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, vs. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC. Defendants.	C.A. No. 20-cv-0782-CFC-CJB

LUPIN LTD. AND LUPIN PHARMACEUTICALS, INC.'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' AMENDED COMPLAINT

Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively "Defendants"), by their attorneys, for their Answer and Affirmative Defenses to the Amended Complaint filed by BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A. (collectively, "Bial"), and Sunovion Pharmaceuticals Inc. ("Sunovion") (collectively, "Plaintiffs") assert their separate defenses as follows.

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Defendants deny all allegation in Plaintiffs' Amended Complaint except those specifically admitted below.

THE PARTIES[1]

1. Defendants lack knowledge or information sufficient to form a belief about the truth of allegations in paragraph 1 and therefore deny them.

[1] Defendants have incorporated the headings that appear in Plaintiffs' Amended Complaint. Defendants do not necessarily agree with the characterization of such headings and do not waive any right to object to those characterizations.

2. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 2 and therefore deny them.

3. Defendants admit that the U.S. Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") lists Sunovion Pharmaceuticals Inc. as the Applicant Holder for New Drug Application ("NDA") No. 022416, APTIOM®. Defendants further admit that the prescribing information for APTIOM®, dated 03/2019, recites, in part:

> **1 INDICATIONS AND USAGE**
>
> APTIOM is indicated for the treatment of partial-onset seizures in patients 4 years of age and older.

Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 3 and therefore deny them.

4. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 4 and therefore deny them.

5. Admitted.

6. Defendants admit that Lupin Ltd. manufactures pharmaceutical products. Defendants deny all other allegations in paragraph 6.

7. Defendants admit that Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Defendants deny all other allegation in paragraph 7.

8. Defendants admit that Lupin Pharmaceuticals, Inc. is an indirect wholly-owned subsidiary of Lupin Ltd. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all other allegations in paragraph 8.

9. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all other allegations in paragraph 9.

10. The allegations in paragraph 10 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all other allegations in paragraph 10.

11. The allegations in paragraph 11 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in paragraph 11.

NATURE OF THE ACTION

12. The allegations in paragraph 12 are legal conclusions to which no answer is required. To the extent that response is required, Defendants admit that Plaintiffs' Amended Complaint is for alleged patent infringement of claims of U.S. Patent Nos. 10,675,287 ("the '287 patent"), 10,695,354 ("the '354 patent"), and 10,702,536 ("the '536 patent") and purports to be a civil action alleging infringement pursuant to Title 35 of the United States Code in connection the submission of Abbreviated New Drug Application ("ANDA") No. 211246 under 21 U.S.C. § 355(j) to the FDA for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny that the Amended Complaint states a proper claim for infringement of the '287 patent, the '354 patent, and the '536 patent and/or that such claims have any merit. Defendants deny all other allegations in paragraph 12.

13. Denied.

14. Defendants admit that on February 23, 2018, Plaintiffs filed Civil Action No. 1:18-cv-00312-CFC-CJB ("the First Suit"), in which Plaintiffs assert claims against Lupin for infringement of claims 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") in connection with Lupin Ltd.'s submission of ANDA

No. 211246. Defendants admit that, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and (iv), Lupin Ltd. transmitted a letter dated January 9, 2018 ("the January 9, 2018 letter") to Plaintiffs notifying them that Lupin Ltd. submitted ANDA No. 211246 to FDA. Lupin further admits that the January 9, 2018 letter states that ANDA No. 211246 included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '431 patent, the '135 patent, the '244 patent, the '929 patent, the '747 patent, and the '954 patent. Defendants further admit that the First Suit included counts for alleged infringement of the '431 patent, the '135 patent, the '244 patent, the '929 patent, the '747 patent, and the '954 patent. Defendants deny all other allegations in paragraph 14.

