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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRAINTREE LABORATORIES, INC., and SEBELA US INC., Plaintiffs, v. HETERO USA INC., HETERO LABS LIMITED, and HETERO LABS LIMITED, VEMAGAL, Defendants.	**Civil Action No. 1:25-cv-13632 (CPO) (EAP)** **DEFENDANT HETERO USA INC.'S ANSWER AND SEPARATE DEFENSES TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT**

Defendant Hetero USA Inc. ("Hetero") hereby files its Answer and Separate Defenses in response to the Complaint for Patent Infringement filed on July 22, 2025, by Plaintiffs Braintree Laboratories, Inc. and Sebela US Inc. ("Plaintiffs").

GENERAL DENIAL

Pursuant to Federal Rule of Civil Procedure 8(b)(3), Hetero denies all allegations in Plaintiffs' Complaint except those specifically 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. 220421 filed or caused to be filed by Defendants 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 contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Plaintiffs' Complaint purports to state 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, "Patents-in-Suit") and that this action purports to arise under the patent laws of the United States, 35 U.S.C. § 100 *et seq.* Hetero further admits that the action purports to relate to Hetero USA's submission of Abbreviated New Drug Application ("ANDA") No. 220421 ("Hetero's ANDA") to the U.S. Food and Drug Administration ("FDA") to seek approval of Hetero's generic product ("Hetero's ANDA Product"). Hetero denies any and all remaining allegations.

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: Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 2 and on that basis denies these 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: Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 3 and on that basis denies these allegations.

4. Upon information and belief, Defendant Hetero USA Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1035 Centennial Ave, Piscataway, NJ, 08854.

ANSWER: Paragraph 4 contains legal conclusions to which no answer is required. To the extent a response is required, Hetero admits that it is a corporation organized and existing under the laws of Delaware and maintains a place of business at 1035 Centennial Ave, Piscataway, NJ 08854. Hetero denies the remaining allegations of Paragraph 4.

5. Upon information and belief, Defendant Hetero Labs Limited, Vemagal, is a division of Hetero Labs Limited, organized and existing under the laws of India.

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent a response is required, Hetero admits that Hetero Labs Limited, Vemagal is a division of Hetero Labs, Limited, organized and existing under the laws of India. Hetero denies the remaining allegations of Paragraph 5.

6. Upon information and belief, Defendant Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

ANSWER: Paragraph 6 contains legal conclusions to which no answer is required. To the extent a response is required, Hetero admits that Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad, 500 018, Andhra Pradesh, India. Hetero denies the remaining allegations of Paragraph 6.

7. Upon information and belief, following any FDA approval of ANDA No. 220421, Defendants will make, use, offer to sell, and/or sell the proposed generic drug product that is the subject of ANDA No. 220421 throughout the United States, and/or import such generic drug product into the United States.

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent a response is required, Hetero states that for purpures of this action only, Hetero does not contest

subject matter jurisdiction, personal jurisdiction, or venue. Hetero denies the remaining allegations of Paragraph 7.

JURISDICTION AND VENUE

8. 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 8 contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits that this action purports to arise under the patent laws of the United States, 35 U.S.C. § et seq. Hetero further does not contest this Court's subject matter jurisdiction solely for the limited purposes of this action, and expressly reserves the right to contest subject matter jurisdiction in any other case as to any other party, including Plaintiffs. Hetero further does not contest personal jurisdiction or venue solely for the limited purposes of this action, and expressly reserves the right to contest personal jurisdiction or venue in any other case as to any other party, including Plaintiffs. Hetero further states that Hetero Labs Limited and Hetero Labs Limited, Vemagal contest personal jurisdiction and venue. Hetero denies the remaining allegations of Paragraph 8.

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

ANSWER: Paragraph 9 contains legal conclusions to which no response is required. To the extent a response is required, Hetero does not contest this Court's personal jurisdiction solely for the limited purposes of this action, and expressly reserves the right to contest personal jurisdiction in any other case as to any other party, including Plaintiffs. Hetero further states that Hetero Labs Limited and Hetero Labs Limited, Vemagal contest personal jurisdiction. Hetero denies the remaining allegations of Paragraph 9.

