IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC.	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and Sunovion Pharmaceuticals Inc. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, "Aurobindo"), allege as follows:

THE PARTIES

1. BIAL - PORTELA & CA S.A. is a Portuguese corporation having its principal place of business at Avenida da Siderurgia Nacional, Coronado (São Romão and São Mamede), 4745 455 Trofa, Portugal.

2. BIAL - HOLDING, S.A. is a Portuguese corporation having its principal place of business at Avenida da Siderurgia Nacional, Coronado (São Romão and São Mamede), 4745 365 Trofa, Portugal.

3. BIAL - PORTELA & CA S.A. and BIAL - HOLDING, S.A. (collectively, "Bial") are in the business of developing innovative therapies for epilepsy, partial-onset seizures, and other related neurological conditions. Bial's asserted patent(s) cover APTIOM®, which is

marketed and sold in this judicial district and throughout the United States by Sunovion Pharmaceuticals Inc. for treating partial-onset seizures in patients 4 years of age and older.

4. Sunovion Pharmaceuticals Inc. ("Sunovion") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

5. On information and belief, Aurobindo Pharma Limited is a corporation organized and existing under the laws of India, with its principal place of business at Galaxy, Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Ranga Reddy District, Hyderabad - 500032, Telangana, India.

6. On information and belief, Aurobindo Pharma Limited is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware.

7. On information and belief, Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520.

8. On information and belief, Aurobindo Pharma USA, Inc. is a wholly owned subsidiary of Aurobindo Pharma Limited.

9. On information and belief, Aurobindo Pharma USA, Inc. is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware, in concert with Aurobindo Pharma Limited.

10. On information and belief, the acts of Aurobindo Pharma Limited complained of herein were done with the cooperation, participation, and assistance of Aurobindo Pharma USA, Inc.

11. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg Abbreviated New Drug Application ("ANDA") No. 216481, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. will act in concert to distribute and sell the generic product described in Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg ANDA No. 216481 ("Aurobindo's Generic Product") throughout the United States, including the State of Delaware.

NATURE OF THE ACTION

12. This is a civil action for patent infringement of U.S. Patent Nos. 8,372,431 ("the '431 patent"), 9,206,135 ("the '135 patent"), 9,566,244 ("the '244 patent"), 9,643,929 ("the '929 patent"), 9,750,747 ("the '747 patent), 9,763,954 ("the '954 patent"), 10,675,287 ("the '287 patent"), 10,695,354 ("the '354 patent"), 10,702,536 ("the '536 patent"), and 10,912,781 ("the '781 patent") (collectively, "the patents-in-suit") arising under the United States Patent Laws, Title 35, United States Code, § 1, *et. seq.*, and in particular under 35 U.S.C. § 271. This action relates to ANDA No. 216481, which Aurobindo filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA"), for approval to market in the United States a generic copy of Plaintiffs' APTIOM® product prior to the expiration of the patents-in-suit.

13. Aurobindo has infringed one or more claims of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 216481 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aurobindo's Generic Product prior to the expiration of the patents-in-suit, or any extensions

thereof. Aurobindo will infringe one or more claims of the patents-in-suit under 35 U.S.C. § 271(a), (b), or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Aurobindo's Generic Product prior to the expiration of the patents-in-suit, or any extensions thereof.

JURISDICTION AND VENUE

14. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

15. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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

17. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because Aurobindo Pharma USA, Inc. is incorporated in the State of Delaware, and Aurobindo Pharma Limited is incorporated in India and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction.

18. This Court has personal jurisdiction over Aurobindo Pharma Limited, *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because Aurobindo Pharma Limited is organized under the laws of India.

19. This Court has personal jurisdiction over Aurobindo Pharma USA, Inc. because, *inter alia*, Aurobindo Pharma USA, Inc. is organized and existing under the laws of the State of Delaware.

20. Upon information and belief, Aurobindo Pharma USA, Inc. maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, Corporation Service Company, located at 251 Little Falls Dr., Wilmington, DE 19808.

