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,	)	
v.	)	Civil Action No. 20-00783-CFC
JUBILANT LIFE SCIENCES LIMITED, JUBILANT PHARMA LIMITED, JUBILANT GENERICS LIMITED, JUBILANT LIFE SCIENCES (USA) INC., and JUBILANT CADISTA PHARMACEUTICALS INC.,	)	
Defendants.	)	

DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

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"), by way of Answer to Plaintiffs' Amended Complaint, state as follows:

Jubilant denies each and every allegation contained in the Amended Complaint, except as specifically admitted or explained herein. To the extent that the headings or any other non-numbered statements in the Amended Complaint contain any allegations, Jubilant denies each and every such allegation.

THE PARTIES

1. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 1 of Plaintiffs' Amended Complaint, and therefore denies all such allegations.

2. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 of Plaintiffs' Amended Complaint, and therefore denies all such allegations.

3. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3 of Plaintiffs' Amended Complaint, and therefore denies all such allegations. To the extent an answer is required, Jubilant admits the following: (1) the electronic version of the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") lists "Sunovion Pharmaceuticals Inc." as the applicant for New Drug Application ("NDA") No. 022416 for APTIOM® brand eslicarbazepine acetate oral tablets, in 200 mg, 400 mg, 600 mg and 800 mg dosage strength; (2) according to the Prescribing Information for APTIOM® brand eslicarbazepine acetate tablets, APTIOM is indicated for treating partial-onset seizures in patients 4 years of age and older; and (3) U.S. Patent Nos. 5,753,646; 8,372,431; 9,566,244; 9,206,135; 9,643,929; 9,750,747; 9,763,954; 10,675,287; 10,695,354; and 10,702,536 are listed in the Orange Book in connection with NDA No. 022416.

4. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4 of Plaintiffs' Amended Complaint, and therefore denies all such allegations.

5. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that 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. Jubilant admits that Jubilant Generics, Jubilant USA, and Jubilant Cadista, which are wholly owned subsidiaries of Jubilant Pharma, which is in turn a subsidiary of Jubilant Life Sciences, are in the business of, *inter alia*, manufacturing, marketing, and selling generic pharmaceutical products throughout the United States, including the State of Delaware. Jubilant denies all other remaining allegations in Paragraph 6.

7. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that 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. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Pharma is a subsidiary of Jubilant Life Sciences.

9. Jubilant admits that Jubilant Generics, Jubilant USA, and Jubilant Cadista, which are wholly owned subsidiaries of Jubilant Pharma, are in the business of, *inter alia*, manufacturing, marketing, and selling generic pharmaceutical products throughout the United States, including the State of Delaware. Jubilant denies all other remaining allegations in Paragraph 9.

10. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that 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. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Generics is a wholly-owned subsidiary of Jubilant Pharma, which is a subsidiary of Jubilant Life Sciences.

12. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Generics is in the business of, *inter alia*, manufacturing, marketing, and selling generic pharmaceutical products the United States. Jubilant denies all other remaining allegations in Paragraph 12.

13. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that 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. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant USA is a subsidiary of Jubilant Pharma, which is a subsidiary of Jubilant Life Sciences.

15. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that: (1) Jubilant USA is in the business of, *inter alia*, marketing and selling generic pharmaceutical products in the United States; and (2) Jubilant USA is the marketing office for Jubilant Life Sciences, Jubilant Pharma, and Jubilant Generics in the United States. Jubilant denies all other remaining allegations in Paragraph 15.

16. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that 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. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Cadista is a subsidiary of Jubilant Pharma, which is a subsidiary of Jubilant Life Sciences.

18. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Cadista is in the business of, *inter alia*, marketing and selling generic pharmaceutical products in the United States. Jubilant denies all other remaining allegations in Paragraph 18.

19. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Generics is a subsidiary of Jubilant Life Sciences. Jubilant denies all other remaining allegations in Paragraph 19.

20. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that it filed ANDA No. 211219 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets throughout the United States, including Delaware but is without information sufficient to admit or deny the remaining allegations contained in this paragraph, and therefore denies all other remaining allegations in Paragraph 20.

NATURE OF THE ACTION

21. Jubilant admits that Plaintiffs' Amended Complaint purports to be an action for patent infringement of U.S. Patent Nos. 10,675,287 ("the '287 patent"), 10,695,354 ("the '354 patent"), and 10,702,536 ("the '536 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. Jubilant admits that it filed ANDA No. 211219 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 version of Plaintiffs' APTIOM® product prior to the expiration of the patents-in-suit. Jubilant denies all other remaining allegations in Paragraph 21.

22. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant denies all allegations in Paragraph 22.

23. Jubilant admits that Plaintiffs previously filed an action against Jubilant for patent infringement of U.S. Patent Nos. 9,750,747 ("the '747 patent"), 8,372,431 ("the '431 patent"), 9,206,135 ("the '135 patent"), 9,566,244 ("the '244 patent"), 9,643,929 ("the '929 patent"), and 9,763,954 ("the '954 patent), and the action included counts for infringement of these patents. Jubilant admits that *Bial - Portela & CA S.A., et al. v. Jubilant Life Sciences Limited, et al.*, C.A. No. 18-336-CFC (the "First Suit") was filed on March 1, 2018. Jubilant admits that it sent a letter dated January 15, 2018 (the "Jubilant Notice Letter") to Plaintiffs concerning the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '954 patent.

