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.	)	
JUBILANT LIFE SCIENCES LIMITED, JUBILANT PHARMA LIMITED, JUBILANT GENERICS LIMITED, JUBILANT LIFE SCIENCES (USA) INC., and JUBILANT CADISTA PHARMACEUTICALS 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 Jubilant Life Sciences Limited ("Jubilant Life Sciences"), Jubilant Pharma Limited ("Jubilant Pharma"), Jubilant Generics Limited ("Jubilant Generics"), Jubilant Life Sciences (USA) Inc. ("Jubilant USA"), and Jubilant Cadista Pharmaceuticals Inc. ("Jubilant Cadista") (collectively, "Jubilant"), 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, Jubilant Life Sciences is a corporation organized and existing under the laws of India, with its principal place of business at 1A, Sector 16A, Noida – 201301, Uttar Pradesh, India.

6. On information and belief, Jubilant Life Sciences 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, Jubilant Pharma is a corporation organized and existing under the laws of Singapore, with its principal place of business at 6 Temasek Boulevard, #20-06 Suntec City Tower Four, Singapore 038986.

8. On information and belief, Jubilant Pharma is a subsidiary of Jubilant Life Sciences.

9. On information and belief, Jubilant 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.

10. On information and belief, Jubilant Generics is a corporation organized and existing under the laws of India, with its principal place of business at 1A, Sector 16A, Noida – 201301, Uttar Pradesh, India.

11. On information and belief, Jubilant Generics is a wholly-owned subsidiary of Jubilant Life Sciences.

12. On information and belief, Jubilant Generics 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.

13. On information and belief, Jubilant USA is a corporation organized and existing under the laws of Delaware, with its principal place of business at 790 Township Line Road, Suite 175, Yardley, Pennsylvania 19067.

14. On information and belief, Jubilant USA is a wholly-owned subsidiary of Jubilant Life Sciences.

15. On information and belief, Jubilant USA 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. On information and belief, Jubilant USA is the marketing office for Jubilant Life Sciences, Jubilant Pharma, and Jubilant Generics in the United States.

16. On information and belief, Jubilant Cadista is a corporation organized and existing under the laws of Delaware, with its principal place of business at 207 Kiley Drive, Salisbury, Maryland 21801.

17. On information and belief, Jubilant Cadista is a wholly-owned subsidiary of Jubilant Life Sciences.

18. On information and belief, Jubilant Cadista 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.

19. On information and belief, the acts of Jubilant Generics complained of herein were done with the cooperation, participation, and assistance of Jubilant Life Sciences, Jubilant Pharma, Jubilant USA, and Jubilant Cadista.

20. 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. 211219, Jubilant will act in concert to distribute and sell the generic product described in Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg ANDA No. 211219 ("Jubilant's Generic Product") throughout the United States, including the State of Delaware.

NATURE OF THE ACTION

21. 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. 211219, which Jubilant 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

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

23. 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.

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

25. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because Jubilant USA and Jubilant Cadista are incorporated in the State of Delaware, and Jubilant Life Sciences being incorporated in India, Jubilant Pharma being incorporated in Singapore, and Jubilant Generics being incorporated in India may be sued in any judicial district in the United States in which they are subject to the Court's personal jurisdiction.

26. This Court has personal jurisdiction over Jubilant Life Sciences *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because Jubilant Life Sciences is organized under the laws of India.

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

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

29. This Court has personal jurisdiction over Jubilant USA because, *inter alia*, Jubilant USA is organized and existing under the laws of the State of Delaware.

30. This Court has personal jurisdiction over Jubilant Cadista because, *inter alia*, Jubilant Cadista is organized and existing under the laws of the State of Delaware.

31. Upon information and belief, Jubilant USA maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, Corporation Service Company, located at 251 Little Falls Drive, Wilmington, DE 19808.

32. Upon information and belief, Jubilant Cadista maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, United Corporate Services, Inc., located at 874 Walker Road, Suite C, Dover, DE 19904.

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

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

35. Upon information and belief, the effort to seek approval for ANDA No. 211219 and to manufacture, import, market, and/or sell Jubilant's Generic Product upon approval has been a cooperative and joint enterprise and venture between Jubilant Life Sciences, Jubilant Pharma, Jubilant Generics, Jubilant USA, and Jubilant Cadista.

