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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRAINTREE LABORATORIES, INC., and SEBELA US INC., Plaintiffs, v. ALKEM LABORATORIES LTD. Defendant.	Civil Action No. 1:25-cv-12118 **DEFENDANT ALKEM LABORATORIES LTD.'S ANSWER TO THE COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant Alkem Laboratories Ltd. ("Defendant" or "Alkem"), by its undersigned attorneys, for its Answer to the Complaint for Patent Infringement from Plaintiffs Braintree Laboratories, Inc. ("Braintree") and Sebela US Inc. (collectively, "Plaintiffs"), states as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Alkem denies the allegations in Plaintiffs' Complaint except those expressly admitted below.

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 10,143,656 (the "'656 Patent"), 11,033,498 (the "'498 Patent"), 11,382,864 (the "'864 Patent"), and 11,638,697 (the "'697 Patent") (collectively, "the Asserted Patents"), arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. § 100, et seq. This action relates to Abbreviated New Drug Application ("ANDA") No. 220426 filed or caused to be filed by Defendant with the U.S. Food and Drug Administration ("FDA") and seeking approval to market a generic version of Braintree's SUTAB® drug product.

ANSWER: Paragraph 1 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that Plaintiffs' Complaint purports to assert an action for patent infringement based on Alkem's filing of Abbreviated New Drug Application ("ANDA") No. 220426 seeking approval from the U.S. Food and Drug Administration ("FDA") to commercially market a generic sodium sulfate, magnesium sulfate, and potassium chloride product prior to the expiration of the patents-in-suit. Alkem is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of Paragraph 1 of the Complaint and therefore denies them.

PARTIES

2. Braintree is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, with its principal place of business at 60 Columbian Street West, Braintree, Massachusetts 02184.

ANSWER: Alkem is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 2 of the Complaint and, therefore, denies all allegations.

3. Sebela US Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 645 Hembree Parkway, Roswell, Georgia 30076. Sebela US Inc. is a parent company of Braintree.

ANSWER: Alkem is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 3 of the Complaint and, therefore, denies all allegations.

4. Upon information and belief, Defendant Alkem is a corporation organized and existing 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.

ANSWER: Admitted.

5. Upon information and belief, Defendant Alkem manufactures and markets drug products for distribution in the United States, including in the District of New Jersey.

ANSWER: Alkem admits that it is a pharmaceutical company that, among other things, develops and markets drug products for the United States market. Alkem denies the remaining allegations in Paragraph 5 of the Complaint.

6. Upon information and belief, following any FDA approval of ANDA No. 220426, Defendant will make, use, offer to sell, and/or sell the proposed generic drug product that is the subject of ANDA No. 220426 throughout the United States, and/or import such generic drug product into the United States.

ANSWER: Alkem admits that it filed ANDA No. 220426 seeking approval from the U.S. Food and Drug Administration ("FDA") to commercially market a generic sodium sulfate, magnesium sulfate, and potassium chloride product prior to the expiration of the patents-in-suit. Alkem denies the remaining allegations in Paragraph 6 of the Complaint.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, 35 U.S.C. § 100, et seq., and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Alkem does not contest personal jurisdiction or venue for the limited purpose of this action only. Alkem denies all remaining allegations of Paragraph 7 of the Complaint.

8. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery, this Court has personal jurisdiction over Defendant.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Alkem does not contest personal jurisdiction for the limited purpose of this action only. Alkem denies all remaining allegations of Paragraph 8 of the Complaint.

9. This Court has personal jurisdiction over Defendant because, upon information and belief, Defendant regularly does business in New Jersey and has engaged in a persistent course of conduct within New Jersey by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including New Jersey, and/or by directly selling pharmaceutical products in New Jersey. Upon information and belief, Defendant will manufacture, market, and/or sell within the United States the generic version of Braintree's SUTAB® drug product described in ANDA No. 220426 if approved by the FDA. If ANDA No. 220426 is approved, the generic version of Braintree's SUTAB® charged with infringing the Asserted Patents would, upon information and belief, among other things, be marketed and

distributed in New Jersey, prescribed by physicians practicing in New Jersey, dispensed by pharmacies located in New Jersey, and/or used by persons in New Jersey, all of which would have a substantial effect on New Jersey.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Alkem does not contest personal jurisdiction for the limited purpose of this action only. Alkem denies all remaining allegations of Paragraph 9 of the Complaint.