24. Jubilant admits that the First Suit did not include counts for infringement of U.S. Patent No. 5,753,646 ("the '646 patent) and that the Jubilant Notice Letter did not assert noninfringement or invalidity of the '646 patent. Jubilant admits that it is maintaining its certification as to the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '954 patent.

JURISDICTION AND VENUE

25. Jubilant repeats and incorporates by reference each of its answers to the foregoing paragraphs as if fully set forth herein.

26. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that Plaintiffs' Amended Complaint purports that this action arises 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, but denies all other remaining allegations in Paragraph 26.

27. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that subject matter jurisdiction over Plaintiffs' patent infringement claims is proper.

28. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant does not contest venue for this particular action.

29. This Paragraph contains legal conclusions to which no answer is required. Jubilant Life Sciences does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 29.

30. This Paragraph contains legal conclusions to which no answer is required. Jubilant Pharma does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 30.

31. This Paragraph contains legal conclusions to which no answer is required. Jubilant Generics does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 31.

32. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant USA is a corporation organized and existing under the laws of Delaware. Jubilant USA does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 32.

33. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Cadista is a corporation organized

and existing under the laws of Delaware. Jubilant Cadista does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 33.

34. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant USA admits that Corporation Service Company, located at 251 Little Falls Drive, Wilmington, DE 19808 is an authorized U.S. agent of Jubilant. Jubilant denies all other remaining allegations in Paragraph 34.

35. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant Cadista admits that United Corporate Services, Inc., located at 874 Walker Rd, Suite C, Dover, DE 19904 is an authorized U.S. agent of Jubilant. Jubilant denies all other remaining allegations in Paragraph 35.

36. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 36.

37. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 37.

38. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Generics seeks approval for ANDA No. 211219 to manufacture, import, market, and/or sell Jubilant's ANDA product upon approval; and that Jubilant Cadista and Jubilant USA are subsidiaries of Jubilant Pharma in the United States, which is a subsidiary of Jubilant Life Sciences. Jubilant denies all other remaining allegations in Paragraph 38.

39. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Generics is involved in preparing, filing and maintaining ANDA No. 211219; and that Jubilant Generics, Jubilant USA, and Jubilant Cadista are subsidiaries of Jubilant Pharma in the United States, which is in turn a subsidiary of Jubilant Life Sciences. Jubilant denies all other remaining allegations in Paragraph 39.

40. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Generics is involved in the drafting, submission, approval and maintenance of ANDA No. 211219; and that Jubilant Generics, Jubilant USA, and Jubilant Cadista are subsidiaries of Jubilant Pharma in the United States, which is in turn a subsidiary of Jubilant Life Sciences. Jubilant denies all other remaining allegations in Paragraph 40.

41. Jubilant does not contest personal jurisdiction in this particular action but denies all allegations in Paragraph 41.

42. Jubilant admits that it filed ANDA No. 211219 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets throughout the United States, including Delaware but is without information sufficient to admit or deny the remaining allegations contained in this paragraph, and therefore denies all other remaining allegations in Paragraph 42.

43. This Paragraph contains legal conclusions to which no answer is required. Jubilant does not contest personal jurisdiction in this particular action. To the extent an answer is required, Jubilant admits that Jubilant Generics, Jubilant USA, and Jubilant Cadista develop, manufacture or market generic prescription drug products in the United States, including in Delaware; and that Jubilant Generics, Jubilant USA, and Jubilant Cadista are subsidiaries of

Jubilant Pharma in the United States, which is a subsidiary of Jubilant Life Sciences. Jubilant denies all other remaining allegations in Paragraph 43.

44. Jubilant does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 44.

45. Jubilant does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 45.

FACTUAL BACKGROUND

The NDA

46. Jubilant admits that according to the electronic version of the FDA's Orange Book publication, "Sunovion" is identified as the applicant for NDA No. 022416 for APTIOM® brand eslicarbazepine acetate tablets, in 200 mg, 400 mg, 600 mg, and 800 mg dosage strengths. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 46, and therefore denies same.

47. Jubilant admits that according to the NDA Approval letter dated November 8, 2013 for NDA No. 022416, the FDA stated, "This new drug application provides for the use of Aptiom (eslicarbazepine acetate) 200 mg, 400 mg, 600 mg, and 800 mg tablets for adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy 18 years and older." Jubilant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 47, and therefore denies same.

48. Jubilant admits that according to the Supplement Approval letter dated August 27, 2015 for NDA No. 022416/S-001, the FDA stated, "This 'Prior Approval' supplemental new drug application provides for the addition of the indication for monotherapy treatment of partial-onset seizures in adults." Jubilant is without knowledge or information

sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 48, and therefore denies same.