21. This Court also has personal jurisdiction over Aurobindo because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Aurobindo satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4) "[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

22. This Court also has personal jurisdiction over Aurobindo because, *inter alia*, this action arises from activities of Aurobindo directed toward Delaware.

23. Upon information and belief, the effort to seek approval for ANDA No. 216481 and to manufacture, import, market, and/or sell Aurobindo's Generic Product upon approval has been a cooperative and joint enterprise and venture between Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc.

24. Upon information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing, and maintaining ANDA No. 216481 and in commercializing

Aurobindo's Generic Product in the United States, including in this judicial district, in accordance with ANDA No. 216481 upon approval.

25. Upon information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. have thus been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of ANDA No. 216481.

26. This Court has personal jurisdiction over Aurobindo by virtue of the fact that, *inter alia*, Aurobindo has committed—or aided, abetted, induced, contributed to, or participated in the commission of—the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs.

27. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of ANDA No. 216481, Aurobindo will market, distribute, and sell Aurobindo's Generic Product described in ANDA No. 216481 throughout the United States, including in Delaware.

28. This Court also has personal jurisdiction over Aurobindo Pharma USA, Inc. because, *inter alia*, Aurobindo Pharma USA, Inc. has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Aurobindo, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Aurobindo Pharma USA, Inc.'s website states that their mission is to "[a]dd value through superior customer service in the distribution of a broad line of generic pharmaceuticals . . . ." (https://www.aurobindousa.com/company/our-story/, accessed on Nov. 29, 2021). Aurobindo Pharma Limited's 2019-2021 annual report states that the company has "[f]iled 586 ANDAs with USFDA and received approval for 425 ANDAs, including 28 tentative[] approvals."

(https://www.aurobindo.com/wp-content/uploads/2020/08/Aurobindo-Pharma-Limited-Annual-Report-2019-20.pdf, at 6, last accessed on Nov. 29, 2021). Aurobindo claims the United States as one of their "core geographies" and the largest market for the company and reports to be "the second largest generic company by Rx dispensed" in the United States. (*Id.* at 11, 53). On information and belief, Aurobindo derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

29. This Court also has personal jurisdiction over Aurobindo because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Aurobindo has previously invoked this Court's jurisdiction by asserting counterclaims in at least 19 other cases. *See, e.g.*, C.A. Nos. 21-cv-1330, 21-cv-843, 21-cv-662, 21-cv-624, 21-cv-003, 20-cv-1589, 20-cv-1528, 20-cv-1426, 20-cv-1099, 20-cv-987, 20-cv-985, 20-cv-949, 20-cv-632, 19-cv-2317, 19-cv-2197, 19-cv-2113, 19-cv-1979, 19-cv-471, and 19-cv-103.

30. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Aurobindo.

FACTUAL BACKGROUND

The NDA

31. Sunovion is the holder of New Drug Application ("NDA") No. 022416 for APTIOM® (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms.

32. The FDA approved NDA No. 022416 on November 8, 2013, for use as adjunctive therapy of partial-onset seizures.

33. The FDA approved NDA No. 022416 on August 27, 2015, for use as monotherapy of partial-onset seizures.

34. The FDA approved NDA No. 022416 on September 13, 2017, for pediatric patients 4 years of age and older.

35. APTIOM® Tablets are prescription drugs approved for the treatment of partial-onset seizures in patients 4 years of age and older. Eslicarbazepine acetate is the active ingredient in the APTIOM® Tablets.

The Patents-in-Suit

36. The '431 patent, titled "Pharmaceutical composition comprising licarbazepine acetate" was duly and legally issued by the United States Patent and Trademark Office on February 12, 2013. A true and correct copy of the '431 patent is attached as Exhibit A.

37. BIAL - PORTELA & CA S.A. owns the rights to the '431 patent. Sunovion is the exclusive licensee in the United States of the '431 patent. The '431 patent will expire on April 17, 2030.

38. The '431 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

39. The '135 patent, titled "Asymmetric catalytic reduction of oxcarbazepine" was duly and legally issued by the United States Patent and Trademark Office on December 8, 2015. A true and correct copy of the '135 patent is attached as Exhibit B.

