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.** **APOTEX INC. AND APOTEX CORP.,** **Defendants.**	**Case No. 1:16-cv-1512**

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 Apotex Inc. and Apotex Corp. (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. Apotex Corp. is a Delaware corporation with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

5. On information and belief, Apotex Corp. 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. Apotex Inc. is a Canadian corporation with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

7. On information and belief, Apotex Inc. 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 Apotex Corp.

8. On information and belief, the acts of Apotex Inc. complained of herein were done with the cooperation, participation, and assistance of Apotex Corp. On information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc.

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"), 8,993,520 ("the '520 patent"), 9,180,194 ("the '194 patent"), and 9,289,586 ("the '586 patent"). This action relates to Abbreviated New Drug Application ("ANDA") No. 209181 submitted in the name of Apotex Inc. 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 and from 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. On information and belief, Apotex Inc. and Apotex Corp. share common officers and directors.

15. According to Defendants' website, "Apotex is a leader in the North American generic pharmaceutical market with #1 ranking in Canada in terms of prescriptions filled, sales volume and value, and a Top 10 position in the U.S.A.," adding that: "We are a vertically integrated company. Our preference is to develop, manufacture and market our own products—from API to finished dosage form to marketing and distribution." http://www.apotex.com/global/bd/namerica.asp.

16. Apotex Corp. is the United States marketing and sales affiliate for Apotex Inc. Defendants issued a press release on May 10, 2011, stating that: "Apotex Corp. is the US

Company [sic] that markets the products of Apotex, Inc. Through its sales and marketing headquarters in Weston, Florida and its operations center in Indianapolis, Apotex Corp. is committed to providing safe and affordable generic medicines."

http://www.apotex.com/global/about/press/20110510.asp.

17. According to Defendants' website, Apotex Corp.'s distribution facility in Indianapolis, Indiana, was awarded a "Verified Accredited Wholesale Distributors" accreditation by the "National Association Boards of Pharmacy."

http://www.apotex.com/us/en/vawd/default.asp. On information and belief, Apotex Corp. has at least one Indiana distribution facility at 2516 Airwest Blvd., Plainfield, IN 46168.

18. Apotex Corp. is a registered corporation in the State of Indiana. Apotex Corp. has been registered in Indiana as a "for-profit foreign corporation" since at least 2009. Apotex Corp. maintains a registered agent in the State of Indiana at 150 West Market Street, Suite 800, Indianapolis, IN 46204.

19. On information and belief, Apotex Corp., either directly or through distributors, currently sells significant quantities of generic drug products in the United States and in the State of Indiana. Those products include, for example, generic versions of Abilify®, Lipitor®, Zithromax®, Plavix®, Cymbalta®, Zyprexa® and Celebrex®. A list of generic products sold by Apotex can be found at

http://www.apotex.com/us/en/products/search.asp?qt=All&qs=&t=All%20Products.

20. Apotex Inc. and Apotex Corp. have availed themselves of this forum previously for the purpose of litigating a patent dispute. For example, Apotex Inc. and Apotex Corp. filed Counterclaims for Declaratory Judgment in at least three different cases in the United States District Court for the Southern District of Indiana. *Eli Lilly and Company, et al. v. Apotex Corp.*

& Apotex Inc., No. 1:14-cv-0586-SEB-TAB, D.I. 40 (S.D. Ind. June 9, 2014); *Eli Lilly and Company v. Apotex Inc. & Apotex Corp.*, No. 1:12-cv-0499-TWP-DKL, D.I. 22 (S.D. Ind. June 8, 2012) (consolidated with case no. 1:12-cv-00086, presently stayed, D.I. 81); *Alcon Manufacturing, Ltd., et al. v. Apotex Inc. & Apotex Corp*., No. 1:06-cv-01642-RLY-TAB, D.I. 21 (S.D. Ind. Dec. 13, 2006).