15. Defendants admit that the First Suit did not include counts for alleged infringement of U.S. Patent No. 5,753,646 ("the '646 patent"). Defendants further admit that the Orange Book lists the expiration date of the '646 patent as June 27, 2021. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j), which included a certification pursuant 21 U.S.C. § 355(j)(2)(A)(vii)(III) for the '646 patent. Defendants admit that, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and (iv), Lupin Ltd. transmitted the January 9, 2018 letter to Plaintiffs notifying them that Lupin Ltd. submitted ANDA No. 211246 to FDA. Lupin further admits that the January 9, 2018 letter states that ANDA No. 211246 included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '431 patent, the '135 patent, the '244 patent, the '929 patent, the '747 patent, and the '954 patent. Defendants deny all other allegations in paragraph 15.

JURISDICTION AND VENUE

16. Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-15, as if fully set forth herein.

17. The allegations in paragraph 17 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiffs' Amended Complaint purports to bring an action for patent infringement under the Patent Laws, 35 U.S.C. § 1 *et seq.* Defendants deny that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg, that are the subject of ANDA No. 211246 would directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '287 patent, the '354 patent, or the '536 patent. Defendants deny all other allegations in paragraph 17.

18. The allegations in paragraph 18 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants state that they do not contest subject matter jurisdiction in this Court solely for purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to the proposed products described in ANDA No. 211246. Defendants deny all other allegations in paragraph 18.

19. The allegations in paragraph 19 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants state that Lupin Ltd. does not contest venue in this Court solely for purposes of Plaintiffs' claims against Lupin Ltd. in this case and solely as they apply to the proposed products described in ANDA No. 211246. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all other allegations in paragraph 19.

20. The allegations in paragraph 20 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants state that Lupin Ltd. does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Lupin Ltd. in this case and solely as they apply to the proposed products described in ANDA No. 211246.

Defendants admit that Lupin Ltd. is a corporation organized and existing under the laws of India. Defendants deny all other allegations in paragraph 20.

21. The allegations in paragraph 21 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants state that Lupin Pharmaceuticals, Inc. does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Lupin Pharmaceuticals, Inc. in this case and solely as they apply to the proposed products described in ANDA No. 211246. Defendants admit that Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all other allegations in paragraph 21.

22. The allegations in paragraph 22 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants state that Lupin Pharmaceuticals, Inc. does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Lupin Pharmaceuticals, Inc. in this case and solely as they apply to the proposed products described in ANDA No. 211246. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all other allegations in paragraph 22.

23. The allegations in paragraph 23 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants state that Lupin Ltd. does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Lupin Ltd. in this case and solely as they apply to the proposed products described in ANDA No. 211246. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all other allegations in paragraph 23.

24. The allegations in paragraph 24 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants state that Lupin Ltd. does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Lupin Ltd. in this case and solely as they apply to the proposed products described in ANDA No. 211246. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all other allegations in paragraph 24.

25. The allegations in paragraph 25 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendant deny all other allegations in paragraph 25.

26. The allegations in paragraph 26 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendant deny all other allegations in paragraph 26.

27. The allegations in paragraph 27 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendant deny all other allegations in paragraph 27.

28. Denied.

29. The allegations in paragraph 29 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Lupin Ltd. submitted ANDA No. 211246 for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 29.

30. The allegations in paragraph 30 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all other allegations in paragraph 30.

31. The allegations in paragraph 31 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants state that Lupin Ltd. does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Lupin Ltd. in this case and solely as they apply to the proposed products described in ANDA No. 211246. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all other allegations in paragraph 31.

32. The allegations in paragraph 32 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that, in the First Suit, Lupin Ltd. did not contest personal jurisdiction solely for purposes of Plaintiffs' alleged claims arising under 35 U.S.C. § 271(e)(2) against Lupin Ltd. in the First Suit and solely as those alleged claims apply to the proposed products described in ANDA No. 211246. Defendants further state that Lupin Ltd. does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Lupin Ltd. in this case and solely as they apply to the proposed products described in ANDA No. 211246. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all other allegations in paragraph 32.