49. Jubilant admits that according to the Supplement Approval letter dated September 13, 2017 for NDA No. 22416/S-009, the FDA stated that "the indication for Aptiom is being expanded to include pediatric patients 4 years of age and older." Jubilant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 49, and therefore denies same.

50. Jubilant admits that according to the Prescribing Information for APTIOM® brand eslicarbazepine acetate tablets, APTIOM® is indicated for the treatment of partial onset seizures in patients 4 years of age and older, and eslicarbazepine acetate is the active ingredient in the APTIOM® Tablets.

The Patents-in-Suit

51. Jubilant admits that according to the online records of the United States Patent and Trademark Office ("USPTO"): (1) the title of the '287 patent is "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate," (2) the '287 patent was issued by the USPTO on June 9, 2020, and (3) a copy of the '287 patent was attached to the Amended Complaint.

52. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits the following: (1) the '287 patent is assigned on its face to Bial-Portela & C.A., S.A.; (2) the '287 patent issued from application no. 16/449,048; (3) according to the online records of the USPTO an assignment by Jose Luis de Almeida and Patricio Manuel Vieira Araujo Soares da Silva to Portela & C.A., S.A. for application no. 16/449,048 is recorded at reel/frame 052849/0982 by a conveyance executed on June 6, 2005 and recorded on June 5, 2020; (4) according to the online records of the USPTO a change of name

conveyance from Portela & C.A., S.A. to Bial-Portela & C.A., S.A. is recorded at reel/frame 052851/0292 by a conveyance executed on July 9, 2009 and recorded on June 5, 2020; and (5) the Orange Book lists the expiration date of the '287 patent as May 6, 2025. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 52, and therefore denies same.

53. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that the '287 patent is listed in the Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

54. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 54 and, therefore, denies them.

55. The prescribing information for Aptiom® speaks for itself and Jubilant denies any allegations inconsistent therewith. Jubilant is without information sufficient to admit or deny the remaining allegations contained in Paragraph 55, and therefore denies them.

56. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

57. Jubilant admits that according to the online records of the United States Patent and Trademark Office ("USPTO"): (1) the title of the '354 patent is "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate," (2) the '354 patent was issued by the USPTO on June 30, 2020, and (3) a copy of the '354 patent was attached to the Amended Complaint.

58. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits the following: (1) the '354 patent is assigned

on its face to Bial-Portela & C.A., S.A.; (2) the '354 patent issued from application no. 16/449,057; (3) according to the online records of the USPTO an assignment by Jose Luis de Almeida and Patricio Manuel Vieira Araujo Soares da Silva to Portela & C.A., S.A. for application no. 16/449,057 is recorded at reel/frame 052858/0205 by a conveyance executed on June 6, 2005 and recorded on June 5, 2020; (4) according to the online records of the USPTO a change of name conveyance from Portela & C.A., S.A. to Bial-Portela & C.A., S.A. is recorded at reel/frame 052851/0527 by a conveyance executed on July 9, 2009 and recorded on June 5, 2020; and (5) the Orange Book lists the expiration date of the '354 patent as May 6, 2025. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 58, and therefore denies same.

59. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that the '354 patent is listed in the Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

60. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 60 and, therefore, denies them.

61. The prescribing information for Aptiom® speaks for itself and Jubilant denies any allegations inconsistent therewith. Jubilant is without information sufficient to admit or deny the remaining allegations contained in Paragraph 61 and, therefore, denies them.

62. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

63. Jubilant admits that according to the online records of the United States Patent and Trademark Office ("USPTO"): (1) the title of the '536 patent is "Methods of Treatment

of Partial Onset Seizures Using Eslicarbazepine Acetate," (2) the '536 patent was issued by the USPTO on July 7, 2020, and (3) a copy of the '536 patent was attached to the Amended Complaint.

64. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits the following: (1) the '536 patent is assigned on its face to Bial-Portela & C.A., S.A.; (2) the '536 patent issued from application no. 15/422,278; (3) according to the online records of the USPTO an assignment by Jose Luis de Almeida and Patricio Manuel Vieira Araujo Soares da Silva to Portela & C.A., S.A. for application no. 15/422,278 is recorded at reel/frame 052803/0684 by a conveyance executed on June 6, 2005 and recorded on June 1, 2020; (4) according to the online records of the USPTO a change of name conveyance from Portela & C.A., S.A. to Bial-Portela & C.A., S.A. is recorded at reel/frame 052794/0187 by a conveyance executed on July 9, 2009 and recorded on May 29, 2020; and (5) the Orange Book lists the expiration date of the '536 patent as May 6, 2025. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 64, and therefore denies same.

65. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that the '536 patent is listed in the Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

66. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 66 and, therefore, denies them.

67. The prescribing information for Aptiom® speaks for itself and Jubilant denies any allegations inconsistent therewith. Jubilant is without information sufficient to admit or deny the remaining allegations contained in Paragraph 67, and therefore denies them.

68. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

The ANDA

69. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant has submitted to the FDA ANDA No. 211219 ("Jubilant's ANDA Product") 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. Jubilant also admits that Jubilant's ANDA refers to and relies upon the APTIOM® NDA and contains data that, according to Jubilant, demonstrates the bioequivalence of Jubilant's ANDA Product and APTIOM®. Jubilant denies all other remaining allegations in Paragraph 69.

70. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant's Notice Letter informed Plaintiffs that the claims of the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent and the '954 patent are invalid and/or will not be infringed by Jubilant's ANDA No. 211219. Jubilant also admits that Jubilant's ANDA No. 211219 contains Paragraph IV certifications to the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent and the '954 patent.

71. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that the Orange Book specifies that the '135 and '929 patents will expire on April 21, 2026 and that the patents-in-suit will expire on May 6, 2025.

72. Admitted.

73. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits Jubilant filed ANDA No. 211219, which contains Paragraph IV certifications to the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent and the '954 patent seeking approval to market Jubilant's ANDA Product prior to the expiration of these patents.

COUNT I

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

74. Jubilant repeats and incorporates by reference each of its answers to the foregoing Paragraphs as if fully set forth herein.

75. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant filed ANDA No. 211219 with the FDA, which contains Paragraph IV certifications to the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent and the '954 patent seeking approval to market Jubilant's ANDA Product prior to the expiration of these patents.

76. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant's ANDA filed with FDA refers to and relies upon the APTIOM® NDA and contains data that, according to Jubilant, demonstrates the bioequivalence of Jubilant's ANDA Product and APTIOM®. Jubilant denies all other remaining allegations in Paragraph 76.

77. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant denies the allegations in Paragraph 77.

78. Jubilant denies the allegations in Paragraph 78.

79. Jubilant denies the allegations in Paragraph 79.

80. Jubilant admits that it was aware of the '287 patent but denies the remaining allegations in Paragraph 80.

81. Jubilant denies the allegations in Paragraph 81.

82. Jubilant admits that it was aware of the '287 patent but denies the remaining allegations in Paragraph 82.

83. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 83.

84. Jubilant denies the allegations in Paragraph 84.

85. Jubilant denies the allegations in Paragraph 85.

86. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 86.

87. Jubilant denies the allegations in Paragraph 87.

COUNT II

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '287 PATENT)

88. Jubilant repeats and incorporates by reference each of its answers to the foregoing Paragraphs as if fully set forth herein.

89. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that Plaintiffs' Amended Complaint purports that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

90. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that an actual controversy exists between Jubilant and Plaintiffs concerning infringement of the '287 patent, but denies that Plaintiffs are entitled to any of the relief they seek and denies the remaining allegations in Paragraph 90.

91. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that Jubilant filed ANDA No. 211219 with the FDA, which contains Paragraph IV certifications to the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent and the '954 patent seeking approval to market Jubilant's ANDA Product prior to the expiration of these patents.

92. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that Jubilant filed ANDA No. 211219 with the FDA, which contains Paragraph IV certifications to the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent and the '954 patent seeking approval to market Jubilant's ANDA Product prior to the expiration of these patents. Jubilant admits that it has engaged in litigation with the Plaintiffs regarding the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent and the '954 patent.

93. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that the FDA could approve Jubilant's ANDA No. 211219 as early as expiration of the '646 patent and the trial is currently scheduled for September 27, 2021.

94. Jubilant admits that it filed ANDA No. 211219 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets. Jubilant is without information sufficient to admit or deny the remaining allegations contained in Paragraph 94, and therefore denies them.

95. Jubilant denies the allegations in Paragraph 95.

96. Jubilant denies the allegations in Paragraph 96.

97. Jubilant admits that it was aware of the '287 patent but denies the remaining allegations in Paragraph 97.

98. Jubilant denies the allegations in Paragraph 98.

99. Jubilant admits that it was aware of the '287 patent but denies the remaining allegations in Paragraph 99.

100. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 100.

101. Jubilant denies the allegations in Paragraph 101.

102. Jubilant denies the allegations in Paragraph 102.

103. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 103.

104. Jubilant denies the allegations in Paragraph 104.

105. Jubilant denies the allegations in Paragraph 105.

106. Jubilant denies the allegations in Paragraph 106.

COUNT III

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

107. Jubilant repeats and incorporates by reference each of its answers to the foregoing Paragraphs as if fully set forth herein.

108. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant filed ANDA No. 211219 with the FDA, which contains Paragraph IV certifications to the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent and the '954 patent seeking approval to market Jubilant's ANDA Product prior to the expiration of these patents.

109. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant's ANDA filed with FDA refers to and relies upon the APTIOM® NDA and contains data that, according to Jubilant, demonstrates the bioequivalence of Jubilant's ANDA Product and APTIOM®. Jubilant denies all other remaining allegations in Paragraph 109.

110. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant denies the allegations in Paragraph 110.

