UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRAINTREE LABORATORIES, INC., and SEBELA US INC.,

Plaintiffs,

v.

Civil Action No. _____

LUPIN LIMITED, LUPIN PHARMACEUTICALS, INC., and LUPIN INC.

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Braintree Laboratories, Inc. ("Braintree") and Sebela US Inc. (collectively, "Plaintiffs"), bring this Complaint for Patent Infringement against Defendants Lupin Limited, Lupin Pharmaceuticals, Inc., and Lupin Inc. (collectively, "Defendants"), and allege as follows:

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"), and 11,382,864 (the "'864 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. 216095 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.

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.

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.

4. Upon information and belief, Defendant Lupin Limited is a corporation organized and existing under the laws of India, having its registered office at Kalpataru Inspire 3rd Floor, Off. Western Express Highway, Santacruz (East), Mumbai 400055, India.

5. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals"), is a corporation organized and existing under the laws of Delaware with a principal place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202, and a regular and established place of business at 400 Campus Drive, Somerset, New Jersey 08873.

6. Upon information and belief, Defendant Lupin Inc. is a corporation organized and existing under the laws of Delaware with a principal place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202, and a regular and established place of business at 400 Campus Drive, Somerset, New Jersey 08873.

7. Upon information and belief, following any FDA approval of ANDA No. 216095, Defendants will make, use, offer to sell, and/or sell the proposed generic drug product that is the subject of ANDA No. 216095 throughout the United States, and/or import such generic drug product into the United States.

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).

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.

10. This Court has personal jurisdiction over Lupin Pharmaceuticals because, upon information and belief, Lupin Pharmaceuticals 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, Lupin Pharmaceuticals has a regular and established place of business in Somerset, New Jersey, and is registered with the state of New Jersey's Department of Health as a drug manufacturer under Registration No. 5005159.

11. This Court has personal jurisdiction over Lupin Inc. because, upon information and belief, Lupin 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, Lupin Inc. has a regular and established place of business in Somerset, New Jersey.

12. Upon information and belief, Lupin Pharmaceuticals and Lupin Inc. act at the direction, and for the benefit, of Lupin Limited, and are controlled and/or dominated by Lupin Limited. Upon information and belief, Lupin Limited, Lupin Pharmaceuticals, and Lupin Inc. operate as a single, integrated business.

13. This Court has personal jurisdiction over Lupin Limited because, for example, Lupin Limited regularly does business in New Jersey and has engaged in a persistent course of conduct within New Jersey directly and/or indirectly through its affiliates, Lupin Pharmaceuticals and Lupin Inc. Upon information and belief, Lupin Limited, Lupin Pharmaceuticals, and Lupin Inc. work in concert either directly or indirectly through one or more of their wholly owned subsidiaries with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in New Jersey. For example, on the website https://www.lupin.com/US/corporate-overview/, Defendants note that their "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. [Their] five locations include commercial manufacturing, product development and formulations, marketing, sales operations, regulatory affairs, legal, compliance, and clinical operations." Upon information and belief, one such physical office location is in Somerset, New Jersey.

14. Upon information and belief, Lupin Limited, Lupin Pharmaceuticals, and Lupin Inc. acted collaboratively in the preparation and submission of ANDA No. 216095 to the FDA. Upon information and belief, Lupin Pharmaceuticals was also listed U.S. Agent for Lupin Limited on at least one other ANDA filed with the FDA in 2015 and has made previous FDA submissions on behalf of Lupin Limited, including at least one Citizen Petition. *See, e.g.*, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/208061Orig1s000ltr.pdf (listing Lupin Pharmaceuticals as "U.S. Agent for Lupin Limited").

15. Upon information and belief, Lupin Limited, Lupin Pharmaceuticals, and Lupin Inc. will manufacture, market, and/or sell within the United States the generic version of Braintree's SUTAB® drug product described in ANDA No. 216095 if approved by the FDA. If ANDA No. 216095 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.

16. 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. 216095, Defendants' manufacturing, marketing and sales of their generic version of Braintree's SUTAB® will cause Braintree substantial injury in New Jersey.

17. In addition, Lupin Limited, Lupin Pharmaceuticals, and Lupin Inc. have previously submitted to the jurisdiction of this Court and have previously availed themselves of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. For example, Lupin Limited sought 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.). Similarly, Lupin Limited and Lupin Pharmaceuticals sought 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.). Finally, Lupin Inc. sought a declaratory judgment of non-infringement and invalidity in *Jazz Pharm. Ireland Ltd. v. Lupin Inc. et al.*, 2:21-cv-14271, D.I. 12 (D.N.J.); *Bausch Health Ireland Ltd. v. Lupin Inc.*, 1:19-cv-09178, D.I. 95 (D.N.J.); and *Bristol Myers Squibb Co. v. Lupin Inc.*, 3:20-cv-07810, D.I. 46 (D.N.J.).

18. In the alternative, this Court may exercise personal jurisdiction over Lupin Limited pursuant to Federal Rule of Civil Procedure 4(k)(2) because Braintree's claims arise under Federal law, and Lupin Limited has 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.

BACKGROUND

19. 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.

20. 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.

THE '656 PATENT

21. 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.

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

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

24. 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.

THE '498 PATENT

25. 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.

26. The '498 Patent, *inter alia*, claims methods of cleansing the colon.

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

28. 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.

THE '864 PATENT

29. 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.

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

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

32. 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.

INFRINGEMENT BY DEFENDANTS

33. By letter dated April 13, 2023 ("Lupin Notice Letter"), Lupin Limited notified Plaintiffs Braintree and Sebela US Inc. that Lupin Limited had submitted ANDA No. 216095 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 Asserted Patents, to engage in the commercial manufacture, use, or sale and/or importation of a proposed generic version of the 0.225 g

magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate composition currently listed in the Orange Book for SUTAB®.