10. This Court has personal jurisdiction over Hetero USA Inc. because, upon information and belief, Hetero USA Inc. 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. On information and belief, Hetero USA Inc. has a regular and established place of business in Piscataway, New Jersey, and is registered with the state of New Jersey's Department of Health as a drug wholesaler under Registration No. 5004050.

ANSWER: Paragraph 10 contains legal conclusions to which no response is required. To the extent a response is required, Hetero USA Inc. does not contest this Court's personal jurisdiction solely for the limited purposes of this action, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Hetero denies the remaining allegations of Paragraph 10.

11. This Court has personal jurisdiction over Hetero Labs Limited, Vemagal, because, upon information and belief, Hetero Labs Limited, Vemagal, 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, Hetero Labs Limited, Vemagal, is a division of defendant Hetero Labs Limited and acts at the direction, and for the benefit of, Hetero Labs Limited, and is controlled and/or dominated by Hetero Labs Limited. Upon information and belief, Hetero Labs Limited, Vemagal, and Hetero Labs Limited operate as a single, integrated business.

ANSWER: Paragraph 11 contains legal conclusions to which no response is required. To the extent a response is required, Hetero states that Hetero Labs Limited, Vemagal contests this Court's personal jurisdiction. Hetero Labs Limited, Vemagal denies the remaining allegations of Paragraph 11.

12. This Court has personal jurisdiction over Hetero Labs Limited because, upon information and belief, Hetero Labs Limited 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.

ANSWER: Paragraph 12 contains legal conclusions to which no response is required. To the extent a response is required, Hetero states that Hetero Labs Limited contests this Court's personal jurisdiction. Hetero Labs Limited denies the remaining allegations of Paragraph 12.

13. Upon information and belief, Defendants acted collaboratively in the preparation and submission of ANDA No. 220421 to the FDA. Upon information and believe, Hetero USA Inc. filed ANDA No. 220421 with the FDA on behalf of itself, Hetero Labs Limited, Vemagal, and Hetero Labs Limited.

ANSWER: Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits that it submitted Hetero's ANDA to the FDA seeking approval to market Hetero's ANDA Product in the United States. Hetero denies the remaining allegations of Paragraph 13.

14. Upon information and belief, Defendants will manufacture, market, and/or sell within the United States the generic version of Braintree's SUTAB® drug product described in ANDA No. 220421 if approved by the FDA. If ANDA No. 220421 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 14 contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits that it submitted Hetero's ANDA to the FDA seeking approval to market Hetero's ANDA Product in the United States. Hetero denies the remaining allegations of Paragraph 14.

15. 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. 220421, Defendants' manufacturing, marketing and sales of their generic version of Braintree's SUTAB® will cause Braintree substantial injury in New Jersey.

ANSWER: Paragraph 15 contains legal conclusions to which no response is required. Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 15, and therefore denies any and all remaining allegations of Paragraph 15.

16. In addition, Hetero USA Inc. and Hetero Labs Limited have previously submitted to the jurisdiction of this Court and have previously availed themselves of this Court by, for example, asserting counterclaims in other civil actions initiated in this jurisdiction. For example, Hetero USA Inc. and Hetero Labs Limited did not contest jurisdiction in New Jersey and filed counterclaims in *Esperion Therapeutics, Inc. v. Hetero USA Inc.*, No. 2:24-cv-06389, Dkt. 24 (D.N.J. Aug. 6, 2024); *Celgene Corp. v. Hetero Labs Ltd.*, No. 2:20-cv-14389, Dkt. 7 (D.N.J. Nov. 13, 2020); *Celgene Corp. v. Hetero Labs Ltd*., No. 2:17-cv-03387, Dkt. 26 (D.N.J. Jul. 13, 2017); *Axsome Malta Ltd. et al. v. Alkem Lab'ys Ltd*., No 2:23-cv-20354, Dkt. 32 (D.N.J. Nov. 17, 2023); *Otsuka Pharm. Co., Ltd. v. Apotex Corp*., No. 1:14-cv-08074, Dkt. 97 (D.N.J. Apr. 24, 2015); *Otsuka Pharm. Co., Ltd. v. Torrent Pharm. Ltd*., No. 1:14-cv-04671, Dkt. 202 (D.N.J. Feb. 2, 2016); *Otsuka Pharm. Co., Ltd. v. Torrent Pharm.*, No. 1:14-cv-01078, Dkt. 38 (D.N.J. Oct. 31, 2014). In addition, Hetero USA Inc. has availed itself of this Court by filing suit in *Symed Labs Ltd. v. Amneal Pharm. LLC*, 2:18-cv-13628 (D.N.J.); *Symed Labs Ltd. v. Amneal Pharm. LLC*, 2:15-cv-08307 (D.N.J.); *Symed Labs Ltd. v. Hikma Pharm. USA Inc.*, 2:15-cv-08304 (D.N.J.); and *Symed Labs Ltd. v. Glenmark Pharm. Inc*., 2:15-cv-08306 (D.N.J.).