111. Jubilant denies the allegations in Paragraph 111.

112. Jubilant denies the allegations in Paragraph 112.

113. Jubilant admits that it was aware of the '354 patent but denies the remaining allegations in Paragraph 113.

114. Jubilant denies the allegations in Paragraph 114.

115. Jubilant admits that it was aware of the '354 patent but denies the remaining allegations in Paragraph 115.

116. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 116.

117. Jubilant denies the allegations in Paragraph 117.

118. Jubilant denies the allegations in Paragraph 118.

119. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 119.

120. Jubilant denies the allegations in Paragraph 120.

COUNT IV

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '354 PATENT)

121. Jubilant repeats and incorporates by reference each of its answers to the foregoing Paragraphs as if fully set forth herein.

122. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that Plaintiffs' Amended Complaint purports that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

123. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that an actual controversy exists between Jubilant and Plaintiffs concerning infringement of the '354 patent, but denies that Plaintiffs are entitled to any of the relief they seek and denies the remaining allegations in Paragraph 123.

124. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that Jubilant filed ANDA No. 211219 with the FDA, which contains Paragraph IV certifications to the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent and the '954 patent seeking approval to market Jubilant's ANDA Product prior to the expiration of these patents.

125. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that Jubilant filed ANDA No. 211219 with the FDA, which contains Paragraph IV certifications to the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent and the '954 patent seeking approval to market Jubilant's ANDA Product prior to the expiration of these patents. Jubilant admits that it has engaged in litigation with the Plaintiffs regarding the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent and the '954 patent.

126. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that the FDA could approve Jubilant's ANDA No. 211219 as early as expiration of the '646 patent and the trial is currently scheduled for September 27, 2021.

127. Jubilant admits that it filed ANDA No. 211219 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets. Jubilant is without

information sufficient to admit or deny the remaining allegations contained in Paragraph 127, and therefore denies them.

128. Jubilant denies the allegations in Paragraph 128.

129. Jubilant denies the allegations in Paragraph 129.

130. Jubilant admits that it was aware of the '354 patent but denies the remaining allegations in Paragraph 130.

131. Jubilant denies the allegations in Paragraph 131.

132. Jubilant admits that it was aware of the '354 patent but denies the remaining allegations in Paragraph 132.

133. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 133.

134. Jubilant denies the allegations in Paragraph 134.

135. Jubilant denies the allegations in Paragraph 135.

136. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 136.

137. Jubilant denies the allegations in Paragraph 137.

138. Jubilant denies the allegations in Paragraph 138.

139. Jubilant denies the allegations in Paragraph 139.

COUNT V

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

140. Jubilant repeats and incorporates by reference each of its answers to the foregoing Paragraphs as if fully set forth herein.

141. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant filed ANDA No. 211219 with the FDA, which contains Paragraph IV certifications to the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent and the '954 patent seeking approval to market Jubilant's ANDA Product prior to the expiration of these patents.

142. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant's ANDA filed with FDA refers to and relies upon the APTIOM® NDA and contains data that, according to Jubilant, demonstrates the bioequivalence of Jubilant's ANDA Product and APTIOM®. Jubilant denies all other remaining allegations in Paragraph 142.

143. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant denies the allegations in Paragraph 143.

144. Jubilant denies the allegations in Paragraph 144.

145. Jubilant denies the allegations in Paragraph 145.

146. Jubilant admits that it was aware of the '536 patent but denies the remaining allegations in Paragraph 146.

147. Jubilant denies the allegations in Paragraph 147.

148. Jubilant admits that it was aware of the '536 patent but denies the remaining allegations in Paragraph 148.

149. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 149.

150. Jubilant denies the allegations in Paragraph 150.

151. Jubilant denies the allegations in Paragraph 151.

152. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 152.

153. Jubilant denies the allegations in Paragraph 153.

COUNT VI

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '536 PATENT)

154. Jubilant repeats and incorporates by reference each of its answers to the foregoing Paragraphs as if fully set forth herein.

155. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that Plaintiffs' Amended Complaint purports that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

156. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that an actual controversy exists between Jubilant and Plaintiffs concerning infringement of the '536 patent, but denies that Plaintiffs are entitled to any of the relief they seek and denies the remaining allegations in Paragraph 156.

157. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that Jubilant filed ANDA No. 211219 with the FDA, which contains Paragraph IV certifications to the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent and the '954 patent seeking approval to market Jubilant's ANDA Product prior to the expiration of these patents.

158. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that Jubilant filed ANDA No. 211219 with the FDA, which contains Paragraph IV certifications to the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent and the '954 patent seeking approval to market Jubilant's ANDA Product prior to the expiration of these patents. Jubilant admits that it has engaged in litigation with the Plaintiffs regarding the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent and the '954 patent.

159. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that the FDA could approve Jubilant's ANDA No. 211219 as early as the expiration of the '646 patent and the trial is currently scheduled for September 27, 2021.

160. Jubilant admits that it filed ANDA No. 211219 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets. Jubilant is without

information sufficient to admit or deny the remaining allegations contained in Paragraph 160, and therefore denies them.

