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Lupin Ltd.. and Lupin Pharmaceuticals, Inc.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

_____	X
	:
BRAINTREE LABORATORIES, INC. and	:
SEBELA US INC.,	:
	:
Plaintiffs,	:
	:
v.	:
	:
LUPIN LIMITED and LUPIN	:
PHARMACEUTICALS, INC.,	:
	:
Defendants.	:
	:
	:
	:
	:
_____	X

Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively “Lupin” or “Defendants”), through their undersigned counsel, hereby answer the First Amended Complaint of Plaintiffs Braintree Laboratories, Inc. (“Braintree”) and Sebela US Inc. (collectively “Plaintiffs”) as follows:

To the extent not specifically admitted herein, the allegations of the First Amended Complaint are denied.

### **NATURE OF THE ACTION**

1. Paragraph 1 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the First Amended Complaint filed by Plaintiffs purports to state a civil action for patent infringement under the United States patent laws, Title 35, United States Code. Defendants admit that Lupin Ltd. submitted Abbreviated New Drug Application (“ANDA”) No. 216095 to the United States Food and Drug Administration (“FDA”). Defendants admit that the First Amended Complaint purports to allege 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”). Except as expressly admitted, Defendants deny each and every allegation in Paragraph 1 of the First Amended Complaint.

### **PARTIES**

2. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 2 of the First Amended Complaint and, therefore, deny each and every allegation in Paragraph 2.

3. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 3 of the First Amended Complaint and, therefore, deny each and every allegation in Paragraph 3.

4. Defendants admit that Lupin Ltd. is a corporation organized and existing under the laws of India, with a registered office at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India. Except as expressly admitted, Defendants deny each and every allegation in Paragraph 4 of the First Amended Complaint.

5. Defendants admit that Lupin Pharmaceutical, Inc. is a corporation organized and existing under the laws of Delaware, with registered office at 111 S. Calvert Street, Harborplace Tower, 21st Floor, Baltimore, MD 21202. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Except as expressly admitted, Defendants deny each and every allegation in Paragraph 5 of the First Amended Complaint.

6. The allegations in Paragraph 6 of the First Amended Complaint are directed to Lupin Inc., which is no longer a party to this action. Accordingly, Defendants need not respond to the allegations in Paragraph 6. To the extent a response is required, Defendants deny each and every allegation in Paragraph 6 of the First Amended Complaint.

7. Defendants admit that Lupin Ltd. submitted ANDA No. 216095 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of the products described therein (“Lupin Ltd.’s ANDA Product”). Except as expressly admitted, Defendants deny each and every allegation in Paragraph 7 of the First Amended Complaint.

### **JURISDICTION AND VENUE**

8. Paragraph 8 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) solely for the claims directed against Lupin Ltd. under 35 U.S.C. § 271(e)(2) related to Lupin Ltd.’s ANDA No. 216095. Furthermore, Lupin Ltd. does not contest venue in this Court concerning ANDA No. 216095 for purposes of this civil action only. Except as expressly admitted, Defendants deny each and every remaining allegation contained in Paragraph 8 of the First Amended Complaint.

9. Paragraph 9 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal

jurisdiction in this Court concerning ANDA No. 216095 for the purposes of this civil action only. Except as expressly admitted, Defendants deny each and every allegation contained in Paragraph 9 of the First Amended Complaint.

10. Paragraph 10 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court concerning ANDA No. 216095 for the purposes of this civil action only. Defendants admit that Lupin Pharmaceuticals, Inc. is registered with the state of New Jersey's Department of Health as a drug manufacturer with Registration No. 5005159. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Except as expressly admitted, Defendants deny each and every allegation contained in Paragraph 10 of the First Amended Complaint.

11. The allegations in Paragraph 11 of the First Amended Complaint are directed to Lupin Inc., which is no longer a party to this action. Accordingly, Defendants need not respond to the allegations in Paragraph 11. To the extent a response is required, Defendants deny each and every allegation in Paragraph 11 of the First Amended Complaint.

