approval of Cipla's Generic Product before expiration of the '944 patent was an act of infringement of the '944 patent by Defendants.

40. If ANDA No. 209533 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Cipla'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.

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

42. Plaintiffs incorporate by reference and reallege Paragraphs 1-41 above as though fully restated herein.

43. Defendants have knowledge of the '944 patent.

44. Upon FDA approval of ANDA No. 209533, Defendants will intentionally encourage acts of direct infringement of the '944 patent by others, with knowledge that their acts are encouraging infringement.

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

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

46. If ANDA No. 209533 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Cipla's Generic Product.

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

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

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

49. Plaintiffs incorporate by reference and reallege Paragraphs 1-48 above as though fully restated herein.

50. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209533 to the FDA seeking approval of Cipla's Generic Product before expiration of the '520 patent was an act of infringement of the '520 patent by Defendants.

51. If ANDA No. 209533 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Cipla'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.

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

53. Plaintiffs incorporate by reference and reallege Paragraphs 1-52 above as though fully restated herein.

54. Defendants have knowledge of the '520 patent.

55. Upon FDA approval of ANDA No. 209533, Defendants will intentionally encourage acts of direct infringement of the '520 patent by others, with knowledge that their acts are encouraging infringement.

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

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

57. If ANDA No. 209533 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Cipla's Generic Product.

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

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

COUNT IV FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 9,180,194)

60. Plaintiffs incorporate by reference and reallege Paragraphs 1-59 above as though fully restated herein.

61. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209533 to the FDA seeking approval of Cipla's Generic Product before expiration of the '194 patent was an act of infringement of the '194 patent by Defendants.

62. If ANDA No. 209533 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Cipla's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '194 patent under 35 U.S.C. § 271.

63. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '194 patent. Plaintiffs do not have an adequate remedy at law.

COUNT V FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 9,180,194)

64. Plaintiffs incorporate by reference and reallege Paragraphs 1-63 above as though fully restated herein.

65. Defendants have knowledge of the '194 patent.

66. Upon FDA approval of ANDA No. 209533, Defendants will intentionally encourage acts of direct infringement of the '194 patent by others, with knowledge that their acts are encouraging infringement.

COUNT VI FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 9,180,194)

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

68. If ANDA No. 209533 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Cipla's Generic Product.

69. On information and belief, Defendants have had and continue to have knowledge that Cipla's Generic Product is especially adapted for a use that infringes the '194 patent.

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

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

71. Plaintiffs incorporate by reference and reallege Paragraphs 1-70 above as though fully restated herein.

72. 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).

73. Defendants submitted ANDA No. 209533, seeking authorization to commercially manufacture, use, offer for sale, and sell Cipla's Generic Product in the United States. Cipla's Generic Product has no substantial non-infringing uses.

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

75. 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 Cipla's Generic Product upon receipt of final FDA approval of ANDA No. 209533, unless enjoined by the Court.

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

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

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

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

80. 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 Cipla's Generic Product according to ANDA No. 209533 would infringe one or more claims of the '944 patent.

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

82. Plaintiffs incorporate by reference and reallege Paragraphs 1-81 above as though fully restated herein.

83. 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).

84. Defendants submitted ANDA No. 209533, seeking authorization to commercially manufacture, use, offer for sale, and sell Cipla's Generic Product in the United States. Cipla's Generic Product has no substantial non-infringing uses.

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

86. 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 Cipla's Generic Product upon receipt of final FDA approval of ANDA No. 209533, unless enjoined by the Court.

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

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

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

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

91. 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 Cipla's Generic Product according to ANDA No. 209533 would infringe one or more claims of the '520 patent.

92. 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.

COUNT IX FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 9,180,194)

93. Plaintiffs incorporate by reference and reallege Paragraphs 1-92 above as though fully restated herein.

94. 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).

95. Defendants submitted ANDA No. 209533, seeking authorization to commercially manufacture, use, offer for sale, and sell Cipla's Generic Product in the United States. Cipla's Generic Product has no substantial non-infringing uses.

96. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Cipla's Generic Product prior to expiration of the '194 patent.

97. 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 Cipla's Generic Product upon receipt of final FDA approval of ANDA No. 209533, unless enjoined by the Court.

98. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Cipla's Generic Product would infringe one or more claims of the '194 patent under 35 U.S.C. § 271(a), (b), and/or (c).

99. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Cipla's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '194 patent.

100. On information and belief, Defendants have had and continue to have knowledge that Cipla's Generic Product is especially adapted for a use that infringes the '194 patent.

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

102. 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 Cipla's Generic Product according to ANDA No. 209533 would infringe one or more claims of the '194 patent.

103. If Defendants' infringement of the '194 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; 8,993,520; and 9,180,194 are valid and enforceable;

b) Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed United States Patent Nos. 8,435,944; 8,993,520; and 9,180,194 by submitting ANDA No. 209533 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Cipla'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 Cipla's Generic Product prior to the expiration of United States Patent Nos. 8,435,944; 8,993,520; and 9,180,194 would constitute infringement of said patents;

d) The effective date of any FDA approval of Cipla's Generic Product shall be no earlier than the latest of the expiration date of United States Patent Nos. 8,435,944; 8,993,520; and 9,180,194 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 Cipla's Generic Product within the United States, or importing Cipla's Generic Product into the United States, until the expiration of United States Patent Nos. 8,435,944; 8,993,520; and 9,180,194 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.

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