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.	)	C.A. No. 21-186-CFC
ALKEM LABORATORIES LIMITED and S&B PHARMA, INC.,	)	
Defendants.	)	

DEFENDANTS ALKEM LABORATORIES LIMITED AND S&B PHARMA, INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Alkem Laboratories Limited ("Alkem") and S&B Pharma, Inc. ("S&B") (collectively, "Defendants") respond to the Complaint by Plaintiffs BIAL - PORTELA & CA S.A. ("Bial"), BIAL - HOLDING, S.A. ("Bial Holding"), and Sunovian Pharmaceuticals Inc. ("Sunovion") (collectively, "Plaintiffs") as follows:

THE PARTIES

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

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

ANSWER: Defendants admit that, according to records available on the website of the United States Patent and Trademark Office ("USPTO"), the asserted patent is assigned to Bial - Portela & CA S.A. Defendants admit that the asserted patent is listed in the electronic version of the publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book"), which is available on the website of the United States Food and Drug Administration ("FDA"), in connection with New Drug Application ("NDA") No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets. Defendants admit that APTIOM® is approved by the FDA 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 any remaining allegations in this paragraph, and therefore deny them.

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

ANSWER: Admitted.

5. On information and belief, Alkem Laboratories is a corporation organized and existing under the laws of India, with its principal place of business at Alkem House, Senapati Bapat Marg, Lower Parel, Mumbai MH 400013 India.

ANSWER: Admitted.

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

ANSWER: Defendants admit that S&B Pharma, Inc. is a corporation organized and existing under the laws of Delaware, with a place of business at 1733 Gilsinn Lane, Fenton, Missouri 63026-2000. Defendants deny that S&B Pharma, Inc. is a proper party to this action. Defendants deny any remaining allegations in this paragraph.

7. On information and belief, S&B Pharma is a corporation organized and existing under the laws of Delaware, with its principal place of business at 405 S Motor Ave, Azusa, California, 91702-3232, United States.

ANSWER: Defendants admit that S&B Pharma, Inc. is a corporation organized and existing under the laws of Delaware, with a place of business at 405 S Motor Ave, Azusa, California, 91702-3232, United States. Defendants deny that S&B Pharma, Inc. is a proper party to this action. Defendants deny any remaining allegations in this paragraph.

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

ANSWER: Defendants admit that S&B Pharma, Inc. is a subsidiary of Alkem. Defendants deny that S&B Pharma, Inc. is a proper party to this action.

9. On information and belief, S&B Pharma is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware, in concert with Alkem Laboratories.

ANSWER: Defendants admit that S&B Pharma, Inc. is in the business of, *inter alia*, manufacturing, marketing, and selling pharmaceutical products in the United States, including in the State of Delaware. Defendants deny that S&B Pharma, Inc. is a proper party to this action. Defendants deny any remaining allegations in this paragraph.

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

ANSWER: Defendants deny that S&B Pharma, Inc. is a proper party to this action. Defendants deny any remaining allegations in this paragraph.

11. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg Abbreviated New Drug Application ("ANDA") No. 211199, Alkem Laboratories and S&B Pharma will act in concert to distribute and sell the generic product described in Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg ANDA No. 211199 ("Alkem's Generic Product") throughout the United States, including the State of Delaware.

ANSWER: Defendants admit that Alkem filed ANDA No. 211199, seeking approval to market Alkem's Generic Product throughout the United States, including in Delaware. Defendants deny any remaining allegations in this paragraph.

NATURE OF THE ACTION

12. This is a civil action for patent infringement of U.S. Patent No. 10,912,781 ("the '781 patent" or "the patent-in-suit") arising under the United States Patent Laws, Title 35, United States Code, § 1, et. seq., and in particular under 35 U.S.C. § 271. This action relates to ANDA No. 211199, which Alkem filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA"), for approval to market in the United States a generic copy of Plaintiffs' APTIOM® product prior to the expiration of the patent-in-suit.

ANSWER: Defendants admit that this purports to be a civil action for patent infringement under the United States Patent Laws, Title 35, United States Code, § 1, *et. seq.*, and in particular under 35 U.S.C. § 271. Defendants admit that this action purports to relate to ANDA No. 211199, which seeks approval to market Alkem's Generic Product in the United States. Defendants deny any remaining allegations in this paragraph.