33. The allegations in paragraph 33 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants state that Lupin Ltd. does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Lupin Ltd. in this case and solely as they apply to the proposed products described in ANDA No. 211246. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny all other allegations in paragraph 33.

FACTUAL BACKGROUND
THE NDA

34. Defendants admit that the Orange Book lists Sunovion Pharmaceuticals Inc. as the Applicant Holder for NDA No. 022416, APTIOM® (eslicarbazepine acetate) oral tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 34 and therefore deny them.

35. Defendants admit that, according to FDA's electronic records, FDA approved NDA No. 022416 on November 8, 2013. Defendants admit that the prescribing information for APTIOM®, dated 11/2013, recites, in part:

> **1 INDICATIONS AND USAGE**
> **1.1 Partial-Onset Seizures**
> APTIOM (eslicarbazepine acetate) is indicated as adjunctive treatment of partial-onset seizures.

Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 35 and therefore deny them.

36. Defendants admit that, according to FDA's electronic records, FDA approved NDA No. 022416/S-001 on August 27, 2015. Defendant admit that the prescribing information for APTIOM®, dated 08/2015, recites, in part:

> **1 INDICATIONS AND USAGE**
>
> APTIOM (eslicarbazepine acetate) is indicated for the treatment of partial-onset seizures as monotherapy or adjunctive therapy.

Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 36 and therefore deny them.

37. Defendants admit that, according to FDA's electronic records, FDA approved NDA No. 22416/S-009 on September 13, 2017. Defendants admit that the prescribing information for APTIOM®, dated 09/2017, recites, in part:

> **1 INDICATIONS AND USAGE**
>
> APTIOM is indicated for the treatment of partial-onset seizures in patients 4 years of age and older.

Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 37 and therefore deny them.

38. Defendants admit that the prescribing information for APTIOM®, dated 03/2019, recites, in part:

> **1 INDICATIONS AND USAGE**
>
> APTIOM is indicated for the treatment of partial-onset seizures in patients 4 years of age and older.

Defendants admit that the Orange Book lists eslicarbazepine acetate as the active ingredient of APTIOM®. Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 38 and therefore deny them.

The Patents-in-Suit

39. Defendants admit that the ’287 patent is entitled “Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate” on the face of the patent. Defendants further admit that the ’287 patent lists June 9, 2020 as the Date of Patent. Defendants further admit on information and belief what purports to be a copy of the ’287 patent is attached to the Amended Complaint as Exhibit A. Defendants deny all other allegations in paragraph 39.

40. Defendants admit that the ’287 patent lists “BIAL-PORTELA & CA S.A.” as the Assignee. Defendants further admit on information and belief that the Orange Book lists the expiration of the ’287 patent as May 6, 2025. Defendants lack knowledge of information sufficient to form a belief about the truth of all other allegations in paragraph 40 and therefore deny them.

41. Defendants acknowledge that the Orange Book lists the '287 patent in connection with NDA No. 022416. Defendants deny all other allegations in paragraph 41.

42. Defendants deny that the allegations accurately and completely recite the limitations of the claims of the '287 patent and, therefore, deny the allegations.

43. Defendants admit that the prescribing information for APTIOM®, dated 03/2019, recites, in part:

1 INDICATIONS AND USAGE

APTIOM is indicated for the treatment of partial-onset seizures in patients 4 years of age and older.