161. Jubilant denies the allegations in Paragraph 161.

162. Jubilant denies the allegations in Paragraph 162.

163. Jubilant admits that it was aware of the '536 patent but denies the remaining allegations in Paragraph 163.

164. Jubilant denies the allegations in Paragraph 164.

165. Jubilant admits that it was aware of the '536 patent but denies the remaining allegations in Paragraph 165.

166. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 166.

167. Jubilant denies the allegations in Paragraph 167.

168. Jubilant denies the allegations in Paragraph 168.

169. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 169.

170. Jubilant denies the allegations in Paragraph 170.

171. Jubilant denies the allegations in Paragraph 171.

172. Jubilant denies the allegations in Paragraph 172.

REQUEST FOR RELIEF

Jubilant denies that Plaintiffs are entitled to any relief. Jubilant requests that the Court dismiss Plaintiffs' Amended Complaint with prejudice, enter judgment in favor of Jubilant, award Jubilant its reasonable attorneys' fees and costs incurred in defending this suit, and award Jubilant such other relief as the Court deems just and proper.

AFFIRMATIVE DEFENSES

Jubilant alleges and asserts the following affirmative defenses in response to the allegations in the Amended Complaint. Jubilant reserves the right to seek leave to assert additional defenses based on the Court's claim construction and as it learns more information through discovery.

FIRST AFFIRMATIVE DEFENSE (NON-INFRINGEMENT)

The manufacture, use or sale of the eslicarbazepine acetate product that is the subject of ANDA No. 211219 has not infringed, is not infringing, and would not, if marketed, infringe, either directly or indirectly, any valid and enforceable claim of the '287 patent, either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE (INVALIDITY)

The claims of the '287 patent are invalid for failure to comply with one or more conditions for patentability as set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or under other judicially-created bases for invalidation.

THIRD AFFIRMATIVE DEFENSE (PROSECUTION HISTORY ESTOPPEL)

Plaintiffs are estopped and/or precluded from asserting that the product described in Jubilant's ANDA No. 211219 infringes the '287 patent by reason of actions taken and statements

made by the applicant for that patent to the PTO during prosecution of the application that lead to the '287 patent.

FOURTH AFFIRMATIVE DEFENSE (NON-INFRINGEMENT)

The manufacture, use or sale of the eslicarbazepine acetate product that is the subject of ANDA No. 211219 has not infringed, is not infringing, and would not, if marketed, infringe, either directly or indirectly, any valid and enforceable claim of the '354 patent, either literally or under the doctrine of equivalents.

FIFTH AFFIRMATIVE DEFENSE (INVALIDITY)

The claims of the '354 patent are invalid for failure to comply with one or more conditions for patentability as set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or under other judicially-created bases for invalidation.

SIXTH AFFIRMATIVE DEFENSE (PROSECUTION HISTORY ESTOPPEL)

Plaintiffs are estopped and/or precluded from asserting that the product described in Jubilant's ANDA No. 211219 infringes the '354 patent by reason of actions taken and statements made by the applicant for that patent to the PTO during prosecution of the application that lead to the '354 patent.

SEVENTH AFFIRMATIVE DEFENSE (NON-INFRINGEMENT)

The manufacture, use or sale of the eslicarbazepine acetate product that is the subject of ANDA No. 211219 has not infringed, is not infringing, and would not, if marketed, infringe, either directly or indirectly, any valid and enforceable claim of the '536 patent, either literally or under the doctrine of equivalents.

EIGHTH AFFIRMATIVE DEFENSE (INVALIDITY)

The claims of the '536 patent are invalid for failure to comply with one or more conditions for patentability as set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or under other judicially-created bases for invalidation.

NINTH AFFIRMATIVE DEFENSE (PROSECUTION HISTORY ESTOPPEL)

Plaintiffs are estopped and/or precluded from asserting that the product described in Jubilant's ANDA No. 211219 infringes the '536 patent by reason of actions taken and statements made by the applicant for that patent to the PTO during prosecution of the application that lead to the '536 patent.

TENTH AFFIRMATIVE DEFENSE (NO WILLFUL INFRINGEMENT)

Plaintiff's claims for enhanced damages, if any, and an award of fees and costs against Jubilant have no basis in fact or law and should be denied.

ELEVENTH AFFIRMATIVE DEFENSE

The Amended Complaint fails to state a claim upon which relief can be granted.

RESERVATION OF ADDITIONAL AFFIRMATIVE DEFENSE

Jubilant reserves the right to assert additional affirmative defenses that may be developed through discovery, or otherwise, in this action.

COUNTERCLAIMS

For its Counterclaims against Plaintiffs, Defendants Jubilant state as follows, without admitting any allegations of the Amended Complaint not expressly admitted and without assuming the burden when such burden would otherwise be on Plaintiffs/Counterclaim-Defendants.

PARTIES

1. 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.

2. 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.

3. 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.

4. 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.

5. 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.

6. Upon information and belief, Plaintiff Bial - Portela & CA S.A. ("Bial - Portela") is a company organized and existing under the laws of Portugal, with its principal place of business at Avenida da Siderurgia Nacional, Coronado (São Romão e São Mamede) 4745-455 Trofa, Portugal.