10. Braintree enjoys sales in New Jersey of its SUTAB® drug product, which is covered by the claims of the Asserted Patents. If the FDA approves ANDA No. 220426, Defendant's manufacturing, marketing and sales of its generic version of Braintree's SUTAB® will cause Braintree substantial injury in New Jersey.

ANSWER: Denied.

11. In addition, Defendant has previously submitted to the jurisdiction of this Court and has previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. For example, Defendant did not contest jurisdiction in the District of New Jersey and filed counterclaims in *Axsome Malta Ltd. v. Alkem Lab'ys Ltd.*, 2:24-cv-10617, Dkt. 9 (D.N.J. Feb. 7, 2025); *Janssen Pharmaceuticals, Inc. v. Alkem Lab'ys Ltd*, 1:23-cv-02939, Dkt. 11 (D.N.J. July 20, 2023); *Axsome Malta Ltd. v. Alkem Lab'ys Ltd.*, 2:23-cv-20354, Dkt. 57 (D.N.J. Dec. 18, 2023); *Jazz Pharm. v. Teva Pharm.*, 2:23-cv-03914, Dkt. 44 (D.N.J. Oct. 2, 2023); *Arbor Pharm., LLC v. Alkem Lab'ys Ltd.*, 1:22-cv-00143, Dkt. 7 (D.N.J. Feb. 17, 2022); *Amgen v. Alkem Lab'ys Ltd.,* 3:18-cv-11265, Dkt. 15 (D.N.J. Aug. 29, 2018); and *Grunenthal Gmbh v. Actavis Elizabeth LLC*, Dkt. 17, 2:13-cv-04507 (D.N.J. Aug. 28, 2013).

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Alkem does not contest personal jurisdiction for the limited purpose of this action only. Alkem denies all remaining allegations of Paragraph 11 of the Complaint.

BACKGROUND

12. Braintree holds approved New Drug Application ("NDA") No. 213135 for SUTAB®. SUTAB® is a sodium sulfate, magnesium sulfate, and potassium chloride osmotic laxative in tablet form. It was approved by the FDA on November 10, 2020. SUTAB® is indicated for cleansing of the colon in preparation for colonoscopy in adults.

ANSWER: Upon information and belief, Alkem admits that Braintree is identified by the electronic version of the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book") as the holder of New Drug Application ("NDA") No. 213135 by which the FDA granted approval for the manufacture and sale of a sodium sulfate, magnesium sulfate, and potassium chloride osmotic laxative in tablet form. Alkem admits that the FDA-approved labeling for SUTAB® states the full and complete FDA-approved indications for SUTAB® and that the labeling speaks for itself. Alkem denies the remaining allegations in Paragraph 12 of the Complaint.

13. Pursuant to 21 U.S.C. § 355 and attendant FDA regulations, the Asserted Patents have been listed in connection with SUTAB® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." SUTAB®, its use, and its formulation, are covered by one or more claims of the Asserted Patents.

ANSWER: Upon information and belief, Alkem admits that FDA's Orange Book lists the patent-in-suit as covering Plaintiffs' SUTAB®. Alkem lacks knowledge or information sufficient

to form a belief as to the truth or falsity of the remaining allegations of Paragraph 13 and, therefore, denies those allegations

THE '656 PATENT

14. Braintree is the lawful owner by assignment of the '656 Patent, entitled "Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using Same," which was duly and legally issued by the U.S. Patent and Trademark Office on December 4, 2018. A true and correct copy of the '656 Patent is attached hereto as **Exhibit A**. The claims of the '656 Patent are valid and enforceable.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '656 patent is entitled "Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using Same," that, on its face, the '656 patent states it was issued on December 4, 2018 and identifies Braintree as the assignee, and that a purported copy of the '656 patent is attached as Exhibit A. Alkem denies that the '656 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 14.