12. Paragraph 12 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny each and every allegation contained in Paragraph 12 of the First Amended Complaint.

13. Paragraph 13 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin Ltd. does not contest personal jurisdiction in this Court concerning ANDA No. 216095 for the purposes of this civil action only. Defendants admit that <http://www.lupin.com/US/corporate-overview/> states "Lupin's generic and specialty presence in the United States includes five physical office locations on the East Coast as

well as a national salesforce operating throughout the country. Our five locations include commercial manufacturing, product development and formulations, marketing, sales operations, regulatory affairs, legal, compliance, and clinical operations.” Except as expressly admitted, Defendants deny each and every allegation contained in Paragraph 13 of the First Amended Complaint.

14. Defendants admit that Lupin Pharmaceuticals, Inc. has previously acted as a U.S. agent for Lupin Ltd. in certain circumstances. Except as expressly admitted, Defendants deny each and every remaining allegation contained in Paragraph 14 of the First Amended Complaint.

15. Paragraph 15 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admits that Lupin Ltd. submitted ANDA No. 216095 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of the Lupin Ltd.’s ANDA Products. Except as expressly admitted, Defendants deny each and every remaining allegation contained in Paragraph 15 of the First Amended Complaint.

16. Paragraph 16 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny each and every allegation contained in Paragraph 16 of the First Amended Complaint.

17. Paragraph 17 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Lupin Ltd. filed counterclaims seeking a declaratory judgment of non-infringement and invalidity in *Teva Branded Pharm. Products R&D, Inc. v. Lupin Ltd.*, 3:21-cv-13247, D.I. 13 (D.N.J.); *Bausch & Lomb, Inc. v. Lupin Ltd.*, 3:22-cv-00534, D.I. 19 (D.N.J.); and *Merck Sharp & Dohme LLC v. Lupin Ltd.*, 2:23-cv-00094, D.I. 18 (D.N.J); and that Lupin Ltd. and Lupin Pharmaceuticals, Inc. filed counterclaims seeking a declaratory judgment of invalidity in *Ortho-McNeil-Janssen*

*Pharmaceuticals, Inc. v. Lupin Pharmaceuticals, Inc.*, 2:10-cv-00322, D.I. 10 (D.N.J.). Certain allegations in Paragraph 17 of the First Amended Complaint are directed to Lupin Inc., which is no longer a party to this action. Accordingly, Defendants need not respond to such allegations in Paragraph 17. Except as expressly admitted, Defendants deny each and every remaining allegation contained in Paragraph 17 of the First Amended Complaint.

18. Paragraph 18 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin Ltd. does not contest personal jurisdiction in this Court concerning ANDA No. 216095 for purposes of this civil action only. Except as expressly admitted, Defendants deny each and every remaining allegation contained in Paragraph 18 of the First Amended Complaint.

### **BACKGROUND**

19. Defendants admit that the electronic version of the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") identifies "BRAINTREE LABORATORIES INC" as holding New Drug Application ("NDA") No. 213135 for SUTAB<sup>®</sup>, which contains sodium sulfate, magnesium sulfate, and potassium chloride. Defendants admit that the FDA website indicates SUTAB<sup>®</sup> was approved on November 10, 2020 and that the prescribing information for SUTAB<sup>®</sup>, with a date of 2020, states that "SUTAB is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults." Except as expressly admitted, Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 19 of the First Amended Complaint and, therefore, deny each and every remaining allegation in Paragraph 19.

20. Paragraph 20 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Orange Book

identifies the Asserted Patents in connection with SUTAB®. Except as expressly admitted, Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 20 of the First Amended Complaint and, therefore, deny each and every remaining allegation in Paragraph 20.