21. In the most recent of the above-cited matters, Defendants answered that: "Apotex Corp. is licensed as a Wholesale Drug Distributor in Indiana and that it provides pharmaceutical drug products some of which may be marketed and provided to residents of this State. . . . For purposes of this Action, Defendants Apotex Inc. and Apotex Corp. are not contesting personal jurisdiction in this District . . . ." *Eli Lilly and Company, et al. v. Apotex Corp. & Apotex Inc.*, No. 1:14-cv-0586-SEB-TAB, D.I. 40 at 5, 6 (S.D. Ind. June 9, 2014). In the matter that went to trial in the Southern District of Indiana, Apotex stated that: "Apotex admits that jurisdiction is proper in this district"; "Apotex Inc. has caused product that was to be sold throughout the United States to be shipped to a facility in Indianapolis, Indiana"; and "Apotex Corp. operates an operations and distribution center in Indianapolis through which it distributes Apotex Inc. products for sale throughout the United States." *Alcon Manufacturing, Ltd., et al. v. Apotex Inc. & Apotex Corp*., No. 1:06-cv-01642-RLY-TAB, D.I. 21 at 3 (S.D. Ind. Dec. 13, 2006).

22. Upon information and belief, the website of Apotex Corp. is http://www.apotexcorp.com, which redirects to the website of Apotex Inc. The website of Apotex Inc., http://www.apotex.com, is directed towards and accessible to residents of the United States, including Indiana and the Southern District of Indiana, and makes available a product catalog describing products made by Apotex Inc. and sold, through Apotex Corp., in the United States, including in Indiana and the Southern District of Indiana. Defendants have

admitted that: "[T]he website http://www.apotexcorp.com is registered to 'Apotex' at 150 Signet Drive, Toronto, Ontario, Canada. . . . Apotex admits that the visitors to the web address http://www.apotexcorp.com are redirected to the web page http:www.apotex.com. Apotex admits that the website http:www.apotex.com is accessible to residents of the United States." *Eli Lilly and Company v. Apotex Inc. & Apotex Corp.*, No. 1:12-cv-0499-TWP-DKL, D.I. 22 at 4-5 (S.D. Ind. June 8, 2012).

23. Apotex Inc. and Apotex Corp., either directly or through distributors, sell products to national and regional retail drug, supermarket, and mass merchandise chains in Indiana, and Apotex Inc. and Apotex Corp. derive substantial revenue from these sales.

24. Apotex Inc. and Apotex Corp. develop and manufacture pharmaceutical products for the United States market, including the State of Indiana.

25. Upon information and belief, Apotex Corp. acts as the agent and official submitter to the FDA of Apotex Inc.'s ANDA No. 209181 at issue in this case. Apotex Inc. participated in the preparation and submission of ANDA No. 209181 and will benefit directly and indirectly from the approval of ANDA No. 209181.

26. 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, as well as operations and/or distribution facilities within the state; and (3) their prior purposeful availment of this forum for the purpose of litigating patent disputes.

FACTUAL BACKGROUND

A. Axiron®

27. 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

28. United States Patent No. 8,419,307 ("the '307 patent"), titled "Spreading Implement," was duly and legally issued by the Patent and Trademark Office ("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

29. 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

30. 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 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

31. 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

32. 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. The '194 Patent

33. 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 by applying a transdermal composition to at least one axilla. 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 F*. 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.

H. The '586 Patent

34. United States Patent No. 9,289,586 ("the '586 patent"), titled "Spreading Implement," was duly and legally issued by the PTO on March 22, 2016. The '586 patent claims, *inter alia*, methods of transdermal administration of a physiologically active agent. The '586 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the '586 patent is attached as *Exhibit G*. Since its date of issue, Acrux has been, and continues to be, the owner of the '586 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the '586 patent. Eli Lilly Export S.A. has licensed its rights in the '586 patent to Lilly.

I. Infringement by Apotex Inc. and Apotex Corp.

35. Apotex Inc. and/or Apotex Corp. filed or caused to be filed with the FDA ANDA No. 209181 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of "Testosterone Topical Solution, 30mg/1.5mL" ("Apotex's Generic Product") in the United States before the expiration of the '307, '449, '944, '861, '520, '194, and '586 patents.