15. The '656 Patent, inter *alia*, claims solid oral formulations for cleansing a colon.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '656 patent is entitled "Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using Same." Alkem denies the remaining allegations in Paragraph 15 of the Complaint.

16. The '656 Patent will expire no earlier than August 4, 2037.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the electronic version of the Orange Book

identifies the patent expiration date of the ’656 patent as August 4, 2037. Alkem denies the remaining allegations in Paragraph 16 of the Complaint.

17. Braintree, as the owner of the entire right, title and interest in the ’656 Patent, possesses the right to sue for infringement of the ’656 Patent.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the ’656 patent identifies Braintree as the assignee. Alkem denies the remaining allegations in Paragraph 17 of the Complaint.

THE ’498 PATENT

18. Braintree is the lawful owner by assignment of the ’498 Patent, entitled “Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Method Of Using Same,” which was duly and legally issued by the U.S. Patent and Trademark Office on June 15, 2021. A true and correct copy of the ’498 Patent is attached hereto as **Exhibit B**. The claims of the ’498 Patent are valid and enforceable.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the ’498 patent is entitled “Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using Same,” that, on its face, the ’498 patent states it was issued on June 15, 2021 and identifies Braintree as the assignee, and that a purported copy of the ’498 patent is attached as Exhibit B. Alkem denies that the ’498 patent was “duly and lawfully issued,” and further denies any remaining allegations of Paragraph 18.

19. The ’498 Patent, *inter alia*, claims methods of cleansing the colon.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the ’498 patent is entitled “Solid Oral Sulfate

Salt Formulations For Cleansing A Colon And Methods Of Using Same." Alkem denies the remaining allegations in Paragraph 19 of the Complaint.

20. The '498 Patent will expire no earlier than August 4, 2037.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the electronic version of the Orange Book identifies the patent expiration date of the '498 patent as August 4, 2037. Alkem denies the remaining allegations in Paragraph 20 of the Complaint.

21. Braintree, as the owner of the entire right, title and interest in the '498 Patent, possesses the right to sue for infringement of the '498 Patent.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '498 patent identifies Braintree as the assignee. Alkem denies the remaining allegations in Paragraph 21 of the Complaint.

THE '864 PATENT

22. Braintree is the lawful owner by assignment of the '864 Patent, entitled "Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Method Of Using Same," which was duly and legally issued by the U.S. Patent and Trademark Office on July 12, 2022. A true and correct copy of the '864 Patent is attached hereto as **Exhibit C**. The claims of the '864 Patent are valid and enforceable.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '864 patent is entitled "Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using Same," that, on its face, the '864 patent states it was issued on July 12, 2022 and identifies Braintree as the assignee, and that a

purported copy of the '864 patent is attached as Exhibit C. Alkem denies that the '864 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 22.

23. The '864 Patent, *inter alia*, claims methods for cleansing a colon of a subject.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '864 patent is entitled "Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using Same." Alkem denies the remaining allegations in Paragraph 22 of the Complaint.

24. The '864 Patent will expire no earlier than August 4, 2037.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the electronic version of the Orange Book identifies the patent expiration date of the '864 patent as August 4, 2037. Alkem denies the remaining allegations in Paragraph 24 of the Complaint.

25. Braintree, as the owner of the entire right, title and interest in the '864 Patent, possesses the right to sue for infringement of the '864 Patent.

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '864 patent identifies Braintree as the assignee. Alkem denies the remaining allegations in Paragraph 25 of the Complaint.

THE '697 PATENT

26. Braintree is the lawful owner by assignment of the '697 Patent, entitled "Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using Same," which was duly and legally issued by the U.S. Patent and Trademark Office on May 2, 2023. A true and correct copy of the '697 Patent is attached hereto as **Exhibit D**. The claims of the '697 Patent are valid and enforceable.