40. BIAL - PORTELA & CA S.A. owns the rights to the '135 patent. Sunovion is the exclusive licensee in the United States of the '135 patent. The '135 patent will expire on April 21, 2026.

41. The '135 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

42. The ’244 patent, titled “Pharmaceutical composition comprising licarbazepine acetate” was duly and legally issued by the United States Patent and Trademark Office on February 14, 2017. A true and correct copy of the ’244 patent is attached as Exhibit C.

43. BIAL - PORTELA & CA S.A. owns the rights to the ’244 patent. Sunovion is the exclusive licensee in the United States of the ’244 patent. The ’244 patent will expire on October 23, 2028.

44. The ’244 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

45. The ’929 patent, titled “Asymmetric catalytic reduction of oxcarbazepine” was duly and legally issued by the United States Patent and Trademark Office on May 9, 2017. A true and correct copy of the ’929 patent is attached as Exhibit D.

46. BIAL - PORTELA & CA S.A. owns the rights to the ’929 patent. Sunovion is the exclusive licensee in the United States of the ’929 patent. The ’929 patent will expire on April 21, 2026.

47. The ’929 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

48. The ’747 patent, titled “Treatments involving eslicarbazepine acetate or eslicarbazepine” was duly and legally issued by the United States Patent and Trademark Office on September 5, 2017. A true and correct copy of the ’747 patent is attached as Exhibit E.

49. BIAL - PORTELA & CA S.A. owns the rights to the ’747 patent. Sunovion is the exclusive licensee in the United States of the ’747 patent. The ’747 patent will expire on August 24, 2032.

50. The ’747 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

51. The ’954 patent, titled “Therapeutical uses of eslicarbazepine” was duly and legally issued by the United States Patent and Trademark Office on September 19, 2017. A true and correct copy of the ’954 patent is attached as Exhibit F.

52. BIAL - PORTELA & CA S.A. owns the rights to the ’954 patent. Sunovion is the exclusive licensee in the United States of the ’954 patent. The ’954 patent will expire on September 13, 2028.

53. The ’954 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

54. The ’287 patent, titled “Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate” was duly and legally issued by the United States Patent and Trademark Office on June 9, 2020. A true and correct copy of the ’287 patent is attached as Exhibit G.

55. BIAL - PORTELA & CA S.A. owns the rights to the ’287 patent. Sunovion is the exclusive licensee in the United States of the ’287 patent. The ’287 patent will expire on May 6, 2025.

56. The ’287 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

57. The prescribing information for APTIOM®, instructs physicians to administer APTIOM® Tablets once-daily for the treatment of partial-onset seizures in patients 4 years of age and older in a dosage of about 1200 mg of eslicarbazepine acetate.

58. Thus, the once-daily use of APTIOM® (Eslicarbazepine Acetate) Tablets in a dosage of about 1200 mg and any generic eslicarbazepine acetate tablets in a dosage of about

1200 mg for the treatment of patients with partial-onset seizures is covered by the '287 patent, and Plaintiffs have the right to enforce the '287 patent.

59. The '354 patent, titled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate" was duly and legally issued by the United States Patent and Trademark Office on June 30, 2020. A true and correct copy of the '354 patent is attached as Exhibit H.

60. BIAL - PORTELA & CA S.A. owns the rights to the '354 patent. Sunovion is the exclusive licensee in the United States of the '354 patent. The '354 patent will expire on May 6, 2025.

61. The '354 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

62. The prescribing information for APTIOM®, instructs physicians to administer APTIOM® Tablets once-daily for the treatment of partial-onset seizures in patients 4 years of age and older.

63. Thus, the once-daily use of APTIOM® (Eslicarbazepine Acetate) Tablets and any generic eslicarbazepine acetate tablets for the treatment of patients with partial-onset seizures is covered by the '354 patent, and Plaintiffs have the right to enforce the '354 patent.

64. The '536 patent, titled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate" was duly and legally issued by the United States Patent and Trademark Office on July 7, 2020. A true and correct copy of the '536 patent is attached as Exhibit I.