36. Upon information and belief, Jubilant Life Sciences, Jubilant Pharma, Jubilant Generics, Jubilant USA, and Jubilant Cadista have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing and maintaining ANDA No. 211219 and in commercializing Jubilant's Generic Product in the United States, including in this judicial district, in accordance with ANDA 211219 upon approval.

37. Upon information and belief, Jubilant Life Sciences, Jubilant Pharma, Jubilant Generics, Jubilant USA, and Jubilant Cadista have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 211219.

38. This Court has personal jurisdiction over Jubilant 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.

39. Upon information and belief, and consistent with their practice with respect to other generic products, following FDA approval of ANDA No. 211219, Jubilant will market, distribute, and sell Jubilant's Generic Product described in ANDA No. 211219 throughout the United States, including in Delaware.

40. This Court also has personal jurisdiction over Jubilant because, *inter alia*, Jubilant Life Sciences, Jubilant Pharma, Jubilant Generics, Jubilant USA, and Jubilant Cadista, acting as an integrated unit, have purposefully availed themselves of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Jubilant Life Sciences, Jubilant Pharma, Jubilant Generics, Jubilant USA, and Jubilant Cadista, either directly or through affiliates, currently sell significant quantities of generic drug products in the United States and in the State of Delaware. According to Jubilant Life Sciences' website, it is "[a]n integrated global pharmaceutical and life sciences company." *See* http://www.jubl.com/about-us/company-profile (accessed February 25, 2018). Jubilant Pharma's website states that "[i]t is Jubilant Pharma's endeavour [*sic*] to develop affordable generics with speed to market." *See* http://www.jubilantpharma.com/product-category.aspx?pid=8 (accessed February 25, 2018). Furthermore, Jubilant Life Sciences' website states that "Jubilant Generics, is one of the business arms of Jubilant Pharma Group" and that Jubilant Generics has "85 filed ANDAs in US." *See* http://www.jubl.com/Uploads/image/726imguf_AW_DFFolder_BacktoBack(United).pdf (accessed February 25, 2018). Additionally, Jubilant Pharma's website states that it is "aiming to expand the sales reach in the United States, directly to the government agencies and distributors through our Jubilant Cadista business." *See* http://www.jubilantpharma.com/cpage.aspx?mpgid=343&pgid=752&spgid=753 (accessed February 25, 2018). Jubilant Cadista's website states that "Jubilant Cadista is one of the fastest growing generic pharmaceutical companies in the US because of our ever increasing product portfolio" and to "[s]tay tuned for the next in a long line of new product launches over the next

months and years." *See* http://www.cadista.com/about-us/product-focus (accessed February 25, 2018). On information and belief, Jubilant 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.

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

FACTUAL BACKGROUND

The NDA

42. 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.

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

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

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

46. 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

47. 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.

48. 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.

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

50. United States Patent No. 9,206,135 (“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.

51. 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.

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

53. 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.

54. 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.

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

56. 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.

57. 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.

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

59. 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.

60. 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.

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

62. 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.

63. 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.

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

The ANDA

65. On information and belief, Jubilant filed ANDA No. 211219 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.

66. ANDA No. 211219 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 Jubilant's Generic Product.

67. On January 18, 2018, Bial and Sunovion received a letter sent by Jubilant, dated January 15, 2018, for ANDA No. 211219 ("Jubilant'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. Jubilant's Notice Letter notified Bial that Jubilant had filed ANDA No. 211219, seeking approval to market Jubilant's Generic Product prior to the expiration of the patents-in-suit.

68. Plaintiffs commenced this action within 45 days of receiving Jubilant's January 15, 2018 Notice Letter.

COUNT I

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

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

70. On information and belief, Jubilant filed ANDA No. 211219 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Jubilant's Generic Product in the United States before the expiration of the '431 patent.

71. On information and belief, Jubilant 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.

72. On information and belief, in its ANDA No. 211219, Jubilant has represented to the FDA that Jubilant's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

73. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211219 seeking approval for the commercial manufacture, use, or sale of Jubilant's Generic Product before the expiration date of the '431 patent, constitutes infringement, either literally or under the doctrine of equivalents.

74. Upon FDA approval of ANDA No. 211219, Jubilant 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 Jubilant'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. 211219 shall be no earlier than the expiration of the '431 patent and any additional periods of exclusivity.