36. Defendants' ANDA No. 209181 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,'520, '194, and '586 patents are invalid, unenforceable, and/or would not be infringed by Apotex's Generic Product.

37. Apotex Inc. and/or Apotex Corp. sent or caused to be sent to Plaintiffs a letter dated May 12, 2016 ("Notice Letter"), notifying Plaintiffs that Apotex's ANDA No. 209181 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Apotex's Generic Product before the expiration of the '307, '944, '861, '520, '194, and '586 patents, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). The Notice Letter states: "Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), we advise you that the FDA has received an Abbreviated New Drug Application ('ANDA') from Apotex for testosterone topical solution 30 mg/1.5 ml actuation ('the Apotex Product'). The ANDA contains the required bioavailability and/or bioequivalence data and/or bioequivalence waiver. The ANDA was submitted under 21 U.S.C. §§ 355(j)(l) and (2)(A), and contains a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the Apotex Product, before the expiration of the '307, '944, . . . '861, '520, '194 and '586 patents, which are listed in the Patent and Exclusivity Information Addendum of the FDA's Orange Book."

38. Apotex's Notice Letter also states that: "Apotex Inc. . . . is providing Notice of the following information to you, as the holder of New Drug Application (NDA) number N022504 for AXIRON® (testosterone) solution, metered; transdermal, 30 mg/1.5 ml actuation, or as the patent owner and/or assignee thereof of the listed U.S. Patent Nos: 8,419,307 (''307 patent'), 8,435,944 (''944 patent'), . . . 8,807,861 (''861 patent'), 8,993,520 (''520 patent'), 9,180,194 (''194 patent'), and 9,289,586 (''586 patent') listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ('the FDA's Orange Book') associated with AXIRON®." Apotex Inc. provided its Detailed Statement accompanying the Notice Letter "through its agent Apotex Corp."

39. The submission of ANDA No. 209181 to the FDA constitutes infringement by Defendants of the '307, '449, '944, '861,'520, '194, and '586 patents under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Apotex's Generic Product would infringe the '307, '449, '944, '861, '520, '194, and '586 patents under 35 U.S.C. § 271(a), (b), and/or (c).

40. Defendants know and intend that physicians will prescribe and patients will take Apotex's Generic Product for which approval is sought in ANDA No. 209181 and therefore, will infringe at least one claim of the patents-in-suit.

41. 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.

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

43. Plaintiffs commenced this action within 45 days of receiving Apotex's May 12, 2016, Notice Letter.

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

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

45. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209181 to the FDA seeking approval of Apotex's Generic Product before expiration of the '307 patent was an act of infringement of the '307 patent by Defendants.

46. If ANDA No. 209181 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Apotex'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.

47. 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)

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

49. Defendants have knowledge of the '307 patent.

50. Upon FDA approval of ANDA No. 209181, 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)

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

52. If ANDA No. 209181 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Apotex's Generic Product.

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

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

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

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

56. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209181 to the FDA seeking approval of Apotex's Generic Product before expiration of the '449 patent was an act of infringement of the '449 patent by Defendants.

57. If ANDA No. 209181 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Apotex'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.

58. 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)

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

60. Defendants have knowledge of the '449 patent.

61. Upon FDA approval of ANDA No. 209181, 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)

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

63. If ANDA No. 209181 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Apotex's Generic Product.

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

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

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

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

67. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209181 to the FDA seeking approval of Apotex's Generic Product before expiration of the '944 patent was an act of infringement of the '944 patent by Defendants.

68. If ANDA No. 209181 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Apotex'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.

69. 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)

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

71. Defendants have knowledge of the '944 patent.

72. Upon FDA approval of ANDA No. 209181, 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)

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

74. If ANDA No. 209181 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Apotex's Generic Product.

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

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

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

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

78. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209181 to the FDA seeking approval of Apotex's Generic Product before expiration of the '861 patent was an act of infringement of the '861 patent by Defendants.