ANSWER: Paragraph 16 contains legal conclusions to which no response is required. To the extent a response is required, Hetero USA does not contest this Court's personal jurisdiction solely for the limited purposes of this action, and expressly reserve the right to contest personal jurisdiction in any other case as to any other party, including Plaintiffs. That Hetero Labs Limited accepted personal jurisdiction solely for the named cases, does not mean that the Court has personal jurisdiction over Hetero Labs Limited. Hetero denies the remaining allegations of Paragraph 16.

17. In the alternative, this Court may exercise personal jurisdiction over Hetero Labs Limited, Vemagal, and Hetero Labs Limited pursuant to Federal Rule of Civil Procedure 4(k)(2) because Braintree's claims arise under Federal law, and Hetero Labs Limited, Vemagal, and Hetero Labs Limited have sufficient contacts with the United States as a whole, including but not limited to

marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this court's exercise of jurisdiction would satisfy due process.

ANSWER: Paragraph 17 contains legal conclusions to which no response is required. Hetero denies the allegations of Paragraph 17.

BACKGROUND

18. 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: Paragraph 18 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, Hetero admits that, according to records available on the FDA website, Braintree is the holder of New Drug Application ("NDA") No. 213135. Hetero admits that, according to records available on the FDA website, on November 10, 2020, the FDA approved the use of SUTAB® in the United States pursuant to NDA No. 213135, and that the package label for SUTAB® dated October 24, 2023 states the following:

SUTAB (sodium sulfate, magnesium sulfate, and potassium chloride) tablets, for oral use
Initial U.S. Approval: 2020

----------RECENT MAJOR CHANGES----------

Dosage and Administration (2.1, 2.2)	10/2023
Warnings and Precautions (5.8)	10/2023

----------INDICATIONS AND USAGE----------

SUTAB is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults. (1)

Hetero lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

19. 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: Paragraph 19 contains legal conclusions to which no answer is required. To the extent a response is required, Hetero admits that the Patents-in-Suit are listed in the Orange Book in connection with SUTAB®. Hetero denies any remaining allegations in this paragraph.

THE '656 PATENT

20. 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 20 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, Hetero admits that according to the electronic records of the U.S. Patent and Trademark Office ("USPTO"), the '656 Patent, titled "SOLID ORAL SULFATE SALT FORMULATIONS FOR CLEANING A COLON AND METHODS OF USING SAME," issued on or about December 4, 2018, and that "BRAINTREE LABORATORIES, INC" appears to be identified as the last recorded assignee of the '656 Patent. Hetero also admits that a purported copy of the '656 Patent is attached as Exhibit A to the Complaint. Hetero denies that the '656 Patent was "duly and legally issued," and any suggestion or implication that the '656 Patent is valid or enforceable. Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 20, and therefore denies any and all remaining allegations of Paragraph 20.

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

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, the claims of the '656 Patent speak for themselves. Hetero denies any and all remaining allegations of Paragraph 21.

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

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, Hetero admits that the electronic version of FDA's Orange Book identifies the purported expiration date of the '656 Patent as August 4, 2037. Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 22, and therefore denies any and all remaining allegations of Paragraph 22.

23. 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 23 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 23, and therefore denies any and all remaining allegations of Paragraph 23.