### **THE '656 PATENT**

21. Paragraph 21 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that, according to the face of the '656 patent, the '656 patent, entitled "Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using Same," issued on December 4, 2018. Defendants admit that the electronic records of the U.S. Patent and Trademark Office identify Braintree as the record owner and assignee of the '656 patent. Defendants admit that what purports to be a copy of the '656 patent is attached to the First Amended Complaint as Exhibit A. Except as expressly admitted, Defendants deny each and every remaining allegation in Paragraph 21 of the First Amended Complaint.

22. Paragraph 22 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the '656 patent is entitled "Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using Same." Except as expressly admitted, Defendants deny each and every remaining allegation in Paragraph 22 of the First Amended Complaint.

23. Paragraph 23 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 23 of the

First Amended Complaint and, therefore, deny each and every remaining allegation in Paragraph 23.

24. Paragraph 24 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 24 of the First Amended Complaint and, therefore, deny each and every remaining allegation in Paragraph 24.

### **THE '498 PATENT**

25. Paragraph 25 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that, according to the face of the '498 patent, the '498 patent, entitled "Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using Same," issued on June 15, 2021. Defendants admit that the electronic records of the U.S. Patent and Trademark Office identify Braintree as the record owner and assignee of the '498 patent. Defendants admit that what purports to be a copy of the '498 patent is attached to the First Amended Complaint as Exhibit B. Except as expressly admitted, Defendants deny each and every remaining allegation in Paragraph 25 of the First Amended Complaint.

26. Paragraph 26 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the '498 patent is entitled "Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using Same." Except as expressly admitted, Defendants deny each and every remaining allegation in Paragraph 26 of the First Amended Complaint.

27. Paragraph 27 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 27 of the First Amended Complaint and, therefore, deny each and every remaining allegation in Paragraph 27.

28. Paragraph 28 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 28 of the First Amended Complaint and, therefore, deny each and every remaining allegation in Paragraph 28.

#### **THE '864 PATENT**

29. Paragraph 29 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that, according to the face of the '864 patent, the '864 patent, entitled "Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using Same," issued on July 12, 2022. Defendants admit that the electronic records of the U.S. Patent and Trademark Office identify Braintree as the record owner and assignee of the '864 patent. Defendants admit that what purports to be a copy of the '864 patent is attached to the First Amended Complaint as Exhibit C. Except as expressly admitted, Defendants deny each and every remaining allegation in Paragraph 29 of the First Amended Complaint.

30. Paragraph 30 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that , the '864 patent is entitled "Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using

Same.” Except as expressly admitted, Defendants deny each and every remaining allegation in Paragraph 30 of the First Amended Complaint.

31. Paragraph 31 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 31 of the First Amended Complaint and, therefore, deny each and every remaining allegation in Paragraph 31.

32. Paragraph 32 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 32 of the First Amended Complaint and, therefore, deny each and every remaining allegation in Paragraph 32.

### **THE '697 PATENT**

33. Paragraph 33 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that, according to the face of the '697 patent, the '697 patent, entitled “Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using Same,” issued on May 2, 2023. Defendants admit that the electronic records of the U.S. Patent and Trademark Office identify Braintree as the record owner and assignee of the '697 patent. Defendants admit that what purports to be a copy of the '697 patent is attached to the First Amended Complaint as Exhibit D. Except as expressly admitted, deny each and every remaining allegation in Paragraph 33 of the First Amended Complaint.

34. Paragraph 34 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the '697 patent is entitled "Solid Oral Sulfate Salt Formulations For Cleansing A Colon And Methods Of Using Same." Except as expressly admitted, Defendants deny each and every remaining allegation in Paragraph 34 of the First Amended Complaint.

35. Paragraph 35 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 35 of the First Amended Complaint and, therefore, deny each and every remaining allegation in Paragraph 35.

36. Paragraph 36 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 36 of the First Amended Complaint and, therefore, deny each and every remaining allegation in Paragraph 36.