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '697 patent is entitled "Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using Same," that, on its face, the '697 patent states it was issued on May 2, 2023 and identifies Braintree as the assignee, and that a purported copy of the '697 patent is attached as Exhibit D. Alkem denies that the '697 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 26.

27. The '697 Patent, *inter alia*, claims solid oral formulations for cleansing a colon.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '697 patent is entitled "Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using Same." Alkem denies the remaining allegations in Paragraph 27 of the Complaint.

28. The '697 Patent will expire no earlier than August 4, 2037.

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the electronic version of the Orange Book identifies the patent expiration date of the '697 patent as August 4, 2037. Alkem denies the remaining allegations in Paragraph 28 of the Complaint.

29. Braintree, as the owner of the entire right, title and interest in the '697 Patent, possesses the right to sue for infringement of the '697 Patent.

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '697 patent identifies Braintree as the assignee. Alkem denies the remaining allegations in Paragraph 29 of the Complaint.

INFRINGEMENT BY DEFENDANT

30. By letter dated May 15, 2025 ("Defendant's Notice Letter"), Alkem notified Plaintiffs Braintree and Sebela US Inc. that it had submitted ANDA No. 220426 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval, prior to the expiration of the '656, '498, '864, and '697 Patents, to engage in the commercial manufacture, use, or sale and/or importation of a proposed generic version of the 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate composition currently listed in the Orange Book for SUTAB®.

ANSWER: Alkem admits that it sent written notice of a Paragraph IV Certification ("Alkem's Notice Letter") to Plaintiffs on or around May 15, 2025. Alkem's Notice Letter speaks for itself. Alkem denies all remaining allegations of Paragraph 30 of the Complaint.

31. By filing ANDA No. 220426, and upon information and belief, Alkem has represented to the FDA that the components of its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate have the same active ingredients, the same route of administration, the same dosage form, and the same strengths as the corresponding components of SUTAB®. By filing ANDA No. 220426, and upon information and belief, Alkem has represented that its proposed generic drug product containing magnesium sulfate, potassium chloride, and sodium sulfate is bioequivalent to SUTAB®.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that its proposed ANDA product is bioequivalent to SUTAB®. Alkem denies the remaining allegations in Paragraph 31 of the Complaint.

32. Alkem has committed an act of infringement, pursuant to 35 U.S.C. § 271(e)(2), by filing ANDA No. 220426 under 21 U.S.C. § 355(j) seeking approval to engage in the commercial

manufacture, use and/or sale of its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate before the expiration of the Asserted Patents.

ANSWER: Denied.

33. Plaintiffs are entitled under 35 U.S.C. § 271(e)(4) to full relief from Alkem's acts of infringement, including an Order by this Court ensuring that the effective date of any approval by the FDA of ANDA No. 220426, relating to Defendant's proposed generic version of SUTAB®, shall not be earlier than the expiration of the exclusivity afforded the Asserted Patents.

ANSWER: Denied.

34. Plaintiffs filed their Complaint before the expiration of the forty-five day period from the day after Plaintiffs received the Defendant's Notice Letter, which was dated May 15, 2025.

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that this action is being brought within 45 days of Alkem's Notice Letter. Alkem denies all remaining allegations of Paragraph 34 of the Complaint.

COUNT I (INFRINGEMENT OF THE '656 PATENT BY DEFENDANT)

35. Each of the preceding paragraphs 1 through 34 is incorporated as if fully set forth.

ANSWER: Alkem incorporates its answers to the preceding paragraphs as if fully set forth herein.