65. BIAL - PORTELA & CA S.A. owns the rights to the '536 patent. Sunovion is the exclusive licensee in the United States of the '536 patent. The '536 patent will expire on May 6, 2025.

66. The ’536 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

67. The prescribing information for APTIOM®, instructs physicians to administer APTIOM® Tablets once-daily for the treatment of partial-onset seizures in patients 4 years of age and older.

68. Thus, the once-daily use of APTIOM® (Eslicarbazepine Acetate) Tablets and any generic eslicarbazepine acetate tablets for the treatment of patients with partial-onset seizures is covered by the ’536 patent, and Plaintiffs have the right to enforce the ’536 patent.

69. The ’781 patent, titled “Pharmaceutical Composition Comprising Licarbazepine Acetate,” was duly and legally issued by the United States Patent and Trademark Office on February 9, 2021. A true and correct copy of the ’781 patent is attached as Exhibit J.

70. BIAL - PORTELA & CA S.A. owns the rights to the ’781 patent. Sunovion is the exclusive licensee in the United States of the ’781 patent. The ’781 patent will expire on October 23, 2028.

71. The ’781 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

The ANDA

72. On information and belief, Aurobindo filed ANDA No. 216481 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms, which are generic versions of Plaintiffs’ APTIOM® (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms.

73. ANDA No. 216481 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or would not be infringed by Aurobindo's Generic Product.

74. Sunovion and Bial received a letter sent by Aurobindo, dated October 20, 2021, purporting to be a "Notification of Paragraph IV Certification" for ANDA No. 216481 ("Aurobindo's Notice Letter") pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Aurobindo's Notice Letter notified Bial that Aurobindo had filed ANDA No. 216481, seeking approval to market Aurobindo's Generic Product prior to the expiration of the patents-in-suit.

75. Plaintiffs commenced this action within 45 days of receiving Aurobindo's October 20, 2021 Notice Letter.

76. On information and belief, following FDA approval of Aurobindo's ANDA No. 216481, Aurobindo will make, use, sell, or offer to sell Aurobindo's Generic Product throughout the United States, or import such generic products into the United States before the patents-in-suit expire.

COUNT I

(INFRINGEMENT OF THE '431 PATENT UNDER 35 U.S.C. § 271(e)(2))

77. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

78. On information and belief, Aurobindo filed ANDA No. 216481 in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's Generic Product in the United States before the expiration of the '431 patent.

79. On information and belief, Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '431 patent are purportedly invalid, unenforceable, and/or not infringed.

80. On information and belief, in its ANDA No. 216481, Aurobindo has represented to the FDA that Aurobindo's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

81. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 216481 seeking approval for the commercial manufacture, use, or sale of Aurobindo's Generic Product before the expiration date of the '431 patent, constitutes infringement, either literally or under the doctrine of equivalents.

82. After FDA approval of ANDA No. 216481, Aurobindo will infringe one or more claims of the '431 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 216481 shall be no earlier than the expiration of the '431 patent and any additional periods of exclusivity.

83. On information and belief, if ANDA No. 216481 is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's Generic Product.

84. Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially adapted for a use that infringes the '431 patent.

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

86. On information and belief, Aurobindo's actions relating to Aurobindo's ANDA No. 216481 complained of herein were done by and for the benefit of Aurobindo.

87. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing infringement of at least one claim of the '431 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT II

(INFRINGEMENT OF THE '135 PATENT UNDER 35 U.S.C. § 271(e)(2))

88. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

89. On information and belief, Aurobindo filed ANDA No. 216481 in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's Generic Product in the United States before the expiration of the '135 patent.

90. On information and belief, Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '135 patent are purportedly invalid, unenforceable, and/or not infringed.

91. On information and belief, in its ANDA No. 216481, Aurobindo has represented to the FDA that Aurobindo's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

92. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 216481 seeking approval for the commercial manufacture, use, or sale of Aurobindo's Generic Product before the expiration date of the '135 patent, constitutes infringement, either literally or under the doctrine of equivalents.