13. Alkem has infringed one or more claims of the '781 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 211199 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Alkem's Generic Product prior to the expiration of the '781 patent, or any extensions thereof. Alkem will infringe one or more claims of the '781 patent under 35 U.S.C. § 271(a), (b), or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Alkem's Generic Product prior to the expiration of the '781 patent, or any extensions thereof.

ANSWER: Denied.

14. Plaintiffs previously filed a separate action in this Court against Alkem for patent infringement, which included counts for 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"). *Bial - Portela & CA S.A., et al. v. Alkem Laboratories Limited*, *et al.,* C.A. No. 18-304-CFC (the "First Suit") was filed on February 22, 2018. The First Suit was filed in response to a letter from Alkem dated January 8, 2018 ("Alkem's First Notice Letter"), purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 211199 pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 as to the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '954 patent. The First Suit included counts for

infringement of the ’747 patent, the ’431 patent, the ’135 patent, the ’244 patent, the ’929 patent, and the ’954 patent.

ANSWER: Defendants admit Plaintiffs filed the First Suit including counts for infringement of the ’747 patent, the ’431 patent, the ’135 patent, the ’244 patent, the ’929 patent, and the ’954 patent. Defendants deny any remaining allegations in this paragraph.

15. Plaintiffs previously filed a separate action in this Court against Alkem for patent infringement, which included counts for 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”). *Bial - Portela & CA S.A., et al. v. Alkem Laboratories Limited*, *et al.,* C.A. No. 20-786-CFC (the “Second Suit”) was filed on June 9, 2020, and an amended complaint was filed on July 7, 2020. Plaintiffs received a letter from Alkem dated November 25, 2020 (“Alkem’s Second Notice Letter”), purporting to be a “Supplemental Notice of Paragraph IV Certification” for ANDA No. 211199 pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 as to the ’287, patent, the ’354 patent, and the ’536 patent. The Second Suit included counts for infringement of the ’287 patent, the ’354 patent, and the ’536 patent.

ANSWER: Defendants admit Plaintiffs filed the Second Suit including counts for infringement of the’287 patent, the ’354 patent, and the ’536 patent. Defendants deny any remaining allegations in this paragraph.

16. The First Suit and the Second Suit did not include counts for infringement of U.S. Patent No. 5,753,646 (“the ’646 patent”), which will expire on June 27, 2021, because Alkem’s First Notice Letter and Alkem’s Second Notice Letter did not assert noninfringement or invalidity of the ’646 patent. Based on information and belief, Alkem is maintaining its certification as to the ’747 patent, the ’431 patent, the ’135 patent, the ’244 patent, the ’929 patent, the ’954 patent, the ’287 patent, the ’354 patent, and the ’536 patent set out in Alkem’s First Notice Letter and Alkem’s Second Notice Letter. Thus, Plaintiffs will continue to prosecute all infringement counts presented in the First Suit and the Second Suit.

ANSWER: Defendants admit the First Suit and Second Suit did not include counts for infringement of the ’646 patent and that Alkem is maintaining its certification as to the ’747 patent, the ’431 patent, the ’135 patent, the ’244 patent, the ’929 patent, the ’954 patent, the ’287 patent, the ’354 patent, and the ’536 patent. Defendants deny any remaining allegations in this paragraph.

JURISDICTION AND VENUE

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

ANSWER: Alkem incorporates its answers to each of the prior paragraphs.

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

ANSWER: Defendants admit that this purports to be a civil action for patent infringement and declaratory judgment 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. Defendants deny any remaining allegations in this paragraph.

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

ANSWER: This paragraph states a legal conclusion to which no answer is required. To the extent an answer is required, Defendants admit that this Court generally has subject matter jurisdiction over a civil action properly alleging infringement of a U.S. patent under 28 U.S.C. §§ 1331 and 1338(a). Defendants deny any remaining allegations in this paragraph.

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

ANSWER: This paragraph states a legal conclusion to which no answer is required. To the extent an answer is required, Alkem does not contest venue in this proceeding. Defendants deny that S&B Pharma, Inc. is a proper party to this action. Defendants deny any remaining allegations in this paragraph.