36. Alkem's submission of ANDA No. 220426 to obtain approval to engage in the commercial manufacture, use, and/or sale of its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate prior to the expiration

of the ’656 Patent constitutes infringement of one or more of the claims of the ’656 Patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

37. Specifically, the composition of Defendant’s proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate and the way it is proposed to be made, used and sold as described in Defendant’s Notice Letter, will, if marketed and sold, infringe each and every limitation of one or more claims of the ’656 Patent, including at least claim 1. According to Defendant’s Notice Letter, and upon information and belief, the components of Defendant’s proposed generic drug product have the same active ingredients, the same route of administration, the same dosage form, and the same strengths as the corresponding components of SUTAB®.

ANSWER: Denied.

38. Upon information and belief, Defendant had actual and constructive knowledge of the ’656 Patent prior to filing ANDA No. 220426, and was aware that the filing of ANDA No. 220426 with the FDA constituted an act of infringement of the ’656 Patent.

ANSWER: Denied.

39. Upon information and belief, use of Defendant’s proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate would infringe one or more claims of the ’656 Patent.

ANSWER: Denied.

40. Upon information and belief, Defendant knows that its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate, and the proposed labeling for that product, are especially made or adapted for use in

infringing the ’656 Patent, and that the proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate and the proposed labeling are not suitable for any substantial noninfringing use. Upon information and belief, Defendant plans and intends to infringe, and will induce and/or contribute to the infringement of, the ’656 Patent, immediately and imminently upon FDA approval of ANDA No. 220426.

ANSWER: Denied.

41. Upon FDA approval of ANDA No. 220426, Defendant will infringe the ’656 Patent by making, using, offering to sell, and selling its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate in the United States and/or importing such proposed generic drug product into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271 (a)-(c), unless enjoined by the Court.

ANSWER: Denied.

42. If infringement of the ’656 Patent by Defendant is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

COUNT II (INFRINGEMENT OF THE ’498 PATENT BY DEFENDANT)

43. Each of the preceding paragraphs 1 through 42 is incorporated as if fully set forth.

ANSWER: Alkem incorporates its answers to the preceding paragraphs as if fully set forth herein.

44. Alkem’s submission of ANDA No. 220426 to obtain approval to engage in the commercial manufacture, use, and/or sale of its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate prior to the expiration

of the ’498 Patent constitutes infringement of one or more of the claims of the ’498 Patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

45. Specifically, the composition of Defendant’s proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate and the way it is proposed to be made, used and sold as described in Defendant’s Notice Letter, will, if marketed and sold, infringe each and every limitation of one or more claims of the ’498 Patent, including at least claim 1. According to Defendant’s Notice Letter, and upon information and belief, the components of Defendant’s proposed generic drug product have the same active ingredients, the same route of administration, the same dosage form, and the same strengths as the corresponding components of SUTAB®.

ANSWER: Denied.

46. Upon information and belief, Defendant had actual and constructive knowledge of the ’498 Patent prior to filing ANDA No. 220426, and was aware that the filing of ANDA No. 220426 with the FDA constituted an act of infringement of the ’498 Patent.

ANSWER: Denied.

47. Upon information and belief, use of Defendant’s proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate would infringe one or more claims of the ’498 Patent.

ANSWER: Denied.

48. Upon information and belief, Defendant knows that its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate, and the proposed labeling for that product, are especially made or adapted for use in

infringing the '498 Patent, and that its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate and the proposed labeling are not suitable for any substantial noninfringing use. Upon information and belief, Defendant plans and intends to infringe, and will induce and/or contribute to the infringement of, the '498 Patent, immediately and imminently upon FDA approval of ANDA No. 220426.

ANSWER: Denied.

49. Upon FDA approval of ANDA No. 220426, Defendant will infringe the '498 Patent by making, using, offering to sell, and selling its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate in the United States and/or importing such proposed generic drug product into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271 (a)-(c), unless enjoined by the Court.

ANSWER: Denied.

50. If infringement of the '498 Patent by Defendant is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

COUNT III (INFRINGEMENT OF THE '864 PATENT BY DEFENDANT)

51. Each of the preceding paragraphs 1 through 50 is incorporated as if fully set forth.

ANSWER: Alkem incorporates its answers to the preceding paragraphs as if fully set forth herein.