93. After FDA approval of ANDA No. 216481, Aurobindo will infringe one or more claims of the '135 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 216481 shall be no earlier than the expiration of the '135 patent and any additional periods of exclusivity.

94. On information and belief, Aurobindo knows, or should know, and intends that physicians will prescribe and patients will take Alkem's Generic Product for which approval is sought in ANDA No. 216481, and therefore will infringe at least one claim in the '135 patent.

95. On information and belief, Aurobindo had knowledge of the '135 patent and, by its promotional activities and proposed package insert for Aurobindo's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '135 patent, either literally or under the doctrine of equivalents.

96. On information and belief, Aurobindo is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '135 patent.

97. The offering to sell, sale, making, and/or importation of Aurobindo's Generic Product would actively induce infringement of at least one of the claims of the '135 patent, either literally or under the doctrine of equivalents. Aurobindo has knowledge and is aware of Plaintiffs' '135 patent, as evidenced by Aurobindo's October 20, 2021 Notice Letter.

98. On information and belief, if ANDA No. 216481 is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's Generic Product.

99. Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially adapted for a use that infringes the '135 patent.

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

101. On information and belief, Aurobindo's actions relating to Aurobindo's ANDA No. 216481 complained of herein were done by and for the benefit of Aurobindo.

102. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing infringement of at least one claim of the '135 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT III

(INFRINGEMENT OF THE '244 PATENT UNDER 35 U.S.C. § 271(e)(2))

103. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

104. On information and belief, Aurobindo filed ANDA No. 216481 in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's Generic Product in the United States before the expiration of the '244 patent.

105. On information and belief, Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '244 patent are purportedly invalid, unenforceable, and/or not infringed.

106. On information and belief, in its ANDA No. 216481, Aurobindo has represented to the FDA that Aurobindo's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

107. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 216481 seeking approval for the commercial manufacture, use, or sale of Aurobindo's Generic Product before the expiration date of the '244 patent, constitutes infringement, either literally or under the doctrine of equivalents.

108. After FDA approval of ANDA No. 216481, Aurobindo will infringe one or more claims of the '244 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 216481 shall be no earlier than the expiration of the '244 patent and any additional periods of exclusivity.

109. On information and belief, if ANDA No. 216481 is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's Generic Product.

110. Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially adapted for a use that infringes the '244 patent.

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

112. On information and belief, Aurobindo's actions relating to Aurobindo's ANDA No. 216481 complained of herein were done by and for the benefit of Aurobindo.

113. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing infringement of at least one claim of the '244 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT IV

(INFRINGEMENT OF THE '929 PATENT UNDER 35 U.S.C. § 271(e)(2))

114. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

115. On information and belief, Aurobindo filed ANDA No. 216481 in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's Generic Product in the United States before the expiration of the '929 patent.

116. On information and belief, Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '929 patent are purportedly invalid, unenforceable, and/or not infringed.

117. On information and belief, in its ANDA No. 216481, Aurobindo has represented to the FDA that Aurobindo's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

118. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 216481 seeking approval for the commercial manufacture, use, or sale of Aurobindo's Generic Product before the expiration date of the '929 patent, constitutes infringement, either literally or under the doctrine of equivalents.

119. After FDA approval of ANDA No. 216481, Aurobindo will infringe one or more claims of the '929 patent, either literally or under the doctrine of equivalents under § 271(a) by

making, using, offering to sell, selling, and/or importing Aurobindo's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 216481 shall be no earlier than the expiration of the '929 patent and any additional periods of exclusivity.

120. On information and belief, if ANDA No. 216481 is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's Generic Product.

121. Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially adapted for a use that infringes the '929 patent.

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

123. On information and belief, Aurobindo's actions relating to Aurobindo's ANDA No. 216481 complained of herein were done by and for the benefit of Aurobindo.

124. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing infringement of at least one claim of the '929 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT V

(INFRINGEMENT OF THE '747 PATENT UNDER 35 U.S.C. § 271(e)(2))

125. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

126. On information and belief, Aurobindo filed ANDA No. 216481 in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's Generic Product in the United States before the expiration of the '747 patent.