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

ANSWER: This paragraph states a legal conclusion to which no answer is required. To the extent an answer is required, Alkem does not contest personal jurisdiction in this proceeding. Defendants deny any remaining allegations in this paragraph.

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

ANSWER: This paragraph states a legal conclusion to which no answer is required. To the extent an answer is required, S&B Pharma does not contest personal jurisdiction in this proceeding. Defendants deny that S&B Pharma, Inc. is a proper party to this action and deny any remaining allegations in this paragraph.

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

ANSWER: This paragraph states a legal conclusion to which no answer is required. To the extent an answer is required, Defendants deny that S&B Pharma, Inc. is a proper party to this action and deny any remaining allegations in this paragraph.

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

ANSWER: This paragraph states a legal conclusion to which no answer is required. To the extent an answer is required, Alkem does not contest personal jurisdiction in this proceeding. Defendants deny any remaining allegations in this paragraph.

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

ANSWER: This paragraph states a legal conclusion to which no answer is required. To the extent an answer is required, Alkem does not contest personal jurisdiction in this proceeding only. Defendants deny any remaining allegations in this paragraph.

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

ANSWER: Denied. Defendants also deny that S&B Pharma, Inc. is a proper party to this action.

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

ANSWER: Denied. Defendants also deny that S&B Pharma, Inc. is a proper party to this action.

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

ANSWER: Denied. Defendants also deny that S&B Pharma, Inc. is a proper party to this action.

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

ANSWER: This paragraph states a legal conclusion to which no answer is required. To the extent an answer is required, Alkem does not contest personal jurisdiction in this proceeding. Defendants deny any remaining allegations in this paragraph.

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

ANSWER: Defendants admit that Alkem filed ANDA No. 211199, seeking approval to market Alkem's Generic Product throughout the United States, including in Delaware. Defendants deny any remaining allegations in this paragraph.

31. This Court also has personal jurisdiction over S&B Pharma because, *inter alia*, S&B Pharma has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, S&B Pharma, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Alkem's website, https://www.alkemlabs.com/pdf/subsidiary-account/19-20/S-B_Pharma_Inc-USA.pdf (accessed February 10, 2021), the contents of which are incorporated herein by reference, states that Alkem - India's principal business objective in the formation of S&B Pharma is to manufacture, formulate and package generic prescription pharmaceutical products for distribution in the United States (U.S.)." On information and belief, S&B Pharma derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

ANSWER: This paragraph states a legal conclusion to which no answer is required. To the extent an answer is required, Defendants deny that S&B Pharma, Inc. is a proper party to this action. Defendants deny any remaining allegations in this paragraph.

32. This Court also has personal jurisdiction over Alkem because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Alkem has previously invoked this Court's jurisdiction by asserting counterclaims in C.A. Nos.18-304-CFC, 20-786-CFC, and at least 16 other cases. *See, e.g.*, 20-cv-00106, 19-cv-01727, 19-cv-01493, 18-cv-01738, 16-cv-00747, 14-cv-00917, 13-cv-01110, and 12-cv-01663.

ANSWER: This paragraph states a legal conclusion to which no answer is required. To the extent an answer is required, Alkem does not contest personal jurisdiction in this proceeding only. Defendants deny any remaining allegations in this paragraph.

33. This Court also has personal jurisdiction over Alkem because Alkem did not contest jurisdiction in the First Suit or the Second Suit.

ANSWER: This paragraph states a legal conclusion to which no answer is required. To the extent an answer is required, Alkem does not contest personal jurisdiction in this proceeding only. Defendants deny any remaining allegations in this paragraph.

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

ANSWER: This paragraph states a legal conclusion to which no answer is required. To the extent an answer is required, Alkem does not contest personal jurisdiction in this proceeding. Defendants deny any remaining allegations in this paragraph.

FACTUAL BACKGROUND

The NDA

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

ANSWER: Defendants admit that, according to records available on the FDA website, Sunovion is the holder of NDA No. 022416. Defendants lack knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore deny them.