52. Alkem's submission of ANDA No. 220426 to obtain approval to engage in the commercial manufacture, use, and/or sale of its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate prior to the expiration

of the ’864 Patent constitutes infringement of one or more of the claims of the ’864 Patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

53. Specifically, the composition of Defendant’s proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate and the way it is proposed to be made, used and sold as described in Defendant’s Notice Letter, will, if marketed and sold, infringe each and every limitation of one or more claims of the ’864 Patent, including at least claim 1. According to Defendant’s Notice Letter, and upon information and belief, the components of Defendant’s proposed generic drug product have the same active ingredients, the same route of administration, the same dosage form, and the same strengths as the corresponding components of SUTAB®.

ANSWER: Denied.

54. Upon information and belief, Defendant had actual and constructive knowledge of the ’864 Patent prior to filing ANDA No. 220426, and was aware that the filing of ANDA No. 220426 with the FDA constituted an act of infringement of the ’864 Patent.

ANSWER: Denied.

55. Upon information and belief, use of Defendant’s proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate would infringe one or more claims of the ’864 Patent.

ANSWER: Denied.

56. Upon information and belief, Defendant knew that its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate, and the proposed labeling for that product, are especially made or adapted for use in

infringing the '864 Patent, and that its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate and the proposed labeling are not suitable for any substantial noninfringing use. Upon information and belief, Defendant plans and intends to infringe, and will induce and/or contribute to the infringement of, the '864 Patent, immediately and imminently upon FDA approval of ANDA No. 220426.

ANSWER: Denied.

57. Upon FDA approval of ANDA No. 220426, Defendant will infringe the '864 Patent by making, using, offering to sell, and selling its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate in the United States and/or importing such proposed generic drug product into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271 (a)-(c), unless enjoined by the Court.

ANSWER: Denied.

58. If infringement of the '864 Patent by Defendant is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

COUNT IV (INFRINGEMENT OF THE '697 PATENT BY DEFENDANT)

59. Each of the preceding paragraphs 1 through 58 is incorporated as if fully set forth.

ANSWER: Alkem incorporates its answers to the preceding paragraphs as if fully set forth herein.

60. Alkem's submission of ANDA No. 220426 to obtain approval to engage in the commercial manufacture, use, and/or sale of its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate prior to the expiration

of the ’697 Patent constitutes infringement of one or more of the claims of the ’697 Patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

61. Specifically, the composition of Defendant’s proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate and the way it is proposed to be made, used and sold as described in Defendant’s Notice Letter, will, if marketed and sold, infringe each and every limitation of at least claim 1 of the ’697 Patent. According to Defendant’s Notice Letter, and upon information and belief, the components of Defendant’s proposed generic drug product have the same active ingredients, the same route of administration, the same dosage form, and the same strengths as the corresponding components of SUTAB®.

ANSWER: Denied.

62. Upon information and belief, Defendant had actual and constructive knowledge of the ’697 Patent prior to filing of ANDA No. 220426, and was aware that the filing of ANDA No. 220426 with the FDA constituted an act of infringement of the ’697 Patent.

ANSWER: Denied.

63. Upon information and belief, use of Defendant’s proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate would infringe at least claim 1 of the ’697 Patent.

ANSWER: Denied.

64. Upon information and belief, Defendant knew that its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate, and the proposed labeling for that product, are especially made or adapted for use in

infringing the '697 Patent, and that the proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate and the proposed labeling are not suitable for any substantial noninfringing use. Upon information and belief, Defendant plans and intends to infringe, and will induce and/or contribute to the infringement of, the '697 Patent, immediately and imminently upon FDA approval of ANDA No. 220426.

ANSWER: Denied.

65. Upon FDA approval of ANDA No. 220426, Defendant will infringe the '697 Patent by making, using, offering to sell, and selling its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate in the United States and/or importing such proposed generic drug product into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271 (a)-(c), unless enjoined by the Court.

