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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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

Plaintiffs,

v.

APPCO PHARMA LLC., and SOMERSET THERAPEUTICS LLC,

Defendants.

Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Braintree Laboratories, Inc. ("Braintree") and Sebela US Inc. (collectively, "Plaintiffs"), bring this Complaint for Patent Infringement against Defendants Appco Pharma LLC and Somerset Therapeutics LLC (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"), 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. 220327 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 Appco Pharma LLC ("Appco") is a corporation organized and existing under the laws of Delaware, having its principal place of business at 262 Old New Brunswick Rd, Piscataway, New Jersey 08854. Appco has an additional operational site at 120 Belmont Dr, Somerset, New Jersey.[1]

5. Upon information and belief, Defendant Somerset Therapeutics LLC ("Somerset"), is a corporation organized and existing under the laws of Delaware with a principal place of business at 300 Franklin Square Dr., Somerset, New Jersey 08873.

6. Upon information and belief, following any FDA approval of ANDA No. 220327, Defendants will make, use, offer to sell, and/or sell the proposed generic drug product that is the subject of ANDA No. 220327 throughout the United States, and/or import such generic drug product into the United States.

[1] *See, e.g.*, http://appcopharma.com/facilities.html.

JURISDICTION AND VENUE

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

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

9. This Court has personal jurisdiction over Appco because, upon information and belief, Appco 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, Appco has regular and established places of business in Piscataway and Somerset, New Jersey, and is registered with the state of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5004511.

10. This Court has personal jurisdiction over Somerset because, upon information and belief, Somerset 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, Somerset 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. 5004837.

11. Upon information and belief, Appco and Somerset acted collaboratively in the preparation and submission of ANDA No. 220327 to the FDA. Upon information and believe, Appco filed ANDA No. 220327 with the FDA on behalf of itself and Somerset.

12. Upon information and belief, Appco and Somerset will manufacture, market, and/or sell within the United States the generic version of Braintree's SUTAB® drug product described in ANDA No. 220327 if approved by the FDA. If ANDA No. 220327 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.

13. 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. 220327, Defendants' manufacturing, marketing and sales of their generic version of Braintree's SUTAB® will cause Braintree substantial injury in New Jersey.

14. In addition, Appco and Somerset 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, Appco brought suit in the District of New Jersey in *Rising Pharma Holdings, Inc. et al v. Cosette Pharma, Inc*, No. 1:24-cv-01435 (D.N.J. 2025) and did not contest jurisdiction in the District of New Jersey in *Pfizer Inc. v. Appco Pharma Ltd.*, No. 3:18-cv-02272, D.I. 15 (D.N.J. April 20, 2018) (asserting counterclaim). Similarly, Somerset did not contest jurisdiction in the District of New Jersey in *In re Selenious Acid Litigation*, No. 2:24-cv-07791, Dkt. No. 75 (D.N.J. 2025) (asserting counterclaim); *American Regent, Inc. v. Somerset Therapeutics, LLC*, No. 2:24-cv-01022, Dkt. No. 12 (D.N.J. 2024) (asserting counterclaim); *American Regent, Inc. v. Somerset Therapeutics, LLC*, No. 2:24-cv-07807, Dkt. No. 10 (D.N.J. 2024) (asserting counterclaim); *Nexus Pharmaceuticals, Inc. v. Somerset Pharma, LLC*, No. 1:23-cv-01248, Dkt. No. 8 (2023) (asserting counterclaim); *Esperion Therapeutics, Inc. v. Renata Ltd.*, No. 2:24-cv-06017, Dkt. No. 35 (D.N.J. 2024) (asserting

counterclaim); or *American Regent, Inc. v. Somerset Therapeutics, LLC*, No. 2:24-cv-01030, Dkt. No. 12 (D.N.J. 2024) (asserting counterclaim).

BACKGROUND

15. 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.

16. 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

17. 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.

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

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

20. 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

21. 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.

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

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

24. 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

25. 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.

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

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

28. 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.

THE '697 PATENT

29. 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.