**ALLEGED INFRINGEMENT BY DEFENDANTS**

37. Defendants admit that Lupin Ltd. sent a letter dated April 13, 2023 to Plaintiffs providing information pursuant to FDCA Section 505(j)(2)(B)(ii) (Lupin Ltd.'s "SUTAB<sup>®</sup> Notice Letter") that provided written notice of the Lupin Ltd.'s ANDA Product. Lupin also admits that the Notice Letter informed Braintree and Sebela that Lupin seeks approval of Lupin's Proposed ANDA Product before the patents-in-suit expire. Except as expressly admitted Defendants deny each and every remaining allegation contained in Paragraph 37.

38. Defendants admit that Lupin Ltd. sent a supplemental letter dated June 16, 2023 to Plaintiffs providing information pursuant to FDCA Section 505(j)(2)(B)(ii) (Lupin Ltd.’s “Supplemental SUTAB<sup>®</sup> Notice Letter”) that provided written notice of the Lupin Ltd.’s ANDA Product. Lupin also admits that the Notice Letter informed Braintree and Sebela that Lupin seeks approval of Lupin’s Proposed ANDA Product before the patents-in-suit expire. Except as expressly admitted Defendants deny each and every remaining allegation contained in Paragraph 38.

39. Defendants admit that Lupin Ltd. submitted ANDA No. 216095 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of the products described. Defendants admit that Lupin Ltd. submitted bioequivalence data to the FDA for the products described in Lupin Ltd.’s ANDA No. 216095. Except as expressly admitted, Defendants deny each and every remaining allegation contained in Paragraph 39 of the First Amended Complaint.

40. Defendants deny each and every allegation contained in Paragraph 40 of the First Amended Complaint.

41. Defendants deny each and every allegation contained in Paragraph 41 of the First Amended Complaint.

42. Paragraph 42 of the First Amended Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiffs’ filed a complaint on May 25, 2023 and that Plaintiffs’ filed a first amended complaint on July 5, 2023. Defendants admits that Lupin Ltd.’s SUTAB<sup>®</sup> Notice Letter was dated April 13, 2023 and Lupin’ Ltd.’s Supplemental SUTAB<sup>®</sup> Notice Letter was dated June 16, 2023. Except as expressly admitted, Defendants deny each and every remaining allegation contained in Paragraph 42 of the First Amended Complaint.

**COUNT I (ALLEGED INFRINGEMENT OF THE '656 PATENT BY DEFENDANTS)**

43. Defendants restate and incorporate by reference their responses to paragraphs 1 through 42 of this Answer as if set forth herein.

44. Defendants deny each and every allegation contained in Paragraph 44 of the First Amended Complaint.

45. Defendants deny each and every allegation contained in Paragraph 45 of the First Amended Complaint.

46. Defendants admit that Lupin Ltd. was aware of the '656 Patent when Lupin Ltd.'s ANDA No. 216095 was filed. Except as expressly admitted, Defendants deny each and every remaining allegation contained in Paragraph 46 of the First Amended Complaint.

47. Defendants deny each and every allegation contained in Paragraph 47 of the First Amended Complaint.

48. Defendants deny each and every allegation contained in Paragraph 48 of the First Amended Complaint.

49. Defendants deny each and every allegation contained in Paragraph 49 of the First Amended Complaint.

50. Defendants deny each and every allegation contained in Paragraph 50 of the First Amended Complaint.

**COUNT II (ALLEGED INFRINGEMENT OF THE '498 PATENT BY DEFENDANTS)**

51. Defendants restate and incorporate by reference their responses to paragraphs 1 through 50 of this Answer as if set forth herein.

52. Defendants deny each and every allegation contained in Paragraph 52 of the First Amended Complaint.

53. Defendants deny each and every allegation contained in Paragraph 53 of the First Amended Complaint.

54. Defendants admit that Lupin Ltd. was aware of the '498 Patent when Lupin Ltd.'s ANDA No. 216095 was filed. Except as expressly admitted, Defendants deny each and every remaining allegation contained in Paragraph 54 of the First Amended Complaint.