ANSWER: Denied.

66. If infringement of the '697 Patent by Defendant is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

GENERAL DENIAL AND RESPONSE TO REQUEST FOR RELIEF

To the extent not specifically admitted above, Alkem hereby denies all allegations in the Complaint. Alkem further denies that Plaintiffs are entitled to any relief whatsoever. Alkem denies that Plaintiffs are entitled to the judgment or other relief prayed for in Paragraphs 1-6 of the Complaint under the heading REQUEST FOR RELIEF.

ALKEM'S DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Alkem avers and asserts the following separate defenses to the Complaint:

FIRST SEPARATE DEFENSE
(INVALIDITY OF THE '656 PATENT)

The claims of the '656 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '656 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220426 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '656 Patent.

THIRD SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '656 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220426 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '656 Patent.

FOURTH SEPARATE DEFENSE
(INVALIDITY OF THE '498 PATENT)

The claims of the '498 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FIFTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '498 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220426 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '498 Patent.

SIXTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '498 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220426 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '498 Patent.

SEVENTH SEPARATE DEFENSE
(INVALIDITY OF THE '864 PATENT)

The claims of the '874 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

EIGHTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '864 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220426 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '864 Patent.

NINTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '864 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220426 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '864 Patent.

TENTH SEPARATE DEFENSE
(INVALIDITY OF THE '697 PATENT)

The claims of the '697 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

ELEVENTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '697 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220426 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '697 Patent.

TWELFTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '697 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220426 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '697 Patent.

THIRTEENTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiffs' Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

FOURTEENTH SEPARATE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

Plaintiffs' Complaint lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), and/or (c).

FIFTEENTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM FOR EXCEPTIONAL OR WILLFUL INFRINGEMENT)

Plaintiffs fail to state a proper claim for an exceptional case and/or willful infringement.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to injunctive relief against Alkem because Plaintiffs' alleged damages are not immediate or irreparable, and therefore Plaintiffs have an adequate remedy at law. Moreover, considering the balance of hardships between the parties, and the public interest in fostering the prompt introduction of generic pharmaceuticals to the market, the equitable remedy of a permanent injunction is not warranted in any event.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to attorney's fees against Alkem because Plaintiffs have not sufficiently alleged, and cannot prove, that this is an exceptional case under 35 U.S.C. § 285.

EIGHTEENTH AFFIRMATIVE DEFENSE

35 U.S.C. § 288 prevents Plaintiffs from recovering any costs associated with this action.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiffs' allegations are barred, in whole or in part, by the doctrines of waiver, estoppel and/or prosecution history estoppel.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Alkem reserves the right to plead additional separate defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

ALKEM'S COUNTERCLAIMS

Defendant Alkem Laboratories Ltd. ("Alkem"), through counsel, hereby submits the following Counterclaims against Braintree Laboratories, Inc. ("Braintree") and Sebela US Inc. (collectively, "Plaintiffs").

PARTIES

1. On information and belief, Braintree is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, with its principal place of business at 60 Columbian Street West, Braintree, Massachusetts 02184.

2. On information and belief, Sebela US Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 645 Hembree Parkway, Roswell, Georgia 30076.

3. Alkem Laboratories Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, 400 013, Maharashtra, India.

NATURE OF THE ACTION

4. Alkem seeks declaratory judgment 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, *et seq.*, that United States Patent Nos. 10,143,656 (the "'656 Patent"), 11,033,498 (the "'498 Patent"), 11,382,864 (the "'864 Patent"), and 11,638,697 (the "'697 Patent") (collectively, "the patents-in-suit") are invalid and/or not infringed.

JURISDICTION AND VENUE

5. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Plaintiffs because, among other reasons, Plaintiffs subjected themselves to the jurisdiction of this Court by filing its complaint here.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b), and by Plaintiffs' choice of forum.

8. There is an actual and justiciable controversy between the parties as to the infringement and invalidity of the patent-in-suit.