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

ANSWER: Defendants admit that, according to records available on the FDA website, on November 8, 2013, the FDA approved the use of APTIOM® (eslicarbazepine acetate) 200, 400, 600, and 800 mg tablets for adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy 18 years and older. Defendants lack knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore deny them.

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

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

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

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

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

ANSWER: Defendants admit that, according to the current FDA-approved prescribing information, APTIOM® is approved for the treatment of partial-onset seizures in patients 4 years of age and older and eslicarbazepine acetate is the active ingredient in APTIOM®. Defendants lack knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore deny them.

The Patent-in-Suit

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

ANSWER: Defendants admit that what purports to be a copy of the ’781 patent was attached to the Complaint as Exhibit A. Defendants deny any remaining allegations in this paragraph.

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

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore deny them.

42. Information regarding the ’781 patent was submitted to the FDA for listing in the Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

ANSWER: Admitted.

43. The ’781 patent covers pharmaceutical compositions comprising licarbazepine acetate.

ANSWER: Defendants admit that the ‘781 patent is entitled “Pharmaceutical Composition Comprising Licarbazepine Acetate.” Defendants deny any remaining allegations in this paragraph.

The ANDA

44. On information and belief, Alkem filed ANDA No. 211199 with the FDA under 21 U.S.C. § 355(j) before January 8, 2018, to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms, which are generic versions of Plaintiffs’ APTIOM® (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms.

ANSWER: Admitted.

45. Alkem’s First Notice Letter alleged 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 the activities described in Alkem’s ANDA No. 211199. Alkem’s First Notice Letter also informed Plaintiffs that Alkem seeks approval to market Alkem’s Generic Product before the ’747, ’431, ’135, ’244, ’929, and ’954 patents expire.

ANSWER: Admitted.

46. Alkem’s Second Notice Letter alleged that the claims of the ’287 patent, the ’354 patent, and the ’536 patent are invalid and/or will not be infringed by the activities described in Alkem’s ANDA No. 211199. Alkem’s Second Notice Letter also informed Plaintiffs that Alkem seeks approval to market Alkem’s Generic Product before the ’287, ’354, and ’536 patents expire.

ANSWER: Admitted.

47. The ’747 patent will expire on August 24, 2032. The ’431 patent will expire on April 17, 2030. The ’135 and ’929 patents will expire on April 21, 2026. The ’244 patent will expire on October 23, 2028. The ’954 patent will expire on September 13, 2028. The ’287, ’354, and ’536 patents will expire on May 6, 2025. The ’781 patent will expire on October 23, 2028.

ANSWER: Defendants admit that, according to the Orange Book, the '747 patent will expire on August 24, 2032, the '431 patent will expire on April 17, 2030, the '135 and '929 patents will expire on April 21, 2026, the '244 patent will expire on October 23, 2028, the '954 patent will expire on September 13, 2028, the '287, '354, and '536 patents will expire on May 6, 2025, and the '781 patent will expire on October 23, 2028. Defendants deny any remaining allegations in this paragraph.

48. Alkem's ANDA No. 211199 has been pending before the FDA since at least January 8, 2018, the date of Alkem's First Notice Letter to Plaintiffs.

ANSWER: Admitted.

49. On information and belief, following FDA approval of Alkem's ANDA No. 211199, Alkem will make, use, sell, or offer to sell Alkem's Generic Product throughout the United States, or import such generic products into the United States before the '781 patent expires.

ANSWER: Defendants admit that Alkem filed ANDA No. 211199, seeking approval to market Alkem's Generic Product in the United States. Defendants deny any remaining allegations in this paragraph.

COUNT I

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

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

ANSWER: Defendants incorporate their answers to each of the prior paragraphs.

51. On information and belief, Alkem filed ANDA No. 211199 in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Alkem's Generic Product in the United States before the expiration of the '781 patent.

ANSWER: Defendants admit that Alkem filed ANDA No. 211199. Alkem has not yet filed a patent certification with respect to the '781 patent. Defendants deny any remaining allegations in this paragraph.

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

ANSWER: Admitted.

53. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211199 seeking approval for the commercial manufacture, use, or sale of Alkem's Generic Product before the expiration date of the '781 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

54. After FDA approval of ANDA No. 211199, Alkem will infringe one or more claims of the '781 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Alkem's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 211199 shall be no earlier than the expiration of the '781 patent and any additional periods of exclusivity.

ANSWER: Denied.

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

ANSWER: Admitted.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

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

ANSWER: Denied.

COUNT II

(DECLARATORY JUDGEMENT OF INFRINGEMENT OF THE '781 PATENT)

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

ANSWER: Defendants incorporate their answers to each of the prior paragraphs.

61. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Defendants admit that Plaintiff purports to bring its claim under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Defendants lack knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore deny them.

62. There is an actual and justiciable controversy between Plaintiffs and Alkem concerning infringement of the '781 patent of sufficient immediacy and reality such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

ANSWER: This paragraph states a legal conclusion to which no answer is required. To the extent an answer is required, Defendants deny the allegations in this paragraph.

63. Alkem has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Alkem's Generic Product prior to expiration of the '781 patent.

ANSWER: This paragraph states a legal conclusion to which no answer is required. To the extent an answer is required, Defendants deny the allegations in this paragraph.

64. Alkem's actions, including, but not limited to, submitting, or causing to be submitted to the FDA, ANDA No. 211199 seeking approval to manufacture, use, import, offer to sell and sell Alkem's Generic Product before the expiration date of the '781 patent and engaging in litigation, indicate a refusal to change the course of their actions in the face of knowledge of the '781 patent and acts by Plaintiffs.

ANSWER: Denied.

65. On information and belief, Alkem intends to manufacture, use, import, offer to sell and/or sell Alkem's Generic Product after FDA approval of ANDA No. 211199.

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

66. After FDA approval of ANDA No. 211199, Alkem will infringe one or more claims of the '781 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Alkem's Generic Product, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c).

ANSWER: Denied.

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

ANSWER: Admitted.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

71. Plaintiffs will be irreparably harmed if Alkem is not enjoined from infringing or actively inducing infringement of at least one claim of the '781 patent.

ANSWER: Denied.

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

ANSWER: Denied.

73. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Alkem's Generic Product prior to

expiration of the '781 patent by Alkem will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '781 patent.

ANSWER: Denied.

RESPONSE TO REQUEST FOR RELIEF

Defendants deny that Plaintiffs are entitled to any relief described in the section of the Complaint entitled "Request for Relief," and deny that Plaintiffs are entitled to any relief whatsoever. Defendants further deny any allegation in the Complaint not specifically admitted above.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE
(Noninfringement)

The manufacture, use, sale, offer for sale, or importation of Alkem's Generic Product has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the patent-in-suit.

SECOND AFFIRMATIVE DEFENSE
(Invalidity)

The claims of the patent-in-suit are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 et seq., at least for the reasons that will be set forth in a notice of paragraph IV certification letter.

THIRD AFFIRMATIVE DEFENSE
(Failure to State a Claim)

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

FOURTH AFFIRMATIVE DEFENSE
(Lack of Jurisdiction)

The Court lacks subject matter jurisdiction for any claim under 35 U.S.C. § 271(a)-(c) because there is no real and immediate case or controversy for any such claim.

FIFTH AFFIRMATIVE DEFENSE
(No Exceptional Case)

Plaintiffs are not entitled to a finding that this case is exceptional under 35 U.S.C. § 285 or otherwise.

SIXTH AFFIRMATIVE DEFENSE
(Improper Party)

S&B Pharma has had and will have no involvement with the research, development, or marketing of Alkem's Generic Product, and therefore is not a proper party to this action.

RESERVATION OF DEFENSES

Defendants reserve the right to assert any and all additional defenses and counterclaims that discovery may reveal.

COUNTERCLAIMS

For its counterclaims against Bial - Portela & CA S.A. ("Bial"), Bial - Holding, S.A. ("Bial Holding"), and Sunovian Pharmaceuticals Inc. ("Sunovion") (collectively, "Counterclaim Defendants"), Alkem Laboratories Limited ("Alkem") states as follows:

PARTIES

1. Alkem is a corporation organized under the laws of India, having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai – 400 013, India.