55. Defendants deny each and every allegation contained in Paragraph 55 of the First Amended Complaint.

56. Defendants deny each and every allegation contained in Paragraph 56 of the First Amended Complaint.

57. Defendants deny each and every allegation contained in Paragraph 57 of the First Amended Complaint.

58. Defendants deny each and every allegation contained in Paragraph 58 of the First Amended Complaint.

**COUNT III (INFRINGEMENT OF THE '865 PATENT BY DEFENDANTS)**

59. Defendants restate and incorporate by reference their responses to paragraphs 1 through 58 of this Answer as if set forth herein.

60. Defendants deny each and every allegation contained in Paragraph 60 of the First Amended Complaint.

61. Defendants deny each and every allegation contained in Paragraph 61 of the First Amended Complaint.

62. Defendants admit that Lupin Ltd. was aware of the '864 Patent when Lupin Ltd.'s ANDA No. 216095 was filed. Except as expressly admitted, Defendants deny each and every remaining allegation contained in Paragraph 62 of the First Amended Complaint.

63. Defendants deny each and every allegation contained in Paragraph 63 of the First Amended Complaint.

64. Defendants deny each and every allegation contained in Paragraph 64 of the First Amended Complaint.

65. Defendants deny each and every allegation contained in Paragraph 65 of the First Amended Complaint.

66. Defendants deny each and every allegation contained in Paragraph 66 of the First Amended Complaint.

**COUNT IV (ALLEGED INFRINGEMENT OF THE '697 PATENT BY DEFENDANTS)**

67. Defendants restate and incorporate by reference their responses to paragraphs 1 through 66 of this Answer as if set forth herein.

68. Defendants deny each and every allegation contained in Paragraph 68 of the First Amended Complaint.

69. Defendants deny each and every allegation contained in Paragraph 69 of the First Amended Complaint.

70. Defendants admit that Lupin Ltd. was aware of the '697 Patent when Lupin Ltd.'s filed an amendment to ANDA No. 216095 certifying to the '697 Patent. Except as expressly admitted, Defendants deny each and every remaining allegation contained in Paragraph 70 of the First Amended Complaint.

71. Defendants deny each and every allegation contained in Paragraph 71 of the First Amended Complaint.

72. Defendants deny each and every allegation contained in Paragraph 72 of the First Amended Complaint.

73. Defendants deny each and every allegation contained in Paragraph 73 of the First Amended Complaint.

74. Defendants deny each and every allegation contained in Paragraph 74 of the First Amended Complaint.

### **RESPONSE TO PRAYER FOR RELIEF**

Defendants deny all allegations not specifically admitted herein, and further deny that Plaintiffs are entitled to the judgment and relief requested in Paragraphs 1-6 of the Request for Relief section of the First Amended Complaint or to any other relief. Defendants respectfully request that the Court: (a) dismiss the First Amended Complaint with prejudice; (b) enter judgment in favor of Defendants; (c) award Defendants the reasonable attorneys' fees and costs of defending this action pursuant to 35 U.S.C. § 285; and (d) award Defendants such further relief as the Court deems just and appropriate.

### **AFFIRMATIVE DEFENSES**

Without prejudice to the denials set forth in their responses to Paragraphs 1 through 61 of the First Amended Complaint, and without undertaking any of the burdens imposed by law on the Plaintiffs, Defendants aver and assert the following separate defenses to the First Amended Complaint. Defendants expressly reserve the right to allege additional defenses as they become known through the course of discovery.

#### **FIRST AFFIRMATIVE DEFENSE** **(Failure to State a Claim)**

Plaintiffs have failed to state a claim for which relief can be granted.

**SECOND AFFIRMATIVE DEFENSE**  
**(Lack of Subject Matter Jurisdiction)**

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

**THIRD AFFIRMATIVE DEFENSE**  
**(Non-Infringement)**

Defendants do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '656 patent, the '498 patent, '864 patent, and the '697 patent.

