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.	)	
ALKEM LABORATORIES LIMITED and S&B PHARMA, 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 Alkem Laboratories Limited ("Alkem Laboratories") and S&B Pharma, Inc. ("S&B Pharma") (collectively, "Alkem"), 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 e 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 e 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, Alkem Laboratories is a corporation organized and existing under the laws of India, with its principal place of business at Alkem House, Senapati Bapat Marg, Lower Parel, Mumbai MH 400013 India.

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

7. On information and belief, S&B Pharma is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1733 Gilsinn Lane, Fenton, Missouri 63026-2000.

8. On information and belief, S&B Pharma is a subsidiary of Alkem Laboratories.

9. On information and belief, S&B Pharma 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 Alkem Laboratories.

10. On information and belief, the acts of Alkem Laboratories complained of herein were done with the cooperation, participation, and assistance of S&B Pharma.

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. 211199, Alkem will act in concert to distribute and sell the generic product described in Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg ANDA No. 211199 ("Alkem'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), and 9,763,954 ("the '954 patent) (collectively, "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. 211199, which Alkem 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.

JURISDICTION AND VENUE

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

14. 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.

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

16. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because S&B Pharma is incorporated in the State of Delaware, and Alkem Laboratories 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.

17. This Court has personal jurisdiction over Alkem Laboratories *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because Alkem Laboratories is organized under the laws

of India.

18. This Court has personal jurisdiction over S&B Pharma because, *inter alia*, S&B Pharma is organized and existing under the laws of the State of Delaware.

19. Upon information and belief, S&B Pharma maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, The Corporation Trust Company, located at Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

20. This Court also has personal jurisdiction over Alkem because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Alkem 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").

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

22. Upon information and belief, the effort to seek approval for ANDA No. 211199 and to manufacture, import, market, and/or sell Alkem's Generic Product upon approval has been a cooperative and joint enterprise and venture between Alkem Laboratories and S&B Pharma.

23. Upon information and belief, Alkem Laboratories and S&B Pharma have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing and maintaining ANDA No. 211199 and in commercializing Alkem's Generic Product in the United States, including in this judicial district, in accordance with ANDA 211199 upon approval.

24. Upon information and belief, Alkem Laboratories and S&B Pharma have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 211199.

25. This Court has personal jurisdiction over Alkem by virtue of the fact that, *inter alia*, it 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.

26. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of ANDA No. 211199, Alkem will market, distribute, and sell Alkem's Generic Product described in ANDA No. 211199 throughout the United States, including in Delaware.

27. This Court also has personal jurisdiction over S&B Pharma because, *inter alia*, S&B Pharma 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, S&B Pharma, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Alkem's website, https://www.alkemlabs.com/admin/Photos/subsidiary-accounts/S&B_Pharma_Inc._FS_FY16-17.pdf (accessed February 15, 2018), the contents of which are incorporated herein by reference, states that "Alkem - India's principal business objective in the formation of S&B Pharma is to manufacture, formulate and package generic prescription pharmaceutical products for distribution in the United States (U.S.)." On information and belief, S&B Pharma 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.

28. This Court also has personal jurisdiction over Alkem because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Alkem has previously invoked this Court's jurisdiction by asserting counterclaims in at least 4 cases. *See, e.g.*, 1-16-cv-00747, 1-14-cv-00917, 1-13-cv-01110, and 1-12-cv-01663.

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

FACTUAL BACKGROUND

The NDA

30. 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.

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

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

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

34. 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

35. United States Patent No. 8,372,431 ("the '431 patent"), entitled "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.

36. 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.

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

38. United States Patent No. 9,206,135 (“the ’135 patent”), entitled “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.

39. 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.

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

41. United States Patent No. 9,566,244 (“the ’244 patent”), entitled “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.

42. 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.

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

44. United States Patent No. 9,643,929 (“the ’929 patent”), entitled “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.

45. 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.

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

47. United States Patent No. 9,750,747 ("the '747 patent"), entitled "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.

48. 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.

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

50. United States Patent No. 9,763,954 ("the '954 patent"), entitled "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.

51. 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.

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

The ANDA

53. On information and belief, Alkem filed ANDA No. 211199 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 Bial's Aptiom® (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms.