75. On information and belief, if ANDA No. 211219 is approved, Jubilant intends to and will offer to sell, sell, and/or import in the United States Jubilant's Generic Product.

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

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

78. On information and belief, Jubilant's actions relating to Jubilant's ANDA No. 211219 complained of herein were done by and for the benefit of Jubilant.

79. Plaintiffs will be irreparably harmed if Jubilant 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))

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

81. On information and belief, Jubilant filed ANDA No. 211219 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Jubilant's Generic Product in the United States before the expiration of the '135 patent.

82. On information and belief, Jubilant 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.

83. On information and belief, in its ANDA No. 211219, Jubilant has represented to the FDA that Jubilant's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

84. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211219 seeking approval for the commercial manufacture, use, or sale of Jubilant's Generic Product before the expiration date of the '135 patent, constitutes infringement, either literally or under the doctrine of equivalents.

85. Upon FDA approval of ANDA No. 211219, Jubilant 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 Jubilant'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. 211219 shall be no earlier than the expiration of the '135 patent and any additional periods of exclusivity.

86. On information and belief, Jubilant knows, or should know, and intends that physicians will prescribe and patients will take Jubilant's Generic Product for which approval is sought in ANDA No. 211219, and therefore will infringe at least one claim in the '135 patent.

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

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

89. The offering to sell, sale, making, and/or importation of Jubilant'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. Jubilant has knowledge and is aware of Plaintiffs' '135 patent, as evidenced by Jubilant's January 15, 2018 Notice Letter.

90. On information and belief, if ANDA No. 211219 is approved, Jubilant intends to and will offer to sell, sell, and/or import in the United States Jubilant's Generic Product.

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

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

93. On information and belief, Jubilant's actions relating to Jubilant's ANDA No. 211219 complained of herein were done by and for the benefit of Jubilant.

94. Plaintiffs will be irreparably harmed if Jubilant 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))

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

96. On information and belief, Jubilant filed ANDA No. 211219 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Jubilant's Generic Product in the United States before the expiration of the '244 patent.

97. On information and belief, Jubilant 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.

98. On information and belief, in its ANDA No. 211219, Jubilant has represented to the FDA that Jubilant’s Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs’ APTIOM® tablets.

99. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211219 seeking approval for the commercial manufacture, use, or sale of Jubilant’s Generic Product before the expiration date of the ’244 patent, constitutes infringement, either literally or under the doctrine of equivalents.

100. Upon FDA approval of ANDA No. 211219, Jubilant 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 Jubilant’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. 211219 shall be no earlier than the expiration of the ’244 patent and any additional periods of exclusivity.

101. On information and belief, if ANDA No. 211219 is approved, Jubilant intends to and will offer to sell, sell, and/or import in the United States Jubilant’s Generic Product.

102. Jubilant has had and continues to have knowledge that Jubilant’s Generic Product is especially adapted for a use that infringes the ’244 patent.

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

104. On information and belief, Jubilant's actions relating to Jubilant's ANDA No. 211219 complained of herein were done by and for the benefit of Jubilant.

105. Plaintiffs will be irreparably harmed if Jubilant 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))

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

107. On information and belief, Jubilant filed ANDA No. 211219 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Jubilant's Generic Product in the United States before the expiration of the '929 patent.

108. On information and belief, Jubilant 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.

109. On information and belief, in its ANDA No. 211219, Jubilant has represented to the FDA that Jubilant's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

110. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211219 seeking approval for the commercial manufacture, use, or sale of Jubilant's Generic Product before the expiration date of the '929 patent, constitutes infringement, either literally or under the doctrine of equivalents.

111. Upon FDA approval of ANDA No. 211219, Jubilant 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 Jubilant'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. 211219 shall be no earlier than the expiration of the '929 patent and any additional periods of exclusivity.

112. On information and belief, if ANDA No. 211219 is approved, Jubilant intends to and will offer to sell, sell, and/or import in the United States Jubilant's Generic Product.

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

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

115. On information and belief, Jubilant's actions relating to Jubilant's ANDA No. 211219 complained of herein were done by and for the benefit of Jubilant.

116. Plaintiffs will be irreparably harmed if Jubilant 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))

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

118. On information and belief, Jubilant filed ANDA No. 211219 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Jubilant's Generic Product in the United States before the expiration of the '747 patent.