127. On information and belief, Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '747 patent are purportedly invalid, unenforceable, and/or not infringed.

128. On information and belief, in its ANDA No. 216481, Aurobindo has represented to the FDA that Aurobindo's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

129. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 216481 seeking approval for the commercial manufacture, use, or sale of Aurobindo's Generic Product before the expiration date of the '747 patent, constitutes infringement, either literally or under the doctrine of equivalents.

130. After FDA approval of ANDA No. 216481, Aurobindo will infringe one or more claims of the '747 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 216481 shall be no earlier than the expiration of the '747 patent and any additional periods of exclusivity.

131. On information and belief, Aurobindo knows, or should know, and intends that physicians will prescribe and patients will take Alkem's Generic Product for which approval is sought in ANDA No. 216481, and therefore will infringe at least one claim in the '747 patent.

132. On information and belief, Aurobindo had knowledge of the '747 patent and, by its promotional activities and proposed package insert for Aurobindo's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '747 patent, either literally or under the doctrine of equivalents.

133. On information and belief, Aurobindo is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '747 patent.

134. The offering to sell, sale, making, and/or importation of Aurobindo's Generic Product would actively induce infringement of at least one of the claims of the '747 patent, either literally or under the doctrine of equivalents. Aurobindo has knowledge and is aware of Plaintiffs' '747 patent, as evidenced by Aurobindo's October 20, 2021 Notice Letter.

135. On information and belief, if ANDA No. 216481 is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's Generic Product.

136. Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially adapted for a use that infringes the '747 patent.

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

138. On information and belief, Aurobindo's actions relating to Aurobindo's ANDA No. 216481 complained of herein were done by and for the benefit of Aurobindo.

139. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing infringement of at least one claim of the '747 patent. Pursuant to 35 U.S.C.

§ 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT VI

(INFRINGEMENT OF THE '954 PATENT UNDER 35 U.S.C. § 271(e)(2))

140. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

141. On information and belief, Aurobindo filed ANDA No. 216481 in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's Generic Product in the United States before the expiration of the '954 patent.

142. On information and belief, Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '954 patent are purportedly invalid, unenforceable, and/or not infringed.

143. On information and belief, in its ANDA No. 216481, Aurobindo has represented to the FDA that Aurobindo's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

144. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 216481 seeking approval for the commercial manufacture, use, or sale of Aurobindo's Generic Product before the expiration date of the '954 patent, constitutes infringement, either literally or under the doctrine of equivalents.

145. After FDA approval of ANDA No. 216481, Aurobindo will infringe one or more claims of the '954 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement

under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 216481 shall be no earlier than the expiration of the '954 patent and any additional periods of exclusivity.

146. On information and belief, Aurobindo knows, or should know, and intends that physicians will prescribe and patients will take Alkem's Generic Product for which approval is sought in ANDA No. 216481, and therefore will infringe at least one claim in the '954 patent.

147. On information and belief, Aurobindo had knowledge of the '954 patent and, by its promotional activities and proposed package insert for Aurobindo's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '954 patent, either literally or under the doctrine of equivalents.

148. On information and belief, Aurobindo is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '954 patent.

149. The offering to sell, sale, making, and/or importation of Aurobindo's Generic Product would actively induce infringement of at least one of the claims of the '954 patent, either literally or under the doctrine of equivalents. Aurobindo has knowledge and is aware of Plaintiffs' '954 patent, as evidenced by Aurobindo's October 20, 2021 Notice Letter.

150. On information and belief, if ANDA No. 216481 is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's Generic Product.

151. Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially adapted for a use that infringes the '954 patent.

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

153. On information and belief, Aurobindo's actions relating to Aurobindo's ANDA No. 216481 complained of herein were done by and for the benefit of Aurobindo.

154. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing infringement of at least one claim of the '954 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT VII

(INFRINGEMENT OF THE '287 PATENT UNDER 35 U.S.C. § 271(e)(2))

155. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

156. On information and belief, Aurobindo filed ANDA No. 216481 in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's Generic Product in the United States before the expiration of the '287 patent.