34. By filing ANDA No. 216095, and upon information and belief, Lupin Limited has represented to the FDA that the components of its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate have the same active ingredients, the same route of administration, the same dosage form, and the same strengths as the corresponding components of SUTAB®. By filing ANDA No. 216095, and upon information and belief, Lupin Limited has represented that its proposed generic drug product containing magnesium sulfate, potassium chloride, and sodium sulfate are bioequivalent to SUTAB®.

35. Lupin Limited has committed an act of infringement, pursuant to 35 U.S.C. § 271(e)(2), by filing ANDA No. 216095 under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and/or sale of its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate before the expiration of the Asserted Patents.

36. Plaintiffs are entitled under 35 U.S.C. § 271(e)(4) to full relief from Lupin Limited's acts of infringement, including an Order by this Court ensuring that the effective date of any approval by the FDA of ANDA No. 216095, relating to Lupin Limited's proposed generic version of SUTAB®, shall not be earlier than the expiration of the exclusivity afforded the Asserted Patents.

37. This Complaint is being filed before the expiration of the forty-five day period from the day after Plaintiffs received the Lupin Notice Letter, which was dated April 13, 2023.

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

38. Each of the preceding paragraphs 1 through 37 is incorporated as if fully set forth.

39. Lupin Limited's submission of ANDA No. 216095 to obtain approval to engage in the commercial manufacture, use, and/or sale of its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate prior to the expiration of the '656 Patent constitutes infringement of one or more of the claims of the '656 Patent under 35 U.S.C. § 271(e)(2)(A).

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

41. Upon information and belief, Defendants had actual and constructive knowledge of the '656 Patent prior to filing ANDA No. 216095, and were aware that the filing of ANDA No. 216095 with the FDA constituted an act of infringement of the '656 Patent.

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

43. Upon information and belief, Defendants know that their proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate, and the proposed labeling for that product, are especially made or adapted for use in infringing the '656 Patent, and that the proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate and the proposed

labeling are not suitable for any substantial noninfringing use. Upon information and belief, 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. 216095.

44. Upon FDA approval of ANDA No. 216095, Defendants will infringe the '656 Patent by making, using, offering to sell, and selling their proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate in the United States and/or importing such proposed generic drug product into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271 (a)-(c), unless enjoined by the Court.

45. 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.

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

46. Each of the preceding paragraphs 1 through 45 is incorporated as if fully set forth.

47. Lupin Limited's submission of ANDA No. 216095 to obtain approval to engage in the commercial manufacture, use, and/or sale of its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate prior to the expiration of the '498 Patent constitutes infringement of one or more of the claims of the '498 Patent under 35 U.S.C. § 271(e)(2)(A).

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

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

49. Upon information and belief, Defendants had actual and constructive knowledge of the '498 Patent prior to filing ANDA No. 216095, and were aware that the filing of ANDA No. 216095 with the FDA constituted an act of infringement of the '498 Patent.

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

51. Upon information and belief, Defendants know that their proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate, and the proposed labeling for that product, are especially made or adapted for use in infringing the '498 Patent, and that their proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate and the proposed labeling are not suitable for any substantial noninfringing use. Upon information and belief, 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. 216095.

52. Upon FDA approval of ANDA No. 216095, Defendants will infringe the '498 Patent by making, using, offering to sell, and selling their proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate in the United States and/or importing such proposed generic drug product into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271 (a)-(c), unless enjoined by the Court.

53. 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.

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

54. Each of the preceding paragraphs 1 through 53 is incorporated as if fully set forth.

55. Lupin Limited's submission of ANDA No. 216095 to obtain approval to engage in the commercial manufacture, use, and/or sale of its proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate prior to the expiration of the '864 Patent constitutes infringement of one or more of the claims of the '864 Patent under 35 U.S.C. § 271(e)(2)(A).

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

57. Upon information and belief, Defendants had actual and constructive knowledge of the '864 Patent prior to filing ANDA No. 216095, and were aware that the filing of ANDA No. 216095 with the FDA constituted an act of infringement of the '864 Patent.

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

59. Upon information and belief, Defendants know that their proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate, and the proposed labeling for that product, are especially made or adapted for use in

infringing the ’864 Patent, and that their proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate and the proposed labeling are not suitable for any substantial noninfringing use. Upon information and belief, 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. 216095.

60. Upon FDA approval of ANDA No. 216095, Defendants will infringe the ’864 Patent by making, using, offering to sell, and selling their proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate in the United States and/or importing such proposed generic drug product into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271 (a)-(c), unless enjoined by the Court.

61. 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.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request that this Court grant the following relief:

1. A judgment that one or more claims of the Asserted Patents are infringed by Lupin Limited’s submission of ANDA No. 216095, and that the making, using, offering to sell, or selling in the United States, or importing into the United States, of Defendants’ proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate by Defendants will directly infringe, actively induce infringement, and/or contribute to the infringement of the Asserted Patents;

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 216095 shall be a date which is not earlier than the expiration

date of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

3. An order permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States, Defendants' proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate until after the expiration date of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

4. Damages or other monetary relief to Plaintiffs if Defendants engage in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of Defendants' proposed generic drug product containing 0.225 g magnesium sulfate, 0.188 g potassium chloride, and 1.479 g sodium sulfate prior to the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

5. That Plaintiffs be awarded their fees and costs of this litigation; and

6. Such further relief as this Court deems proper and just, including but not limited to any appropriate relief under Title 35.

Date: May 25, 2023

s/Keith J. Miller
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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in this case is not the subject of any action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: May 25, 2023

s/ Keith J. Miller
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