Defendants further admit that the prescribing information for APTIOM®, dated 03/2019, recites, in part:

2.2 General Dosing Recommendations

Monotherapy and Adjunctive Therapy

Adult Patients

The recommended initial dosage of APTIOM is 400 mg administered orally once daily. For some patients, treatment may be initiated at 800 mg once daily if the need for seizure reduction outweighs an increased risk of adverse reactions during initiation *[see Adverse Reactions (6.1)]*. Dosage should be increased in weekly increments of 400 mg to 600 mg, based on clinical response and tolerability, to a recommended maintenance dosage of 800 mg to 1600 mg once daily. For patients on APTIOM monotherapy, the 800 mg once daily maintenance dose should generally be considered in patients who are unable to tolerate a 1200 mg daily dose. For patients on APTIOM adjunctive therapy, the 1600 mg daily dose should generally be considered in patients who did not achieve a satisfactory response with a 1200 mg daily dose.

Pediatric Patients (4 to 17 Years of Age)

In pediatric patients 4 to 17 years of age, the recommended dosing regimen is dependent upon body weight and is administered orally once daily. The recommended initial dosage of APTIOM is shown in Table 1. Dosage should be increased based on clinical response and tolerability, no more frequently than once per week. Titration increments should not exceed those shown in Table 1. The daily maintenance dosage should not exceed the maintenance dosage for each body weight range shown in Table 1.

Table 1: APTIOM Once Daily Dosage Schedule for Pediatric Patients 4 to 17 Years of Age

Body Weight Range	Initial and Maximum Titration Increment Dosage (mg/day)	Maintenance Dosage (mg/day)
11 to 21 kg	200	400 to 600
22 to 31 kg	300	500 to 800
32 to 38 kg	300	600 to 900
more than 38 kg	400	800 to 1200

Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 43 and therefore deny them.

44. The allegations of paragraph 44 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in paragraph 44.

45. Defendants admit that the '354 patent is entitled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate" on the face of the patent. Defendants further admit that the '354 patent lists June 30, 2020 as the Date of Patent. Defendants further admit on information and belief that what purports to be a copy of the '354 patent is attached to the Amended Complaint as Exhibit B. Defendants deny all other allegations in paragraph 45.

46. Defendants admit that the '354 patent lists "BIAL-PORTER & CA S.A." as the Assignee. Defendants further admit on information and belief that the Orange Book lists the expiration of the '354 patent as May 6, 2025. Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 46 and therefore deny them.

47. Defendants acknowledge that the Orange Book lists the '354 patent in connection with NDA No. 022416. Defendants deny all other allegations in paragraph 47.

48. Defendants deny that the allegations accurately and completely recite the limitations of the claims of the '354 patent and, therefore, deny the allegations.

49. Defendants admit that the prescribing information for APTIOM®, dated 03/2019, recites, in part:

> **1 INDICATIONS AND USAGE**
>
> APTIOM is indicated for the treatment of partial-onset seizures in patients 4 years of age and older.

Defendants further admit that the prescribing information for APTIOM®, dated 03/2019, recites, in part:

2.2 General Dosing Recommendations

Monotherapy and Adjunctive Therapy

Adult Patients

The recommended initial dosage of APTIOM is 400 mg administered orally once daily. For some patients, treatment may be initiated at 800 mg once daily if the need for seizure reduction outweighs an increased risk of adverse reactions during initiation *[see Adverse Reactions (6.1)]*. Dosage should be increased in weekly increments of 400 mg to 600 mg, based on clinical response and tolerability, to a recommended maintenance dosage of 800 mg to 1600 mg once daily. For patients on APTIOM monotherapy, the 800 mg once daily maintenance dose should generally be considered in patients who are unable to tolerate a 1200 mg daily dose. For patients on APTIOM adjunctive therapy, the 1600 mg daily dose should generally be considered in patients who did not achieve a satisfactory response with a 1200 mg daily dose.

Pediatric Patients (4 to 17 Years of Age)

In pediatric patients 4 to 17 years of age, the recommended dosing regimen is dependent upon body weight and is administered orally once daily. The recommended initial dosage of APTIOM is shown in Table 1. Dosage should be increased based on clinical response and tolerability, no more frequently than once per week. Titration increments should not exceed those shown in Table 1. The daily maintenance dosage should not exceed the maintenance dosage for each body weight range shown in Table 1.