157. On information and belief, Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '287 patent are purportedly invalid, unenforceable, and/or not infringed.

158. On information and belief, in its ANDA No. 216481, Aurobindo has represented to the FDA that Aurobindo's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

159. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 216481 seeking approval for the commercial manufacture, use, or sale of Aurobindo's

Generic Product before the expiration date of the '287 patent, constitutes infringement, either literally or under the doctrine of equivalents.

160. After FDA approval of ANDA No. 216481, Aurobindo will infringe one or more claims of the '287 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 216481 shall be no earlier than the expiration of the '287 patent and any additional periods of exclusivity.

161. On information and belief, Aurobindo knows, or should know, and intends that physicians will prescribe and patients will take Alkem's Generic Product for which approval is sought in ANDA No. 216481, and therefore will infringe at least one claim in the '287 patent.

162. On information and belief, Aurobindo had knowledge of the '287 patent and, by its promotional activities and proposed package insert for Aurobindo's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '287 patent, either literally or under the doctrine of equivalents.

163. On information and belief, Aurobindo is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '287 patent.

164. The offering to sell, sale, making, and/or importation of Aurobindo's Generic Product would actively induce infringement of at least one of the claims of the '287 patent, either

literally or under the doctrine of equivalents. Aurobindo has knowledge and is aware of Plaintiffs' '287 patent, as evidenced by Aurobindo's October 20, 2021 Notice Letter.

165. On information and belief, if ANDA No. 216481 is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's Generic Product.

166. Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially adapted for a use that infringes the '287 patent.

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

168. On information and belief, Aurobindo's actions relating to Aurobindo's ANDA No. 216481 complained of herein were done by and for the benefit of Aurobindo.

169. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing infringement of at least one claim of the '287 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT VIII

(INFRINGEMENT OF THE '354 PATENT UNDER 35 U.S.C. § 271(e)(2))

170. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

171. On information and belief, Aurobindo filed ANDA No. 216481 in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's Generic Product in the United States before the expiration of the '354 patent.

172. On information and belief, Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '354 patent are purportedly invalid, unenforceable, and/or not infringed.

173. On information and belief, in its ANDA No. 216481, Aurobindo has represented to the FDA that Aurobindo's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

174. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 216481 seeking approval for the commercial manufacture, use, or sale of Aurobindo's Generic Product before the expiration date of the '354 patent, constitutes infringement, either literally or under the doctrine of equivalents.

175. After FDA approval of ANDA No. 216481, Aurobindo will infringe one or more claims of the '354 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 216481 shall be no earlier than the expiration of the '354 patent and any additional periods of exclusivity.

176. On information and belief, Aurobindo knows, or should know, and intends that physicians will prescribe and patients will take Alkem's Generic Product for which approval is sought in ANDA No. 216481, and therefore will infringe at least one claim in the '354 patent.

177. On information and belief, Aurobindo had knowledge of the '354 patent and, by its promotional activities and proposed package insert for Aurobindo's Generic Product, knows

or should know that it will induce direct infringement of at least one of the claims of the '354 patent, either literally or under the doctrine of equivalents.

178. On information and belief, Aurobindo is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '354 patent.

179. The offering to sell, sale, making, and/or importation of Aurobindo's Generic Product would actively induce infringement of at least one of the claims of the '354 patent, either literally or under the doctrine of equivalents. Aurobindo has knowledge and is aware of Plaintiffs' '354 patent, as evidenced by Aurobindo's October 20, 2021 Notice Letter.

180. On information and belief, if ANDA No. 216481 is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's Generic Product.

181. Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially adapted for a use that infringes the '354 patent.

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

183. On information and belief, Aurobindo's actions relating to Aurobindo's ANDA No. 216481 complained of herein were done by and for the benefit of Aurobindo.

184. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing infringement of at least one claim of the '354 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT IX

(INFRINGEMENT OF THE '536 PATENT UNDER 35 U.S.C. § 271(e)(2))

185. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

186. On information and belief, Aurobindo filed ANDA No. 216481 in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's Generic Product in the United States before the expiration of the '536 patent.