7. Upon information and belief, Plaintiff Bial - Holding, S.A. ("Bial - Holding") is a corporation organized and existing under the laws of Portugal, with its principal place of business at Avenida da Siderurgia Nacional, Coronado (São Romão e São Mamede) 4745-365 Trofa, Portugal.

8. Plaintiff 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.

JURISDICTION AND VENUE

9. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the patent laws of the United States, Title 35 of the United States Code.

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367, 2201, and 2202.

11. Plaintiffs/Counterclaim-Defendants Bial - Portela, Bial - Holding, and Sunovion (collectively, "Bial") are subject to personal jurisdiction in this Judicial District because Plaintiffs subjected themselves to the jurisdiction of this Court by filing their Amended Complaint here. Plaintiffs Bial are also subject to personal jurisdiction in this Judicial District because: (i) Sunovion sells products here, including the APTIOM® product that is the subject of this case, (ii) Bial - Portela regularly practices business here, (iii) Bial - Holding regularly practices business here, and (iv) Plaintiffs Bial have purposefully availed themselves of the benefits of jurisdiction in the State of Delaware.

12. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) and by Counterclaim-Defendants' choice of forum in filing its Amended Complaint against Jubilant here.

13. As a consequence of Plaintiffs/Counterclaim-Defendants' Amended Complaint against Jubilant, there is now an actual, substantial, continuing and justiciable controversy between the parties as to the infringement, validity, and enforceability of the patents-in-suit.

THE CONTROVERSY

14. The United States Patent and Trademark Office ("USPTO") issued the '287 patent on June 9, 2020, naming Bial-Portela & C.A., S.A. as the assignee on the face of the patent.

15. Upon information and belief, Bial-Portela & C.A., S.A. is the owner of the '287 patent based on an assignment by Jose Luis de Almeida and Patricio Manuel Vieira Araujo Soares da Silva to Portela & C.A., S.A. for application no. 16/449,048 recorded at reel/frame 052849/0982 by a conveyance executed on June 6, 2005 and recorded on June 5, 2020 and a change of name conveyance from Portela & C.A., S.A. to Bial-Portela & C.A., S.A. recorded at reel/frame 052851/0292 by a conveyance executed on July 9, 2009 and recorded on June 5, 2020.

16. The United States Patent and Trademark Office ("USPTO") issued the '354 patent on June 30, 2020, naming Bial-Portela & C.A., S.A. as the assignee on the face of the patent.

17. Upon information and belief, Bial-Portela & C.A., S.A. is the owner of the '354 patent based on an assignment by Jose Luis de Almeida and Patricio Manuel Vieira Araujo Soares da Silva to Portela & C.A., S.A. for application no. 16/449,057 recorded at reel/frame 052858/0205 by a conveyance executed on June 6, 2005 and recorded on June 5, 2020 and a change of name conveyance from Portela & C.A., S.A. to Bial-Portela & C.A., S.A. recorded at reel/frame 052851/0527 by a conveyance executed on July 9, 2009 and recorded on June 5, 2020.

18. The USPTO issued the '536 patent on July 7, 2020, naming Bial-Portela & C.A., S.A. as the assignee on the face of the patent.

19. Upon information and belief, Bial-Portela & C.A., S.A. is the owner of the '536 patent based on an assignment by Jose Luis de Almeida and Patricio Manuel Vieira Araujo Soares da Silva to Portela & C.A., S.A. for application no. 15/422,278 recorded at reel/frame 052803/0684 by a conveyance executed on June 6, 2005 and recorded on June 1, 2020 and a

change of name conveyance from Portela & C.A., S.A. to Bial-Portela & C.A., S.A. recorded at reel/frame 052794/0187 by a conveyance executed on July 9, 2009 and recorded on May 29, 2020.

20. Upon information and belief, Sunovion holds NDA No. 022416 for APTIOM® brand eslicarbazepine acetate oral tablets in 200, 400, 600, and 800 mg dosage strengths.

21. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq., as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") must follow when determining whether to approve for marketing brand and generic drugs.

22. Under the FFDCA, an applicant seeking to market a new brand drug must prepare an NDA for review by the FDA. See 21 U.S.C. § 355.

23. An NDA may include the patent number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. See 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2).

24. An NDA holder is required to submit to the FDA the patent number of each patent relevant to the drug for which the NDA was submitted to the FDA. The FDA automatically lists the NDA holder's disclosed patents pursuant to 21 U.S.C. §§ 355(b)(1) and (c)(2) in the Orange Book.

25. Upon information and belief, Sunovion caused the patents-in-suit (the '287, '354, and '536 patents) to be listed in the Orange Book in connection with NDA No. 022416.

32. Jubilant filed Abbreviated New Drug Application No. 211219 ("Jubilant ANDA") seeking FDA approval to market its formulation of eslicarbazepine acetate oral tablets

in 200, 400, 600, and 800 mg dosage strengths ("Jubilant ANDA Product") and referenced NDA No. 022416. As part of Jubilant's ANDA, Jubilant submitted a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), commonly called a "paragraph IV certification," that the '431, '135, '244, '929, '747 and '954 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of Jubilant's ANDA Product. Jubilant has not yet submitted a paragraph IV certification that the '287, '354 and '536 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of Jubilant's ANDA Product.