Table 1: APTIOM Once Daily Dosage Schedule for Pediatric Patients 4 to 17 Years of Age

Body Weight Range	Initial and Maximum Titration Increment Dosage (mg/day)	Maintenance Dosage (mg/day)
11 to 21 kg	200	400 to 600
22 to 31 kg	300	500 to 800
32 to 38 kg	300	600 to 900
more than 38 kg	400	800 to 1200

Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 49 and therefore deny them.

50. The allegations of paragraph 50 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in paragraph 50.

51. Defendants admit that the ’536 patent is entitled “Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate” on the face of the patent. Defendants further admit that the ’536 patent lists July 7, 2020 as the Date of Patent. Defendants further admit on

information and belief that what purports to be a copy of the '536 patent is attached to the Amended Complaint as Exhibit C. Defendants deny all other allegations in paragraph 51.

52. Defendants admit that the '536 patent lists "BIAL-PORTELA & CA S.A." as the Assignee. Defendants further admit on information and belief that the Orange Book lists the expiration date of the '536 patent as May 6, 2025. Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 52 and therefore deny them.

53. Defendants acknowledge that the Orange Book lists the '536 patent in connection with NDA No. 022416. Defendants deny all other allegations in paragraph 53.

54. Defendants deny that the allegations accurately and completely recite the limitations of the claims of the '536 patent and, therefore, deny the allegations.

55. Defendants admit that the prescribing information for APTIOM®, dated 03/2019, recites, in part:

> **1 INDICATIONS AND USAGE**
>
> APTIOM is indicated for the treatment of partial-onset seizures in patients 4 years of age and older.

Defendants further admit that the prescribing information for APTIOM®, dated 03/2019, recites, in part:

2.2 General Dosing Recommendations

Monotherapy and Adjunctive Therapy

Adult Patients

The recommended initial dosage of APTIOM is 400 mg administered orally once daily. For some patients, treatment may be initiated at 800 mg once daily if the need for seizure reduction outweighs an increased risk of adverse reactions during initiation *[see Adverse Reactions (6.1)]*. Dosage should be increased in weekly increments of 400 mg to 600 mg, based on clinical response and tolerability, to a recommended maintenance dosage of 800 mg to 1600 mg once daily. For patients on APTIOM monotherapy, the 800 mg once daily maintenance dose should generally be considered in patients who are unable to tolerate a 1200 mg daily dose. For patients on APTIOM adjunctive therapy, the 1600 mg daily dose should generally be considered in patients who did not achieve a satisfactory response with a 1200 mg daily dose.

Pediatric Patients (4 to 17 Years of Age)

In pediatric patients 4 to 17 years of age, the recommended dosing regimen is dependent upon body weight and is administered orally once daily. The recommended initial dosage of APTIOM is shown in Table 1. Dosage should be increased based on clinical response and tolerability, no more frequently than once per week. Titration increments should not exceed those shown in Table 1. The daily maintenance dosage should not exceed the maintenance dosage for each body weight range shown in Table 1.

Table 1: APTIOM Once Daily Dosage Schedule for Pediatric Patients 4 to 17 Years of Age

Body Weight Range	Initial and Maximum Titration Increment Dosage (mg/day)	Maintenance Dosage (mg/day)
11 to 21 kg	200	400 to 600
22 to 31 kg	300	500 to 800
32 to 38 kg	300	600 to 900
more than 38 kg	400	800 to 1200

Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 55 and therefore deny them.

56. The allegations of paragraph 56 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in paragraph 56.

The ANDA

57. Defendants admit that, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and (iv), Lupin Ltd. transmitted the January 9, 2018 letter to Plaintiffs notifying them that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants further admit that ANDA No. 211246 identifies

APTIOM® (eslicarbazepine acetate) tablets, 200 mg, 400 mg, 600 mg, and 800 mg, as the Reference Listed Drug. Defendants deny all other allegations in paragraph 57.