**FOURTH AFFIRMATIVE DEFENSE**  
**(Invalidity)**

One or more claims of the '656 patent, the '498 patent, '864 patent, and the '697 patent are invalid for failure to comply with one or more of the conditions set forth in 35 U.S.C. §§ 101 et seq., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112 and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patents and/or the defenses recognized in 35 U.S.C. § 282.

**FIFTH AFFIRMATIVE DEFENSE**  
**(Not a Proper Party)**

Lupin Pharmaceutical Inc. is not a proper party to this action.

**SIXTH AFFIRMATIVE DEFENSE**  
**(Additional Defenses)**

Defendants reserve the right to present any additional defenses or counterclaims that discovery may reveal.

### **COUNTERCLAIMS**

Defendant/Counterclaimant Lupin Limited (“Lupin Ltd.”) brings the following Counterclaims against Plaintiffs/Counterdefendants Braintree Laboratories, Inc. (“Braintree”) and Sebela US Inc. (collectively “Plaintiffs”) for a declaratory judgment that 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”) are invalid and/or not infringed by the manufacture, use, sale, offer for sale, or importation of the product that is the subject of Lupin Ltd.’s Abbreviated New Drug Application (“ANDA”) No. 216095 (“Lupin Ltd.’s ANDA Product”).

### **PARTIES**

1. Lupin Ltd. is a corporation organized and existing under the laws of India, with a registered office at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

2. On information and belief, and based on Counterdefendant’s allegations, 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.

3. On information and belief, and based on Counterdefendant’s allegations, 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.

### **JURISDICTION AND VENUE**

6. Lupin Ltd. seeks a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

7. The Court has jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and 35 U.S.C. § 271(e)(2).

8. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b), and by Counterdefendants' choice of forum.

9. This is an action based upon an actual controversy between the parties concerning the invalidity and/or non-infringement of the '656 patent, the '498 patent, '864 patent, and the '697 patent and Lupin Ltd.'s right to continue to seek approval of Lupin Ltd.'s ANDA No. 216095 for Lupin Ltd.'s ANDA Product.

10. Lupin Ltd. has been and presently is engaged in the submission of documents to the Food & Drug Administration ("FDA") in connection with ANDA No. 216095, and those documents seek approval of Lupin Ltd.'s ANDA Product. Counterdefendants have alleged that the submission of Lupin Ltd.'s ANDA No. 216095 infringes, will infringe, will induce infringement, or will contribute to infringement of one or more claims of the '656 patent, the '498 patent, '864 patent, and the '697 patent.

11. Counterdefendants have filed in this Court an infringement action to enforce the '656 patent, the '498 patent, '864 patent, and the '697 patent against Lupin Ltd.

12. On information and belief, and according to Counterdefendants' allegations, Braintree is the assignee of the '656 patent, the '498 patent, '864 patent, and the '697 patent.

13. On information and belief, and according to Counterdefendants' allegations, Braintree is the holder of New Drug Application ("NDA") No. 213135 for SUTAB® (sodium sulfate, magnesium sulfate, and potassium chloride osmotic laxative for cleansing of the colon in preparation for colonoscopy in adults) tablets.

14. Lupin Ltd. has denied that it has, continues to, or will infringe, induce infringement of, and/or contribute to the infringement of, any valid and/or enforceable claim of the '656 patent, the '498 patent, '864 patent, and the '697 patent.

15. Lupin Ltd. has further asserted that one or more claims of the '656 patent, the '498 patent, '864 patent, and the '697 patent are invalid for failure to comply with one or more of the conditions set forth in 35 U.S.C. §§ 101 et seq., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112 and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patents and/or the defenses recognized in 35 U.S.C. § 282.

16. The '656 patent, the '498 patent, '864 patent, and the '697 patent are listed in the electronic version of the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to SUTAB®.