THE '498 PATENT

24. 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 24 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, Hetero admits that according to the electronic records of the USPTO,

the ’498 Patent, titled “SOLID ORAL SULFATE SALT FORMULATIONS FOR CLEANING A COLON AND METHODS OF USING SAME,” issued on or about June 15, 2021, and that “BRAINTREE LABORATORIES, INC” appears to be identified as the last recorded assignee of the ’498 Patent. Hetero also admits that a purported copy of the ’498 Patent is attached as Exhibit B to the Complaint. Hetero denies that the ’498 Patent was “duly and legally issued,” and any suggestion or implication that the ’498 Patent is valid or enforceable. Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 24, and therefore denies any and all remaining allegations of Paragraph 24.

25. The ’498 Patent, *inter alia*, claims solid oral formulations for cleansing a colon.

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, the claims of the ’498 Patent speak for themselves. Hetero denies any and all remaining allegations of Paragraph 25.

26. The ’498 Patent will expire no earlier than August 4, 2037.

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, Hetero admits that the electronic version of FDA’s Orange Book identifies the purported expiration date of the ’498 Patent as August 4, 2037. Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 26, and therefore denies any and all remaining allegations of Paragraph 26.

27. 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 27 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 27, and therefore denies any and all remaining allegations of Paragraph 27.

THE '864 PATENT

28. 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 28 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, Hetero admits that according to the electronic records of the USPTO, the '864 Patent, titled "SOLID ORAL SULFATE SALT FORMULATIONS FOR CLEANSING A COLON AND METHODS OF USING SAME," issued on or about July 12, 2022, and that "BRAINTREE LABORATORIES, INC" appears to be identified as the last recorded assignee of the '864 Patent. Hetero also admits that a purported copy of the '864 Patent is attached as Exhibit C to the Complaint. Hetero denies that the '864 Patent was "duly and legally issued," and any suggestion or implication that the '864 Patent is valid or enforceable. Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 28, and therefore denies any and all remaining allegations of Paragraph 28.

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

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, the claims of the '864 Patent speak for themselves. Hetero denies any and all remaining allegations of Paragraph 29.

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

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, Hetero admits that the electronic version of FDA's Orange Book identifies the purported expiration date of the '864 Patent as August 4, 2037. Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 30, and therefore denies any and all remaining allegations of Paragraph 30.

31. 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 31 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 31, and therefore denies any and all remaining allegations of Paragraph 31.

THE '697 PATENT

32. 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 32 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, Hetero admits that according to the electronic records of the USPTO,

the '697 Patent, titled "SOLID ORAL SULFATE SALT FORMULATIONS FOR CLEANSING A COLON AND METHODS OF USING SAME," issued on or about May 2, 2023, and that "BRAINTREE LABORATORIES, INC" appears to be identified as the last recorded assignee of the '697 Patent. Hetero also admits that a purported copy of the '697 Patent is attached as Exhibit D to the Complaint. Hetero denies that the '697 Patent was "duly and legally issued," and any suggestion or implication that the '697 Patent is valid or enforceable. Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 32, and therefore denies any and all remaining allegations of Paragraph 32.

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

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, the claims of the '697 Patent speak for themselves. Hetero denies any and all remaining allegations of Paragraph 33.

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

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, Hetero admits that the electronic version of FDA's Orange Book identifies the purported expiration date of the '697 Patent as August 4, 2037. Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 34, and therefore denies any and all remaining allegations of Paragraph 34.

35. 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 35 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 35, and therefore denies any and all remaining allegations of Paragraph 35.

INFRINGEMENT

36. By letter dated June 11, 2025 ("Defendants' Notice Letter"), Hetero USA Inc. notified Plaintiffs Braintree and Sebela US Inc. that, on behalf of itself and Hetero Labs Limited, Vemagal, and Hetero Labs Limited, it had submitted ANDA No. 220421 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 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride composition currently listed in the Orange Book for SUTAB®.

ANSWER: Hetero admits that it sent a letter dated June 11, 2025 to Plaintiffs regarding Hetero's ANDA Product comprising tablets containing 1.479 grams of sodium sulfate, 0.225 grams of magnesium sulfate, and 0.188 grams of potassium chloride, providing notice that an "ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A) and contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ('Paragraph IV Certification') to obtain approval to engage in the commercial manufacture, use, or sale of Hetero's ANDA Product, before the expiration of the Challenged Patents." Hetero denies any remaining allegations in this paragraph.