2. On information and belief, Bial is a Portuguese corporation having its principal place of business at Avenida da Siderurgia Nacional, Coronado (São Romão e São Mamede) 4745-455 Trofa, Portugal.

3. On information and belief, Bial Holding is a Portuguese corporation having its principal place of business at Avenida da Siderurgia Nacional, Coronado (São Romão e São Mamede) 4745-365 Trofa, Portugal.

4. On information and belief, 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

5. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. The Court has personal jurisdiction over Counterclaim Defendants because Counterclaim Defendants commenced and continue to maintain this action against Alkem in this judicial district.

8. Venue for these counterclaims is proper in this judicial District pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1400(b).

ACTS GIVING RISE TO THESE COUNTERCLAIMS

9. On information and belief, Sunovion is the holder of New Drug Application ("NDA") No. 022416 for APTIOM® (eslicarbazepine acetate) Tablets, 200 mg, 400 mg, 600 mg, and 800 mg.

10. On information and belief, Sunovion submitted the following United States patent to the United States Food and Drug Administration ("FDA") for listing in the electronic version of FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange

Book") in connection with APTIOM®: U.S. Patent No. 10,912,781 ("the '781 patent" or "the patent-in-suit").

11. On information and belief, Bial is the assignee of the patent-in-suit.

12. On information and belief, Bial Holding is the parent corporation of Bial.

13. Alkem has filed Abbreviated New Drug Application ("ANDA") No. 211199, and will file a certification provided for in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the patent-in suit is invalid, unenforceable, and/or will not be infringed by the product that is the subject of ANDA No. 211199 ("Alkem's ANDA Product").

FIRST COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '781 Patent)

14. Alkem restates and realleges each of the foregoing paragraphs 1-13 as if fully set forth herein.

15. Counterclaim Defendants have accused Alkem of infringing the '781 patent.

16. Alkem denies infringement of the '781 patent and alleges that the manufacture, use, sale, offer for sale, or importation of Alkem's ANDA Product has not infringed, does not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '781 patent.

17. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Alkem and Counterclaim Defendants regarding the infringement of the '781 patent.

18. Alkem is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of Alkem's ANDA Product has not infringed, does not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly,

or contributorily, and would not induce infringement of, any valid or enforceable claim of the '781 patent.

SECOND COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '781 Patent)

19. Alkem restates and realleges each of the foregoing paragraphs 1-18 as if fully set forth herein.

20. Counterclaim Defendants have accused Alkem of infringing the '781 patent.

21. Alkem denies infringement of the '781 patent and alleges that the claims of the '781 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq.*, at least for the reasons that will be set forth in a notice of paragraph IV certification letter.

22. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Alkem and Counterclaim Defendants regarding the validity of the '781 patent.

23. Alkem is entitled to a judicial declaration that the claims of the '781 patent are invalid under one or more of 35 U.S.C. § 101 *et seq.*

PRAYER FOR RELIEF

WHEREFORE, Alkem respectfully prays for judgment in its favor and against Counterclaim Defendants:

(a) Declaring that the manufacture, use, sale, offer for sale, or importation of Alkem's ANDA Product has not infringed, does not infringe, and would not infringe any valid or enforceable claim of the patent-in-suit, either literally or under the doctrine of equivalents;

(b) Declaring that the manufacture, use, sale, offer for sale, or importation of Alkem's ANDA Product has not induced, does not induce, and would not induce the infringement of any valid or enforceable claim of the patent-in-suit;

(c) Declaring that the manufacture, use, sale, offer for sale, or importation of Alkem's ANDA Product has not contributorily infringed, does not contributorily infringe, and would not contributorily infringe any valid or enforceable claim of the patent-in-suit;

(d) Declaring that each of the claims of the patent-in-suit is invalid under one or more of 35 U.S.C. § 101 *et seq.*;

(e) Ordering that the Complaint be dismissed with prejudice and judgment entered in favor of Alkem;

(f) Declaring this case exceptional and awarding Alkem its reasonable attorney's fees and costs of these Counterclaims pursuant to 35 U.S.C. § 285; and

(g) Awarding Alkem such other relief as the Court may deem just and proper.

Respectfully submitted,

GREENBERG TRAURIG, LLP

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Dated: March 3, 2021