79. If ANDA No. 209181 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Apotex'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.

80. 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)

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

82. Defendants have knowledge of the '861 patent.

83. Upon FDA approval of ANDA No. 209181, 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)

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

85. If ANDA No. 209181 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Apotex's Generic Product.

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

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

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

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

89. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209181 to the FDA seeking approval of Apotex's Generic Product before expiration of the '520 patent was an act of infringement of the '520 patent by Defendants.

90. If ANDA No. 209181 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Apotex'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.

91. 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)

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

93. Defendants have knowledge of the '520 patent.

94. Upon FDA approval of ANDA No. 209181, 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)

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

96. If ANDA No. 209181 is approved, Defendants intends to and will offer to sell, sell, or import into the United States Apotex's Generic Product.

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

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

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

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

100. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209181 to the FDA seeking approval of Apotex's Generic Product before expiration of the '194 patent was an act of infringement of the '194 patent by Defendants.

101. If ANDA No. 209181 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Apotex'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.

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

103. Plaintiffs incorporate by reference and reallege Paragraphs 1-102 above as though fully restated herein.

104. Defendants have knowledge of the '194 patent.

105. Upon FDA approval of ANDA No. 209181, Defendants will intentionally encourage acts of direct infringement of the '194 patent by others, with knowledge that their acts are encouraging infringement.

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

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

107. If ANDA No. 209181 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Apotex's Generic Product.

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

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

COUNT XIX FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 9,289,586)

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

111. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209181 to the FDA seeking approval of Apotex's Generic Product before expiration of the '586 patent was an act of infringement of the '586 patent by Defendants.

112. If ANDA No. 209181 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Apotex's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '586 patent under 35 U.S.C. § 271.

113. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '586 patent. Plaintiffs do not have an adequate remedy at law.

COUNT XX FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 9,289,586)

114. Plaintiffs incorporate by reference and reallege Paragraphs 1-113 above as though fully restated herein.

115. Defendants have knowledge of the '586 patent.

116. Upon FDA approval of ANDA No. 209181, Defendants will intentionally encourage acts of direct infringement of the '586 patent by others, with knowledge that their acts are encouraging infringement.

COUNT XXI FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 9,289,586)

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

118. If ANDA No. 209181 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Apotex's Generic Product.

119. On information and belief, Defendants have had and continue to have knowledge that Apotex's Generic Product is especially adapted for a use that infringes the '586 patent.

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

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

121. Plaintiffs incorporate by reference and reallege Paragraphs 1-120 above as though fully restated herein.

122. 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).

123. Defendants submitted ANDA No. 209181, seeking authorization to commercially manufacture, use, offer for sale, and sell Apotex's Generic Product in the United States. Apotex's Generic Product has no substantial non-infringing uses.

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

125. 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 Apotex's Generic Product upon receipt of final FDA approval of ANDA No. 209181, unless enjoined by the Court.

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

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

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

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

130. 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 Apotex's Generic Product according to ANDA No. 209181 would infringe one or more claims of the '307 patent.

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

132. Plaintiffs incorporate by reference and reallege Paragraphs 1-131 above as though fully restated herein.

133. 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).

134. Defendants submitted ANDA No. 209181, seeking authorization to commercially manufacture, use, offer for sale, and sell Apotex's Generic Product in the United States. Apotex's Generic Product has no substantial non-infringing uses.

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

136. 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 Apotex's Generic Product upon receipt of final FDA approval of ANDA No. 209181, unless enjoined by the Court.

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

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

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

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

141. 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 Apotex's Generic Product according to ANDA No. 209181 would infringe one or more claims of the '449 patent.

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

143. Plaintiffs incorporate by reference and reallege Paragraphs 1-142 above as though fully restated herein.

144. 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).