37. By filing ANDA No. 220421, and upon information and belief, Defendants have represented to the FDA that the components of their proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride has 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. 220421, and upon information and belief, Defendants have represented that their proposed generic version of SUTAB® containing sodium sulfate, magnesium sulfate, and potassium chloride is bioequivalent to SUTAB®.

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. To the extent Hetero is required to respond, Hetero admits that Hetero USA seeks FDA approval to market the Hetero ANDA Product in the United States. Hetero denies any remaining allegations in this paragraph.

38. Defendants have committed an act of infringement, pursuant to 35 U.S.C. § 271(e)(2), by filing ANDA No. 220421 under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and/or sale of their proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride before the expiration of the Asserted Patents.

ANSWER: Denied.

39. Plaintiffs are entitled under 35 U.S.C. § 271(e)(4) to full relief from Defendants' acts of infringement, including an Order by this Court ensuring that the effective date of any approval by the FDA of ANDA No. 220421, relating to Defendants' proposed generic version of SUTAB®, shall not be earlier than the expiration of the exclusivity afforded the Asserted Patents.

ANSWER: Denied.

40. Plaintiffs filed their Complaint before the expiration of the forty-five day period from the day after Plaintiffs received the Defendants' Notice Letter, which was dated June 11, 2025.

ANSWER: Admitted.

COUNT I (INFRINGEMENT OF THE '656 PATENT)

41. Each of the preceding paragraphs 1 through 40 is incorporated as if fully set forth.

ANSWER: Hetero restates and incorporates by reference each of its responses to Paragraphs 1-40 as if fully set forth herein.

42. Defendants' submission of ANDA No. 220421 to obtain approval to engage in the commercial manufacture, use, and/or sale of their proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride 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.

43. Specifically, the composition of Defendants' proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride and the way it is proposed to be made, used and sold as described in Defendants' 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 Defendants' Notice Letter, and upon information and belief, the components of Defendants' proposed generic version of SUTAB® has the same active ingredients, the same route of administration, the same dosage form, and the same strengths as the corresponding components of SUTAB®.

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent Hetero is required to respond, Hetero admits that Hetero USA seeks FDA approval to market the Hetero ANDA Product in the United States. Hetero denies any remaining allegations in this paragraph.

44. Upon information and belief, Defendants had actual and constructive knowledge of the '656 Patent prior to filing ANDA No. 220421, and were aware that the filing of ANDA No. 220421 with the FDA constituted an act of infringement of the '656 Patent.

ANSWER: Denied.

45. Upon information and belief, use of Defendants' proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride would infringe one or more claims of the '656 Patent.

ANSWER: Denied.

46. Upon information and belief, Defendants know that their proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride, and the proposed labeling for that product, is especially made or adapted for use in infringing the '656 Patent, and that the proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride and the proposed labeling are not suitable for any substantial noninfringing use. Upon information and belief, Defendants plan and intend to infringe, and will induce and/or contribute to the infringement of, the '656 Patent, immediately and imminently upon FDA approval of ANDA No. 220421.

ANSWER: Denied.

47. Upon FDA approval of ANDA No. 220421, Defendants will infringe the '656 Patent by making, using, offering to sell, and selling their proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride 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.

48. If infringement of the '656 Patent by Defendants 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)

49. Each of the preceding paragraphs 1 through 48 is incorporated as if fully set forth.

ANSWER: Hetero restates and incorporates by reference each of its responses to Paragraphs 1-48 as if fully set forth herein.

50. Defendants' submission of ANDA No. 220421 to obtain approval to engage in the commercial manufacture, use, and/or sale of their proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride 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.

51. Specifically, the composition of Defendants' proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride and the way it is proposed to be made, used and sold as described in Defendants' 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 Defendants' Notice Letter, and upon information and belief, the components of Defendants' proposed generic version of SUTAB® has the same active

ingredients, the same route of administration, the same dosage form, and the same strengths as the corresponding components of SUTAB®.