119. On information and belief, Jubilant 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.

120. On information and belief, in its ANDA No. 211219, Jubilant has represented to the FDA that Jubilant's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

121. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211219 seeking approval for the commercial manufacture, use, or sale of Jubilant's Generic Product before the expiration date of the '747 patent, constitutes infringement, either literally or under the doctrine of equivalents.

122. Upon FDA approval of ANDA No. 211219, Jubilant 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 Jubilant'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. 211219 shall be no earlier than the expiration of the '747 patent and any additional periods of exclusivity.

123. On information and belief, Jubilant knows, or should know, and intends that physicians will prescribe and patients will take Jubilant's Generic Product for which approval is sought in ANDA No. 211219, and therefore will infringe at least one claim in the '747 patent.

124. On information and belief, Jubilant had knowledge of the ’747 patent and, by its promotional activities and proposed package insert for Jubilant’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.

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

126. The offering to sell, sale, making, and/or importation of Jubilant’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. Jubilant has knowledge and is aware of Plaintiffs’ ’747 patent, as evidenced by Jubilant’s January 15, 2018 Notice Letter.

127. On information and belief, if ANDA No. 211219 is approved, Jubilant intends to and will offer to sell, sell, and/or import in the United States Jubilant’s Generic Product.

128. Jubilant has had and continues to have knowledge that Jubilant’s Generic Product is especially adapted for a use that infringes the ’747 patent.

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

130. On information and belief, Jubilant’s actions relating to Jubilant’s ANDA No. 211219 complained of herein were done by and for the benefit of Jubilant.

131. Plaintiffs will be irreparably harmed if Jubilant 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))

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

133. On information and belief, Jubilant filed ANDA No. 211219 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Jubilant's Generic Product in the United States before the expiration of the '954 patent.

134. On information and belief, Jubilant 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.

135. On information and belief, in its ANDA No. 211219, Jubilant has represented to the FDA that Jubilant's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

136. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211219 seeking approval for the commercial manufacture, use, or sale of Jubilant's Generic Product before the expiration date of the '954 patent, constitutes infringement, either literally or under the doctrine of equivalents.

137. Upon FDA approval of ANDA No. 211219, Jubilant 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 Jubilant'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. 211219 shall be no earlier than the expiration of the '954 patent and any additional periods of exclusivity.

138. On information and belief, Jubilant knows, or should know, and intends that physicians will prescribe and patients will take Jubilant's Generic Product for which approval is sought in ANDA No. 211219, and therefore will infringe at least one claim in the '954 patent.

139. On information and belief, Jubilant had knowledge of the '954 patent and, by its promotional activities and proposed package insert for Jubilant'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.

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

141. The offering to sell, sale, making, and/or importation of Jubilant'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. Jubilant has knowledge and is aware of Plaintiffs' '954 patent, as evidenced by Jubilant's January 15, 2018 Notice Letter.

142. On information and belief, if ANDA No. 211219 is approved, Jubilant intends to and will offer to sell, sell, and/or import in the United States Jubilant's Generic Product.

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

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

145. On information and belief, Jubilant's actions relating to Jubilant's ANDA No. 211219 complained of herein were done by and for the benefit of Jubilant.

146. Plaintiffs will be irreparably harmed if Jubilant 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 Jubilant has infringed at least one claim of the patents-in-suit through Jubilant's submission of ANDA No. 211219 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Jubilant'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 Jubilant's making, using, offering to sell, selling or importing Jubilant'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 Jubilant'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 Jubilant and all persons acting in concert with Jubilant from commercially manufacturing, using, offering for

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

/s/ Steven J. Balick

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

Of Counsel:

James B. Monroe
Jennifer H. Roscetti
Charles T. Collins-Chase
Lauren J. Dowty
Danielle C. Pfifferling
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4431
(202) 408-4000

Attorneys for Plaintiffs BIAL - PORTELA & CA S.A. and BIAL - HOLDING, S.A.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen A. Jacobs

Jack B. Blumenfeld (#1014)
Karen A. Jacobs (#2881)
1201 North Market Street, 16th Floor
Wilmington, DE 19801
(302) 658-9200
jblumenfeld@mnat.com
kjacobs@mnat.com

Attorneys for Plaintiff Sunovion Pharmaceuticals Inc.

Dated: March 1, 2018