54. ANDA No. 211199 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 Alkem's Generic Product.

55. On January 9, 2018 and January 10, 2018, Sunovion and Bial, respectively, received a letter sent by Alkem, dated January 8, 2018, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 211199 ("Alkem'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. Alkem's Notice Letter notified Bial that Alkem had filed ANDA No. 211199, seeking approval to market Alkem's Generic Product prior to the expiration of the patents-in-suit.

56. Plaintiffs commenced this action within 45 days of receiving Alkem's January 8, 2018 Notice Letter.

COUNT I

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

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

58. On information and belief, Alkem filed ANDA No. 211199 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Alkem's Generic Product in the United States before the expiration of the '431 patent.

59. On information and belief, Alkem 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.

60. On information and belief, in its ANDA No. 211199, Alkem has represented to the FDA that Alkem's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

61. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211199 seeking approval for the commercial manufacture, use, or sale of Alkem's Generic Product before the expiration date of the '431 patent, constitutes infringement, either literally or under the doctrine of equivalents.

62. Upon FDA approval of ANDA No. 211199, Alkem 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 Alkem's Generic Product, and/or 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. 211199 shall be no earlier than the expiration of the '431 patent and any additional periods of exclusivity.

63. On information and belief, if ANDA No. 211199 is approved, Alkem intends to and will offer to sell, sell, and/or import in the United States Alkem's Generic Product.

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

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

66. On information and belief, Alkem's actions relating to Alkem's ANDA No. 211199 complained of herein were done by and for the benefit of Alkem.

67. Plaintiffs will be irreparably harmed if Alkem is not enjoined from infringing and/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))

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

69. On information and belief, Alkem filed ANDA No. 211199 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Alkem's Generic Product in the United States before the expiration of the '135 patent.

70. On information and belief, Alkem 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.

71. On information and belief, in its ANDA No. 211199, Alkem has represented to the FDA that Alkem's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

72. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211199 seeking approval for the commercial manufacture, use, or sale of Alkem's Generic Product before the expiration date of the '135 patent, constitutes infringement, either literally or under the doctrine of equivalents.

73. Upon FDA approval of ANDA No. 211199, Alkem 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 Alkem'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. 211199 shall be no earlier than the expiration of the '135 patent and any additional periods of exclusivity.

74. On information and belief, Alkem 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. 211199, and therefore will infringe at least one claim in the '135 patent.

75. On information and belief, Alkem had knowledge of the '135 patent and, by its promotional activities and proposed package insert for Alkem'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.

76. On information and belief, Alkem 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 Alkem's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '135 patent.

77. The offering to sell, sale, making, and/or importation of Alkem'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. Alkem has knowledge and is aware of Plaintiffs' '135 patent, as evidenced by Alkem's January 8, 2018 Notice Letter.

78. On information and belief, if ANDA No. 211199 is approved, Alkem intends to and will offer to sell, sell, and/or import in the United States Alkem's Generic Product.

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

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

81. On information and belief, Alkem's actions relating to Alkem's ANDA No. 211199 complained of herein were done by and for the benefit of Alkem.

82. Plaintiffs will be irreparably harmed if Alkem 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))

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

84. On information and belief, Alkem filed ANDA No. 211199 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Alkem's Generic Product in the United States before the expiration of the '244 patent.

85. On information and belief, Alkem 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.

86. On information and belief, in its ANDA No. 211199, Alkem has represented to the FDA that Alkem's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

87. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211199 seeking approval for the commercial manufacture, use, or sale of Alkem's Generic Product before the expiration date of the '244 patent, constitutes infringement, either literally or under the doctrine of equivalents.

88. Upon FDA approval of ANDA No. 211199, Alkem 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 Alkem's Generic Product, and/or 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. 211199 shall be no earlier than the expiration of the '244 patent and any additional periods of exclusivity.

89. On information and belief, if ANDA No. 211199 is approved, Alkem intends to and will offer to sell, sell, and/or import in the United States Alkem's Generic Product.

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

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

92. On information and belief, Alkem's actions relating to Alkem's ANDA No. 211199 complained of herein were done by and for the benefit of Alkem.

93. Plaintiffs will be irreparably harmed if Alkem is not enjoined from infringing and/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))

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

95. On information and belief, Alkem filed ANDA No. 211199 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Alkem's Generic Product in the United States before the expiration of the '929 patent.

96. On information and belief, Alkem 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.

97. On information and belief, in its ANDA No. 211199, Alkem has represented to the FDA that Alkem's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

98. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211199 seeking approval for the commercial manufacture, use, or sale of Alkem's Generic Product before the expiration date of the '929 patent, constitutes infringement, either literally or under the doctrine of equivalents.