33. On March 1, 2018, Plaintiffs/Counterclaim-Defendants Bial sued Jubilant, alleging infringement of the '431, '135, '244, '929, '747 and '954 patents. There has been and is now an actual and justiciable controversy between Jubilant and Bial as to whether the drug products described in ANDA No. 211219 infringe, induce infringement, or contribute to the infringement of any valid, enforceable claims of the patents-in-suit.

34. Jubilant and Plaintiffs/Counterclaim-Defendants have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment with respect to the patents-in-suit. The patents-in-suit effectively delay FDA approval of the drug products described in ANDA No. 211219.

COUNT I

(Declaratory Judgment of Non-Infringement of the '287 Patent by Jubilant's ANDA Product and Declaratory Judgment of Invalidity of the '287 Patent)

35. Jubilant repeats and incorporates by reference Paragraphs 1-34 of its Counterclaims as if fully set forth herein.

36. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a

declaration that no valid claim of the '287 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Jubilant's ANDA Product described by ANDA No. 211219 and that all claims of the '287 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

37. There is an actual, substantial, and continuing justiciable case or controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will infringe any valid and enforceable claim of the '287 patent.

38. Jubilant is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will not infringe, directly or indirectly, any valid claim of the '287 patent.

COUNT II

(Declaratory Judgment of Non-Infringement of the '354 Patent by Jubilant's ANDA Product and Declaratory Judgment of Invalidity of the '354 Patent)

39. Jubilant repeats and incorporates by reference Paragraphs 1-38 of its Counterclaims as if fully set forth herein.

40. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '354 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Jubilant's ANDA Product described by

ANDA No. 211219 and that all claims of the '354 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

41. There is an actual, substantial, and continuing justiciable case or controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will infringe any valid and enforceable claim of the '354 patent.

42. Jubilant is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will not infringe, directly or indirectly, any valid claim of the '354 patent, and/or that all claims of the '354 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

COUNT III

(Declaratory Judgment of Non-Infringement of the '536 Patent by Jubilant's ANDA Product and Declaratory Judgment of Invalidity of the '536 Patent)

43. Jubilant repeats and incorporates by reference Paragraphs 1-42 of its Counterclaims as if fully set forth herein.

44. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '536 patent will be infringed by the manufacture, use, sale,

offer for sale, or importation into the United States of Jubilant's ANDA Product described by ANDA No. 211219 and that all claims of the '536 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

45. There is an actual, substantial, and continuing justiciable case or controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will infringe any valid and enforceable claim of the '536 patent.

46. Jubilant is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will not infringe, directly or indirectly, any valid claim of the '536 patent.

PRAYER FOR RELIEF

WHEREFORE, Jubilant respectfully requests the Court enter a Judgment and Order in its favor and against Counterclaim-Defendants to include:

(a) A declaration that Jubilant's submission of ANDA No. 211219 seeking FDA approval to market its ANDA Product described therein prior to the expiration of the '287 patent has not infringed, and does not infringe, any valid and enforceable claim of the '287 patent;

(b) A declaration that Jubilant's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Jubilant's ANDA Product described by ANDA No. 211219 does not, and will not, infringe any valid and enforceable claim of the '287 patent;

(c) A declaration that the claims of the '287 patent are invalid;

(d) A declaration that Jubilant's submission of ANDA No. 211219 seeking FDA approval to market its ANDA Product described therein prior to the expiration of the '354 patent has not infringed, and does not infringe, any valid and enforceable claim of the '354 patent;

(e) A declaration that Jubilant's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Jubilant's ANDA Product described by ANDA No. 211219 does not, and will not, infringe any valid and enforceable claim of the '354 patent;

(f) A declaration that the claims of the '354 patent are invalid;

(g) A declaration that Jubilant's submission of ANDA No. 211219 seeking FDA approval to market its ANDA Product described therein prior to the expiration of the '536 patent has not infringed, and does not infringe, any valid and enforceable claim of the '536 patent;

(h) A declaration that Jubilant's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Jubilant's ANDA Product described by ANDA No. 211219 does not, and will not, infringe any valid and enforceable claim of the '536 patent;

(i) A declaration that the claims of the '536 patent are invalid;

(j) A declaration that Counterclaim-Defendants are entitled to no damages, interest, costs, or other relief from or against Jubilant;

(k) A declaration that this case is exceptional in favor of Jubilant and awarding attorneys' fees pursuant to 35 U.S.C. § 285, other statutes or rules, or the inherent power of the Court;

(l) An award of costs and expenses;

(m) A declaration that Counterclaim-Defendants are not entitled to injunctive relief; and

(n) Such other and further relief as the Court may deem just and proper.

August 11, 2020

PRICKETT, JONES & ELLIOTT, P.A.

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