58. Defendants admit that, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and (iv), Lupin Ltd. transmitted the January 9, 2018 letter to Plaintiffs notifying them that Lupin Ltd. submitted ANDA No. 211246 to FDA. Lupin further admits that the January 9, 2018 letter states that ANDA No. 211246 included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '431 patent, the '135 patent, the '244 patent, the '929 patent, the '747 patent, and the '954 patent. Defendants deny all other allegations in paragraph 58.

59. Defendants admit that the Orange Book lists the expiration date of the '135 patent and the '929 patent as April 21, 2026. Defendants further admit that the Orange Book lists the expiration date of the '287 patent, the '354 patent, and the '536 patent as May 6, 2025. Defendants deny all other allegations in paragraph 59.

60. Defendants admit that, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and (iv), Lupin Ltd. transmitted the January 9, 2018 letter to Plaintiffs notifying them that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 60.

61. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants acknowledge that ANDA No. 211246 was submitted prior to the expiration of the '287 patent, the '354 patent, and '536 patent. Defendants deny all other allegations in paragraph 61.

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

62. Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-61, as if fully set forth herein.

63. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants acknowledge that ANDA No. 211246 was submitted prior to the expiration of the '287 patent. Defendants deny all other allegations in paragraph 63.

64. The allegations in paragraph 64 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants state that ANDA No. 211246 speaks for itself. Defendants further admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants further admit that ANDA No. 211246 identifies APTIOM® (eslicarbazepine acetate) tablets, 200 mg, 400 mg, 600 mg, and 800 mg, as the Reference Listed Drug and that ANDA No. 211246 contains information intended to establish bioequivalence with the Reference Listed Drug. Defendants deny all other allegations in paragraph 64.

65. Denied.

66. Denied.

67. Denied.

68. Denied.

69. Denied.

70. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants acknowledge that the Orange Book lists the '287 patent in connection with NDA No. 022416. Defendants deny all other allegations in paragraph 70.

71. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 71.

72. Denied.

73. Denied.

74. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 74.

75. Denied.

COUNT II
(DECLARATORY JUDGEMENT OF INFRINGEMENT OF THE ’287 PATENT)

76. Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-75, as if fully set forth herein.

77. The allegations in paragraph 77 state legal conclusions to which no answer is required. To the extent that a response is required, Defendants admit that Plaintiffs’ claims purport to arise under 28 U.S.C. § 2201 and 2202. Defendants deny all other allegations in paragraph 77.

78. The allegations in paragraph 78 state legal conclusions to which no answer is required. To the extent that a response is required, Defendants admit that Plaintiffs’ Amended Complaint against Defendants purports to be a civil action alleging infringement of the ’287 patent and seeking a declaratory judgment of infringement of the ’287 patent pursuant to Title 35 of the United States Code. Defendants deny all other allegations in paragraph 78.

79. The allegations in paragraph 79 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Lupin Ltd. submitted

ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants acknowledge that ANDA No. 211246 was submitted prior to the expiration of the '287 patent. Defendants deny all other allegations in paragraph 79.

80. Denied.

81. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants acknowledge that ANDA No. 211246 was submitted prior to the expiration of the '287 patent. Defendants deny all other allegations in paragraph 81.

82. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 82.

83. Denied.

84. Denied.

85. Denied.

86. Denied.

87. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants acknowledge that the Orange Book lists the '287 patent in connection with NDA No. 022416. Defendants deny all other allegations in paragraph 87.

88. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 88.

89. Denied.

90. Denied.

91. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 91.

92. Denied.

93. Denied.

94. Denied.

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

95. Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-94, as if fully set forth herein.

96. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants acknowledge that ANDA No. 211246 was submitted prior to the expiration of the '354 patent. Defendants deny all other allegations in paragraph 96.