99. Upon FDA approval of ANDA No. 211199, Alkem 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 Alkem's Generic Product, and/or 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. 211199 shall be no earlier than the expiration of the '929 patent and any additional periods of exclusivity.

100. On information and belief, if ANDA No. 211199 is approved, Alkem intends to and will offer to sell, sell, and/or import in the United States Alkem's Generic Product.

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

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

103. On information and belief, Alkem's actions relating to Alkem's ANDA No. 211199 complained of herein were done by and for the benefit of Alkem.

104. Plaintiffs will be irreparably harmed if Alkem is not enjoined from infringing and/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))

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

106. On information and belief, Alkem filed ANDA No. 211199 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Alkem's Generic Product in the United States before the expiration of the '747 patent.

107. On information and belief, Alkem 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.

108. On information and belief, in its ANDA No. 211199, Alkem has represented to the FDA that Alkem's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

109. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211199 seeking approval for the commercial manufacture, use, or sale of Alkem's Generic Product before the expiration date of the '747 patent, constitutes infringement, either literally or under the doctrine of equivalents.

110. Upon FDA approval of ANDA No. 211199, Alkem 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 Alkem'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. 211199 shall be no earlier than the expiration of the '747 patent and any additional periods of exclusivity.

111. On information and belief, Alkem 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. 211199, and therefore will infringe at least one claim in the '747 patent.

112. On information and belief, Alkem had knowledge of the '747 patent and, by its promotional activities and proposed package insert for Alkem'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.

113. On information and belief, Alkem 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 Alkem's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '747 patent.

114. The offering to sell, sale, making, and/or importation of Alkem'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. Alkem has knowledge and is aware of Plaintiffs' '747 patent, as evidenced by Alkem's January 8, 2018 Notice Letter.

115. On information and belief, if ANDA No. 211199 is approved, Alkem intends to and will offer to sell, sell, and/or import in the United States Alkem's Generic Product.

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

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

118. On information and belief, Alkem's actions relating to Alkem's ANDA No. 211199 complained of herein were done by and for the benefit of Alkem.

119. Plaintiffs will be irreparably harmed if Alkem 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))

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

121. On information and belief, Alkem filed ANDA No. 211199 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Alkem's Generic Product in the United States before the expiration of the '954 patent.

122. On information and belief, Alkem 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.

123. On information and belief, in its ANDA No. 211199, Alkem has represented to the FDA that Alkem's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

124. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211199 seeking approval for the commercial manufacture, use, or sale of Alkem's Generic Product before the expiration date of the '954 patent, constitutes infringement, either literally or under the doctrine of equivalents.

125. Upon FDA approval of ANDA No. 211199, Alkem 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 Alkem'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. 211199 shall be no earlier than the expiration of the ’954 patent and any additional periods of exclusivity.

126. On information and belief, Alkem 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. 211199, and therefore will infringe at least one claim in the ’954 patent.

127. On information and belief, Alkem had knowledge of the ’954 patent and, by its promotional activities and proposed package insert for Alkem’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.

128. On information and belief, Alkem 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 Alkem’s Generic Product according to the instructions in the proposed package insert in a way that directly infringes the ’954 patent.

129. The offering to sell, sale, making, and/or importation of Alkem’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. Alkem has knowledge and is aware of Plaintiffs’ ’954 patent, as evidenced by Alkem’s January 8, 2018 Notice Letter.

130. On information and belief, if ANDA No. 211199 is approved, Alkem intends to and will offer to sell, sell, and/or import in the United States Alkem’s Generic Product.

131. Alkem has had and continues to have knowledge that Alkem’s Generic Product is especially adapted for a use that infringes the ’954 patent.

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

133. On information and belief, Alkem's actions relating to Alkem's ANDA No. 211199 complained of herein were done by and for the benefit of Alkem.

134. Plaintiffs will be irreparably harmed if Alkem 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.

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 Alkem has infringed at least one claim of the patents-in-suit through Alkem's submission of ANDA No. 211199 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Alkem'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 Alkem's making, using, offering to sell, selling or importing Alkem'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 Alkem'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 Alkem and all persons acting in concert with Alkem from commercially manufacturing, using, offering for sale,

or selling Alkem's Generic Product within the United States, or importing Alkem'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 Alkem and all persons acting in concert with Alkem 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.

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