THE CONTROVERSY

9. Alkem holds Abbreviated New Drug Application ("ANDA") No. 220426 for sodium sulfate, magnesium sulfate, and potassium chloride tablets.

10. On or about June 25, 2025, Plaintiffs filed the present action against Alkem alleging infringement of the patents-in-suit. Accordingly, there is a real, substantial, and continuing justiciable controversy between the parties concerning the patents-in-suit.

11. Alkem and Plaintiffs have adverse legal interests with respect to the patents-in-suit of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

COUNT I
Declaratory Judgment of Invalidity of the '656 Patent

12. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

13. Each and every asserted claim of United States Patent No. 10,143,656 is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116, and/or is invalid under any other ground provided by 35 U.S.C. § 282 and/or based on other judicially-created bases for invalidity.

COUNT II
Declaratory Judgment of Noninfringement of the '656 Patent

14. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

15. Alkem has not infringed, induced infringement, or contributed to the infringement, and Alkem will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of U.S. Patent No. 10,143,656.

COUNT III
Declaratory Judgment of Invalidity of the '498 Patent

16. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

17. Each and every asserted claim of United States Patent No. 11,033,498 is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116, and/or is invalid under any other ground provided by 35 U.S.C. § 282 and/or based on other judicially-created bases for invalidity.

COUNT IV
Declaratory Judgment of Noninfringement of the '498 Patent

18. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

19. Alkem has not infringed, induced infringement, or contributed to the infringement, and Alkem will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of U.S. Patent No. 11,033,498.

COUNT V
Declaratory Judgment of Invalidity of the '864 Patent

20. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

21. Each and every asserted claim of United States Patent No. 11,382,864 is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116, and/or is invalid under any other ground provided by 35 U.S.C. § 282 and/or based on other judicially-created bases for invalidity.

COUNT VI
Declaratory Judgment of Noninfringement of the '864 Patent

22. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

23. Alkem has not infringed, induced infringement, or contributed to the infringement, and Alkem will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of U.S. Patent No. 11,382,864.

COUNT VII
Declaratory Judgment of Invalidity of the '697 Patent

24. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

25. Each and every asserted claim of United States Patent No. 11,638,697 is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116, and/or is invalid under any other ground provided by 35 U.S.C. § 282 and/or based on other judicially-created bases for invalidity.

COUNT VIII
Declaratory Judgment of Noninfringement of the '697 Patent

26. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

27. Alkem has not infringed, induced infringement, or contributed to the infringement, and Alkem will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of U.S. Patent No. 11,638,697.

ALKEM'S REQUEST FOR RELIEF

WHEREFORE, Alkem respectfully requests that:

(a) Judgment be entered that the Complaint against Alkem is dismissed with prejudice and that Plaintiffs take nothing thereby;

(b) Judgment be entered that each claim of the patents-in-suit is invalid;

(c) The Court permanently enjoin Plaintiffs or any of their assigns or successors from asserting that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of Alkem's ANDA No. 220426 infringe or will infringe any valid claim of the patents-in-suit;

(d) This case be deemed an exceptional case within the meaning of 35 U.S.C. § 285;

(e) Alkem be awarded its reasonable costs and attorney fees; and

(f) The Court award Alkem such other and further relief as this Court may deem necessary, just and proper.

Dated: August 25, 2025

Respectfully submitted,

/s/ Rebekah R. Conroy

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Counsel for Defendant Alkem Laboratories, Ltd.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, Defendant Alkem Laboratories Ltd., by and through its undersigned counsel, hereby certifies that the matter in controversy is not subject to any other action pending in any court, or any pending arbitration or administrative proceeding known to Defendant.

Dated: August 25, 2025

/s/Rebekah R. Conroy

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Counsel for Defendant Alkem Laboratories, Ltd.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendant Alkem Laboratories Ltd., by and through its undersigned counsel, hereby certifies that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: August 25, 2025

/s/ Rebekah R. Conroy

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