187. On information and belief, Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '536 patent are purportedly invalid, unenforceable, and/or not infringed.

188. On information and belief, in its ANDA No. 216481, Aurobindo has represented to the FDA that Aurobindo's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

189. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 216481 seeking approval for the commercial manufacture, use, or sale of Aurobindo's Generic Product before the expiration date of the '536 patent, constitutes infringement, either literally or under the doctrine of equivalents.

190. After FDA approval of ANDA No. 216481, Aurobindo will infringe one or more claims of the '536 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA

No. 216481 shall be no earlier than the expiration of the '536 patent and any additional periods of exclusivity.

191. On information and belief, Aurobindo knows, or should know, and intends that physicians will prescribe and patients will take Alkem's Generic Product for which approval is sought in ANDA No. 216481, and therefore will infringe at least one claim in the '536 patent.

192. On information and belief, Aurobindo had knowledge of the '536 patent and, by its promotional activities and proposed package insert for Aurobindo's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '536 patent, either literally or under the doctrine of equivalents.

193. On information and belief, Aurobindo is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Aurobindo's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '536 patent.

194. The offering to sell, sale, making, and/or importation of Aurobindo's Generic Product would actively induce infringement of at least one of the claims of the '536 patent, either literally or under the doctrine of equivalents. Aurobindo has knowledge and is aware of Plaintiffs' '536 patent, as evidenced by Aurobindo's October 20, 2021 Notice Letter.

195. On information and belief, if ANDA No. 216481 is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's Generic Product.

196. Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially adapted for a use that infringes the '536 patent.

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

198. On information and belief, Aurobindo's actions relating to Aurobindo's ANDA No. 216481 complained of herein were done by and for the benefit of Aurobindo.

199. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing infringement of at least one claim of the '536 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT X

(INFRINGEMENT OF THE '781 PATENT UNDER 35 U.S.C. § 271(e)(2))

200. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

201. On information and belief, Aurobindo filed ANDA No. 216481 in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's Generic Product in the United States before the expiration of the '781 patent.

202. On information and belief, Aurobindo filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '781 patent are purportedly invalid, unenforceable, and/or not infringed.

203. On information and belief, in its ANDA No. 216481, Aurobindo has represented to the FDA that Aurobindo's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

204. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 216481 seeking approval for the commercial manufacture, use, or sale of Aurobindo's Generic Product before the expiration date of the '781 patent, constitutes infringement, either literally or under the doctrine of equivalents.

205. After FDA approval of ANDA No. 216481, Aurobindo will infringe one or more claims of the '781 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 216481 shall be no earlier than the expiration of the '781 patent and any additional periods of exclusivity.

206. On information and belief, if ANDA No. 216481 is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's Generic Product.

207. Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially adapted for a use that infringes the '781 patent.

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

209. On information and belief, Aurobindo's actions relating to Aurobindo's ANDA No. 216481 complained of herein were done by and for the benefit of Aurobindo.

210. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing infringement of at least one claim of the '781 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the patents-in-suit through Aurobindo's submission of ANDA

No. 216481 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's Generic Product in the United States before the expiration of the patents-in-suit;

B. The entry of judgment under 35 U.S.C. § 271(a), (b), and/or (c) that Aurobindo's making, using, offering to sell, selling, or importing Aurobindo's Generic Product prior to the expiration of the patents-in-suit will infringe, actively induce infringement, and/or contribute to the infringement of the patents-in-suit under 35 U.S.C. § 271(a), (b), and/or (c);

C. The issuance of an order that the effective date of any FDA approval of Aurobindo's Generic Product shall be no earlier than the expiration date of the patents-in-suit and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Aurobindo and all persons acting in concert with Aurobindo from commercially manufacturing, using, offering for sale, or selling Aurobindo's Generic Product within the United States, or importing Aurobindo's Generic Product into the United States, until the expiration of the patents-in-suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Aurobindo and all persons acting in concert with Aurobindo from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the patents-in-suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

G. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

ASHBY & GEDDES

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