97. The allegations in paragraph 97 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants state that ANDA No. 211246 speaks for itself. Defendants further admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants further admit that ANDA No. 211246 identifies APTIOM® (eslicarbazepine acetate) tablets, 200 mg, 400 mg, 600 mg, and 800 mg, as the Reference Listed Drug and that ANDA No. 211246 contains information intended to establish bioequivalence with the Reference Listed Drug. Defendants deny all other allegations in paragraph 97.

98. Denied.

99. Denied.

100. Denied.

101. Denied.

102. Denied.

103. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants acknowledge that the Orange Book lists the '354 patent in connection with NDA No. 022416. Defendants deny all other allegations in paragraph 103.

104. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 104.

105. Denied.

106. Denied.

107. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 107.

108. Denied.

COUNT IV
(DECLARATORY JUDGEMENT OF INFRINGEMENT OF THE '354 PATENT)

109. Defendants repeat and re-allege their answers to each of the preceding paragraph 1-108, as if fully set forth herein.

110. The allegations in paragraph 110 state legal conclusions to which no answer is required. To the extent that a response is required, Defendants admit that Plaintiffs' claim

purport to arise under 28 U.S.C. § 2201 and 2202. Defendants deny all other allegations in paragraph 110.

111. The allegations in paragraph 111 state legal conclusions to which no answer is required. To the extent that a response is required, Defendants admit that Plaintiffs' Amended Complaint against Defendants purports to be a civil action alleging infringement of the '354 patent and seeking a declaratory judgment of infringement of the '354 patent pursuant to Title 35 of the United States Code. Defendants deny all other allegations in paragraph 111.

112. The allegations in paragraph 112 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants acknowledge that ANDA No. 211246 was submitted prior to the expiration of the '354 patent. Defendants deny all other allegations in paragraph 112.

113. Denied.

114. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants acknowledge that ANDA No. 211246 was submitted prior to the expiration of the '354 patent. Defendants deny all other allegations in paragraph 114.

115. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 115.

116. Denied.

117. Denied.

118. Denied.

119. Denied.

120. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants acknowledge that the Orange Book lists the '354 patent in connection with NDA No. 022416. Defendants deny all other allegations in paragraph 103.

121. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 121.

122. Denied.

123. Denied.

124. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 124.

125. Denied.

126. Denied.

127. Denied.

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

128. Defendants repeat and re-allege their answers to each of the preceding paragraph 1-127, as if fully set forth herein.

129. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants acknowledge that ANDA No. 211246 was submitted prior to the expiration of the '536 patent. Defendants deny all other allegations in paragraph 129.

130. The allegations in paragraph 130 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants state that ANDA No. 211246 speaks for itself. Defendants further admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants further admit that ANDA No. 211246 identifies APTIOM® (eslicarbazepine acetate) tablets, 200 mg, 400 mg, 600 mg, and 800 mg, as the Reference Listed Drug and that ANDA No. 211246 contains information intended to establish bioequivalence with the Reference Listed Drug. Defendants deny all other allegations in paragraph 130.

131. Denied.

132. Denied.

133. Denied.

134. Denied.

135. Denied.

136. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants acknowledge that the Orange Book lists the ’536 patent in connection with NDA No. 022416. Defendants deny all other allegations in paragraph 136.

137. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 137.

138. Denied.

139. Denied.

140. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 140.

141. Denied.

COUNT VI
(DECLARATORY JUDGEMENT OF INFRINGEMENT OF THE '536 PATENT)

142. Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-141, as if fully set forth herein.

143. The allegations in paragraph 143 state legal conclusions to which no answer is required. To the extent that a response is required, Defendants admit that Plaintiffs' claims purport to arise under 20 U.S.C. § 2201 and 2202. Defendants deny all other allegations in paragraph 143.