145. Defendants submitted ANDA No. 209181, seeking authorization to commercially manufacture, use, offer for sale, and sell Apotex's Generic Product in the United States. Apotex's Generic Product has no substantial non-infringing uses.

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

147. 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 Apotex's Generic Product upon receipt of final FDA approval of ANDA No. 209181, unless enjoined by the Court.

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

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

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

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

152. 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 Apotex's Generic Product according to ANDA No. 209181 would infringe one or more claims of the '944 patent.

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

154. Plaintiffs incorporate by reference and reallege Paragraphs 1-153 above as though fully restated herein.

155. 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).

156. Defendants submitted ANDA No. 209181, seeking authorization to commercially manufacture, use, offer for sale, and sell Apotex's Generic Product in the United States. Apotex's Generic Product has no substantial non-infringing uses.

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

158. 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 Apotex's Generic Product upon receipt of final FDA approval of ANDA No. 209181, unless enjoined by the Court.

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

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

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

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

163. 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 Apotex's Generic Product according to ANDA No. 209181 would infringe one or more claims of the '861 patent.

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

165. Plaintiffs incorporate by reference and reallege Paragraphs 1-164 above as though fully restated herein.

166. 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).

167. Defendants submitted ANDA No. 209181, seeking authorization to commercially manufacture, use, offer for sale, and sell Apotex's Generic Product in the United States. Apotex's Generic Product has no substantial non-infringing uses.

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

169. 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 Apotex's Generic Product upon receipt of final FDA approval of ANDA No. 209181, unless enjoined by the Court.

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

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

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

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

174. 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 Apotex's Generic Product according to ANDA No. 209181 would infringe one or more claims of the '520 patent.

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

176. Plaintiffs incorporate by reference and reallege Paragraphs 1-175 above as though fully restated herein.

177. 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).

178. Defendants submitted ANDA No. 209181, seeking authorization to commercially manufacture, use, offer for sale, and sell Apotex's Generic Product in the United States. Apotex's Generic Product has no substantial non-infringing uses.

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

180. 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 Apotex's Generic Product upon receipt of final FDA approval of ANDA No. 209181, unless enjoined by the Court.

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

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

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

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

185. 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 Apotex's Generic Product according to ANDA No. 209181 would infringe one or more claims of the '194 patent.

186. 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.

COUNT XXVIII FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 9,289,586)

187. Plaintiffs incorporate by reference and reallege Paragraphs 1-186 above as though fully restated herein.

188. 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).

189. Defendants submitted ANDA No. 209181, seeking authorization to commercially manufacture, use, offer for sale, and sell Apotex's Generic Product in the United States. Apotex's Generic Product has no substantial non-infringing uses.

190. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Apotex's Generic Product prior to expiration of the '586 patent.

191. 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 Apotex's Generic Product upon receipt of final FDA approval of ANDA No. 209181, unless enjoined by the Court.

192. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Apotex's Generic Product would infringe one or more claims of the '586 patent under 35 U.S.C. § 271(a), (b), and/or (c).

193. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Apotex's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '586 patent.

194. On information and belief, Defendants have had and continue to have knowledge that Apotex's Generic Product is especially adapted for a use that infringes the '586 patent.

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

196. 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 Apotex's Generic Product according to ANDA No. 209181 would infringe one or more claims of the '586 patent.

197. If Defendants' infringement of the '586 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; 8,993,520; 9,180,194; and 9,289,586 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; 8,993,520; 9,180,194; and 9,289,586 by submitting ANDA No. 209181 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Apotex'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 Apotex's Generic Product prior to the expiration of United States Patent Nos. 8,419,307; 8,177,449; 8,435,944; 8,807,861; 8,993,520; 9,180,194; and 9,289,586 would constitute infringement of said patents;

d) The effective date of any FDA approval of Apotex'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; 8,993,520; 9,180,194; and 9,289,586 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 Apotex's Generic Product within the United States, or importing Apotex'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; 8,993,520; 9,180,194; and 9,289,586 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: June 20, 2016

/s/ Jan M. Carroll

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