17. Lupin Ltd.'s ANDA includes a certification pursuant to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '656 patent, the '498 patent, '864 patent, and the '697 patent, indicating that in the opinion of Lupin Ltd. and to the best of its knowledge, no valid, enforceable claim of any of the '656 patent, the '498 patent, '864 patent, and the '697 patent will be infringed by the manufacture, use, importation, offer for sale, or sale of Lupin Ltd.'s ANDA Products. On April 17, 2023, Lupin Ltd., pursuant to Section 505(j)(2)(B) of the FDCA, provided via FedEx® delivery written notifications to Counterdefendants that Lupin Ltd. filed ANDA No. 216095 with the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '656 patent, the '498 patent, and the '864 patent are invalid and/or will not be infringed by Lupin Ltd.'s ANDA Product (Lupin Ltd.'s "SUTAB Notice Letter"). On June 16, 2023, Lupin Ltd., pursuant to Section 505(j)(2)(B) of the

FDCA, provided via FedEx® delivery written notifications to Counterdefendants that Lupin Ltd. submitted an amendment to ANDA No. 216095, including a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '697 patent is invalid and/or will not be infringed by Lupin Ltd.'s ANDA Product (Lupin Ltd.'s "Supplemental SUTAB Notice Letter." On information and belief, and according to Counterdefendants' allegations, Counterdefendants received the SUTAB Notice Letter and the Supplemental SUTAB Notice Letter.

18. In view of the foregoing, a conflict of asserted rights has arisen between Lupin Ltd. and Counterdefendants with respect to the non-infringement and invalidity of the relevant claims of the '656 patent, the '498 patent, '864 patent, and the '697 patent, and as to Lupin Ltd.'s right to obtain FDA approval of Lupin Ltd.'s ANDA Product. An actual controversy therefore exists between Counterdefendants and Lupin Ltd.

**FIRST COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT**  
**(U.S. PATENT NO. 10,143,656)**

19. Lupin Ltd. realleges Paragraphs 1–18 as though fully set forth herein.

20. Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '656 patent.

21. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '656 patent.

22. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '656 patent.

**SECOND COUNTERCLAIM – DECLARATION OF INVALIDITY**  
**(U.S. PATENT NO. 10,143,656)**

23. Lupin Ltd. realleges Paragraphs 1–22 as though fully set forth herein.

24. The claims of the '656 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 et seq., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

25. Lupin Ltd. is entitled to a judicial determination that the claims of the '656 patent are invalid.

**THIRD COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT**  
**(U.S. PATENT NO. 11,033,498)**

26. Lupin Ltd. realleges Paragraphs 1–25 as though fully set forth herein.

27. Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '498 patent.

28. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '498 patent.

29. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '498 patent.

**FOURTH COUNTERCLAIM – DECLARATION OF INVALIDITY**  
**(U.S. PATENT NO. 11,033,498)**

30. Lupin Ltd. realleges Paragraphs 1–29 as though fully set forth herein.

31. The claims of the '498 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 et seq., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

32. Lupin Ltd. is entitled to a judicial determination that the claims of the '498 patent are invalid.

**FIFTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT**  
**(U.S. PATENT NO. 11,382,864)**

33. Lupin Ltd. realleges Paragraphs 1–32 as though fully set forth herein.

34. Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '864 patent.

35. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '864 patent.

36. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '864 patent.

**SIXTH COUNTERCLAIM – DECLARATION OF INVALIDITY**  
**(U.S. PATENT NO. 11,382,864)**

37. Lupin Ltd. realleges Paragraphs 1–36 as though fully set forth herein.

38. The claims of the '864 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 et seq., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

39. Lupin Ltd. is entitled to a judicial determination that the claims of the '864 patent are invalid.

**SEVENTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT**  
**(U.S. PATENT NO. 11,638,697)**

40. Lupin Ltd. realleges Paragraphs 1–39 as though fully set forth herein.

41. Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '697 patent.

42. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '697 patent.

43. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '697 patent.

**EIGHTH COUNTERCLAIM – DECLARATION OF INVALIDITY**  
**(U.S. PATENT NO. 11,638,697)**

44. Lupin Ltd. realleges Paragraphs 1–43 as though fully set forth herein.

45. The claims of the '697 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 et seq., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

46. Lupin Ltd. is entitled to a judicial determination that the claims of the '697 patent are invalid.

**DEMAND FOR JUDGMENT**

WHEREFORE, Lupin Ltd. prays for the following relief:

A. That the Court order the First Amended Complaint dismissed with prejudice and judgment be entered in favor of Lupin Ltd.;

B. That a judgment be entered declaring that Lupin Ltd. does not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '656 patent, the '498 patent, the '864 patent, and the '697 patent;

C. That a judgment be entered declaring that the manufacture, import, use, sale, and/or offer to sell Lupin Ltd.'s ANDA Product, has not infringed, does not, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid and/or enforceable claim of the '656 patent, the '498 patent, the '864 patent, and the '697 patent;

D. That a judgment be entered declaring the claims of the '656 patent, the '498 patent, the '864 patent, and/or the '697 patent invalid;

E. That the Court declare that Lupin Ltd. has the lawful right to manufacture, import, use, sell, and/or offer to sell Lupin Ltd.'s ANDA Product in the United States once the product is approved by the FDA;

F. That Lupin Ltd. and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Lupin Ltd. or any of its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Lupin Ltd., or charging any of them either orally or in writing with infringement of the '656 patent, the '498 patent, the '864 patent, and the '697 patent;

G. That a judgment be entered, declaring that this action is an exceptional case within the meaning of 35 U.S.C. § 285 and that Lupin Ltd. is therefore entitled to recover its reasonable attorneys' fees upon prevailing in this action;

H. That Lupin Ltd. be awarded costs, attorney's fees, and other relief, both legal and equitable, to which it may be justly entitled; and

I. That Lupin Ltd. be awarded such other and further relief as is just and proper.

MIDLIGE RICHTER LLC  
*Attorneys for Defendants,*  
*Lupin Ltd. and Lupin Pharmaceuticals, Inc.*

By: s/ James S. Richter  
James S. Richter  
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Dated: July 25, 2023

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*Attorneys for Defendants Lupin Limited and  
Lupin Pharmaceuticals, Inc.*

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2**

Pursuant to Local Civil Rules 11.2, the undersigned counsel for Defendants certifies that, to the best of his knowledge, information and belief, the matter in controversy is not the subject of any other action or proceeding.

Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. by their undersigned counsel, hereby certify that, the patents at issue in this action, U.S. Patent Nos. 10,143,656, 11,033,498, 11,382,864, and 11,638,697, have been asserted against Lupin by Plaintiffs Braintree Laboratories, Inc. (“Braintree”) and Sebela US Inc. (Collectively “Plaintiffs”) in this action (Civil Action No. 23-2853).

\_\_\_\_\_  
s/ James S. Richter  
James S. Richter

Dated: July 25, 2023

**LOCAL CIVIL RULE 201.1 CERTIFICATION**

Under Local Civil Rule 201.1, the undersigned counsel hereby certifies that to my knowledge, Plaintiffs’ Complaint and Defendants’ Counterclaims seeks injunctive and other equitable relief, and therefore this action is not appropriate for compulsory arbitration.

\_\_\_\_\_  
s/ James S. Richter  
James S. Richter

Dated: July 25, 2023

**CERTIFICATE OF SERVICE**

I hereby certify that on July 25, 2023, copies of the foregoing Answer, Affirmative Defenses and Counterclaims were served by ECF and email on all counsel of record.

I certify that the foregoing statements made by are true. I am aware that if any of the foregoing statements are willfully false, I am subject to punishment.

s/ James S. Richter

James S. Richter

Dated: July 25, 2023