144. The allegations in paragraph 144 state legal conclusions to which no answer is required. To the extent that a response is required, Defendants admit that Plaintiffs' Amended Complaint against Defendants purports to be a civil action alleging infringement of the '536 patent and seeking a declaratory judgment of infringement of the '536 patent pursuant to Title 35 of the United States Code. Defendants deny all other allegations in paragraph 144.

145. The allegations in paragraph 145 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit the Lupin Ltd. submitted ANDA No. 211246 to FDA seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants acknowledge that ANDA No. 211246 was submitted prior to the expiration of the '536 patent. Defendants deny all other allegations in paragraph 145.

146. Denied

147. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants acknowledge that ANDA No. 211246 was submitted prior to the expiration of the '536 patent. Defendants deny all other allegations in paragraph 147.

148. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 148.

149. Denied.

150. Denied.

151. Denied.

152. Denied.

153. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants acknowledge that the Orange Book lists the '536 patent in connection with NDA No. 022416. Defendants deny all other allegations in paragraph 153.

154. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 154.

155. Denied.

156. Denied.

157. Defendants admit that Lupin Ltd. submitted ANDA No. 211246 to FDA under 21 U.S.C. § 355(j) for eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. Defendants deny all other allegations in paragraph 157.

158. Denied.

159. Denied.

160. Denied.

REQUEST FOR RELIEF

Defendants deny all remaining allegations not specifically admitted herein. Defendants further deny that Plaintiffs are entitled to any judgment or relief requested in the Amended Complaint, or to any relief whatsoever. Defendants respectfully request that the Court: (a) dismiss the Amended Complaint with prejudice; (b) enter judgment in favor of Defendants; (c) award Defendants the reasonable attorneys' fees and costs of defending this action pursuant to 35 U.S.C. § 285; and (d) award Defendants such further relief as the Court deems just and appropriate.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in their Answer and without admitting any allegations of the Amended Complaint not otherwise admitted, Defendants aver and assert the following Affirmative Defenses to Plaintiffs' Amended Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,675,287)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg, that are the

subject of ANDA No. 211246 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’287 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,675,287)

Upon information and belief, the claims of the ’287 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

THIRD AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,695,354)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg, that are the subject of ANDA No. 211246 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’354 patent.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,695,354)

Upon information and belief, the claims of the ’354 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

FIFTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,702,536)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the proposed eslicarbazepine acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg, that are the

subject of ANDA No. 211246 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '536 patent.

SIXTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,702,536)

Upon information and belief, the claims of the '536 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

SEVENTH AFFIRMATIVE DEFENSE
(Failure to State a Claim)

The Amended Complaint in whole or in part fails to state a claim upon which relief can be granted.

EIGHTH AFFIRMATIVE DEFENSE
(Improper Party)

Lupin Pharmaceuticals, Inc. is not a proper party under 35 U.S.C. § 271(e)(2)(A).

NINTH AFFIRMATIVE DEFENSE
(No Costs)

Plaintiffs are barred by 35 U.S.C. § 288 from recovering any cost associated with the suit.

TENTH AFFIRMATIVE DEFENSE
(Lack of Subject Matter Jurisdiction)

This Court lacks subject matter jurisdiction over any and all claims asserted against Lupin Pharmaceuticals, Inc. and any and all claims asserted under 35 U.S.C. § 271(a), (b) or (c).

ELEVENTH AFFIRMATIVE DEFENSE
(Failure to State an Exceptional Case and/or Willful Infringement)

The Amended Complaint fails to state a claim for exceptional case and/or willful infringement under 35 U.S.C. § 285 and/or 35 U.S.C. § 271(e)(4).

RESERVATION OF DEFENSES

Defendants expressly reserve the right to supplement and/or amend their Answer to Plaintiffs' Amended Complaint, including, but not limited to, supplementation and/or amendment of their defenses and amplifications of denials, as additional facts and information become known through the course of this case and discovery hereby reserve any and all defenses.

Date: August 11, 2020

PHILLIPS McLAUGHLIN & HALL, P.A.

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