ANSWER: Paragraph 51 contains legal conclusions to which no answer is required. To the extent Hetero is required to respond, Hetero admits that Hetero USA seeks FDA approval to market the Hetero ANDA Product in the United States. Hetero denies any remaining allegations in this paragraph.

52. Upon information and belief, Defendants had actual and constructive knowledge of the '498 Patent prior to filing ANDA No. 220421, and were aware that the filing of ANDA No. 220421 with the FDA constituted an act of infringement of the '498 Patent.

ANSWER: Denied.

53. Upon information and belief, use of Defendants' proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride would infringe one or more claims of the '498 Patent.

ANSWER: Denied.

54. Upon information and belief, Defendants know that their proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride, and the proposed labeling for that product, is especially made or adapted for use in infringing the '498 Patent, and that their proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride and the proposed labeling are not suitable for any substantial noninfringing use. Upon information and belief, Defendants plan and intend to infringe, and will induce and/or contribute to the infringement of, the '498 Patent, immediately and imminently upon FDA approval of ANDA No. 220421.

ANSWER: Denied.

55. Upon FDA approval of ANDA No. 220421, Defendants will infringe the '498 Patent by making, using, offering to sell, and selling their proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride 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.

56. If infringement of the '498 Patent by Defendants 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)

57. Each of the preceding paragraphs 1 through 56 is incorporated as if fully set forth.

ANSWER: Hetero restates and incorporates by reference each of its responses to Paragraphs 1-56 as if fully set forth herein.

58. Defendants' submission of ANDA No. 220421 to obtain approval to engage in the commercial manufacture, use, and/or sale of their proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride 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.

59. Specifically, the composition of Defendants' proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride and the way it is proposed to be made, used and sold as described in Defendants' 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 Defendants' Notice Letter, and upon information and belief, the components of Defendants' proposed generic version of SUTAB® has the same active ingredients, the same route of administration, the same dosage form, and the same strengths as the corresponding components of SUTAB®.

ANSWER: Paragraph 59 contains legal conclusions to which no answer is required. To the extent Hetero is required to respond, Hetero admits that Hetero USA seeks FDA approval to market the

Hetero ANDA Product in the United States. Hetero denies any remaining allegations in this paragraph.

60. Upon information and belief, Defendants had actual and constructive knowledge of the '864 Patent prior to filing ANDA No. 220421, and were aware that the filing of ANDA No. 220421 with the FDA constituted an act of infringement of the '864 Patent.

ANSWER: Denied.

61. Upon information and belief, use of Defendants' proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride would infringe one or more claims of the '864 Patent.

ANSWER: Denied.

62. Upon information and belief, Defendants know that their proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride, and the proposed labeling for that product, is especially made or adapted for use in infringing the '864 Patent, and that their proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride and the proposed labeling are not suitable for any substantial noninfringing use. Upon information and belief, Defendants plan and intend to infringe, and will induce and/or contribute to the infringement of, the '864 Patent, immediately and imminently upon FDA approval of ANDA No. 220421.

ANSWER: Denied.

63. Upon FDA approval of ANDA No. 220421, Defendants will infringe the '864 Patent by making, using, offering to sell, and selling their proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride 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.

64. If infringement of the '864 Patent by Defendants 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)

65. Each of the preceding paragraphs 1 through 64 is incorporated as if fully set forth.

ANSWER: Hetero restates and incorporates by reference each of its responses to Paragraphs 1-64 as if fully set forth herein.

66. Defendants' submission of ANDA No. 220421 to obtain approval to engage in the commercial manufacture, use, and/or sale of their proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride 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.

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

ANSWER: Paragraph 67 contains legal conclusions to which no answer is required. To the extent Hetero is required to respond, Hetero admits that Hetero USA seeks FDA approval to market the Hetero ANDA Product in the United States. Hetero denies any remaining allegations in this paragraph.

68. Upon information and belief, Defendants had actual and constructive knowledge of the '697 Patent prior to filing of ANDA No. 220421, and were aware that the filing of ANDA No. 220421 with the FDA constituted an act of infringement of the '697 Patent.

ANSWER: Denied.

69. Upon information and belief, use of Defendants' proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride would infringe at least claim 1 of the '697 Patent.

ANSWER: Denied.

70. Upon information and belief, Defendants know that their proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride, and the proposed labeling for that product, is especially made or adapted for use in infringing the '697 Patent, and that the proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride and the proposed labeling are not suitable for any substantial noninfringing use. Upon information and belief, Defendants plan and intend to infringe, and will induce and/or contribute to the infringement of, the '697 Patent, immediately and imminently upon FDA approval of ANDA No. 220421.

ANSWER: Denied.

71. Upon FDA approval of ANDA No. 220421, Defendants will infringe the '697 Patent by making, using, offering to sell, and selling their proposed generic version of SUTAB® containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride 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.

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

ANSWER: Denied.

RESPONSE TO PRAYER FOR RELIEF

Hetero denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief, or to any relief whatsoever, and further request that judgment be entered in favor of Hetero,

dismissing Plaintiffs' Complaint with prejudice, awarding Hetero attorneys' fees and costs incurred defending this action, and granting such further relief as this Court may deem just and proper.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, and without any admission or implication as to burden of proof and expressly reserving its right to assert any additional defenses or counterclaims that discovery may reveal, Hetero asserts the following defenses:

FIRST DEFENSE
(NON-INFRINGEMENT OF THE ASSERTED PATENTS BY HETERO'S ANDA PRODUCT)

The manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Product does not and will not infringe any valid and/or enforceable claims of the Asserted Patents, either literally or by the doctrine of equivalents.

SECOND DEFENSE
(INVALIDITY OF THE ASSERTED PATENTS)

One or more claims of the Asserted Patents are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including without limitation, one or more of Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

THIRD DEFENSE
(NO INDUCEMENT)

Hetero has not induced, does not induce, and will not induce infringement of any valid, enforceable claim of the Asserted Patents by manufacturing, using, selling, offering for sale, importing, and/or marketing Hetero's ANDA product.

FOURTH DEFENSE
(NO CONTRIBUTORY INFRINGEMENT)

Hetero has not contributed, does not contribute, and will not contribute to infringement of any valid, enforceable claim of the Asserted Patents by manufacturing, using, selling, offering for sale, importing, and/or marketing Hetero's ANDA product.

FIFTH DEFENSE
(PROSECUTION HISTORY ESTOPPEL)

Plaintiffs' claims are barred by the doctrine of prosecution history estoppel. The claims of the Asserted Patents are so limited as not to cover the manufacturing, using, selling, offering for sale, importing, and/or marketing Hetero's ANDA product, as a result of the arguments, statements, representations, or amendments made to the United States Patent and Trademark Office during the prosecution of the applications leading to issuance of the Asserted Patents.

SIXTH DEFENSE
(NOT AN EXCEPTIONAL CASE)

Hetero's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

SEVENTH DEFENSE
(SAFE HARBOR UNDER 35 U.S.C. § 271(e)(1))

In accordance with 35 U.S.C. § 271(e)(1), Hetero's actions do not constitute infringement.

EIGHTH DEFENSE
(ADDITIONAL DEFENSES DISCOVERY MAY REVEAL)

Any additional defenses that discovery may reveal.

RESERVATION OF DEFENSES

Hetero hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure, Local Patent Rules, United States Patent Law and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this action, including unenforceability.

Dated: September 26, 2025

Respectfully submitted,

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Attorneys for Hetero USA Inc.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned counsel hereby certifies that this matter in controversy is the subject of no other matter pending in this Court, but is related to the following:

- *Braintree Labs., Inc., et al. v. Lupin Limited, et al.,* Civil Action No. 23-2853 (CPO) (EAP)
- *Braintree Labs., Inc., et al. v. Appco Pharma LLC, et al.,* Civil Action No. 25-10876 (CPO) (EAP)
- *Braintree Labs., Inc., et al. v. Alkem Labs. Ltd., et al.,* Civil Action No. 25-12118 (CPO) (EAP)

Dated: September 26, 2025

Respectfully submitted,

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LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel hereby certifies that the parties in this action seek injunctive and declaratory relief and therefore, this action is not appropriate for compulsory arbitration.

Dated: September 26, 2025

Respectfully submitted,

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