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

31. The ’697 Patent will expire no earlier than August 4, 2037.

32. 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.

INFRINGEMENT BY DEFENDANTS

33. By letter dated May 2, 2025 (“Defendants’ Notice Letter”), Appco notified Plaintiffs Braintree and Sebela US Inc. that, on behalf of itself and Somerset, Appco had submitted ANDA No. 220327 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®.

34. By filing ANDA No. 220327, and upon information and belief, Appco and Somerset have represented to the FDA that the components of their proposed generic drug product containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride 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. 220327, and upon information and belief, Appco and Somerset have represented that their proposed generic drug product containing sodium sulfate, magnesium sulfate, and potassium chloride is bioequivalent to SUTAB®.

35. Appco and Somerset have committed an act of infringement, pursuant to 35 U.S.C. § 271(e)(2), by filing ANDA No. 220327 under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and/or sale of their proposed generic drug product containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride before the expiration of the Asserted Patents.

36. Plaintiffs are entitled under 35 U.S.C. § 271(e)(4) to full relief from Appco and Somerset's acts of infringement, including an Order by this Court ensuring that the effective date of any approval by the FDA of ANDA No. 220327, relating to Defendants' proposed generic version of SUTAB®, shall not be earlier than the expiration of the exclusivity afforded the Asserted Patents.

37. 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 May 2, 2025.

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. Appco and Somerset's submission of ANDA No. 220327 to obtain approval to engage in the commercial manufacture, use, and/or sale of their proposed generic drug product 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).

40. Specifically, the composition of Defendants' proposed generic drug product 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 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. 220327, and were aware that the filing of ANDA No. 220327 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 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.

43. Upon information and belief, Defendants know that their proposed generic drug product containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride, 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 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. 220327.

44. Upon FDA approval of ANDA No. 220327, Defendants will infringe the '656 Patent by making, using, offering to sell, and selling their proposed generic drug product 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.

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. Appco and Somerset's submission of ANDA No. 220327 to obtain approval to engage in the commercial manufacture, use, and/or sale of their proposed generic drug product 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).

48. Specifically, the composition of Defendants' proposed generic drug product 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 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. 220327, and were aware that the filing of ANDA No. 220327 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 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.

51. Upon information and belief, Defendants know that their proposed generic drug product containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride, 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 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. 220327.

52. Upon FDA approval of ANDA No. 220327, Defendants will infringe the '498 Patent by making, using, offering to sell, and selling their proposed generic drug product 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.

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. Appco and Somerset's submission of ANDA No. 220327 to obtain approval to engage in the commercial manufacture, use, and/or sale of their proposed generic drug product 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).

56. Specifically, the composition of Defendants' proposed generic drug product 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 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. 220327, and were aware that the filing of ANDA No. 220327 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 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.

59. Upon information and belief, Defendants know that their proposed generic drug product containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride, 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 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. 220327.

60. Upon FDA approval of ANDA No. 220327, Defendants will infringe the '864 Patent by making, using, offering to sell, and selling their proposed generic drug product 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.

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.

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

62. Each of the preceding paragraphs 1 through 61 is incorporated as if fully set forth.

63. Appco and Somerset's submission of ANDA No. 220327 to obtain approval to engage in the commercial manufacture, use, and/or sale of their proposed generic drug product 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).

64. Specifically, the composition of Defendants' proposed generic drug product 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 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®.

65. Upon information and belief, Defendants had actual and constructive knowledge of the '697 Patent prior to filing of ANDA No. 220327 with the FDA constituted an act of infringement of the '697 Patent.

66. Upon information and belief, use of Defendants' proposed generic drug product 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.

67. Upon information and belief, Defendants know that their proposed generic drug product containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride, and the proposed labeling for that product, are especially made or adapted for use in infringing the '697 Patent, and that the proposed generic drug product containing 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. 220327.

68. Upon FDA approval of ANDA No. 220327, Defendants will infringe the '697 Patent by making, using, offering to sell, and selling their proposed generic drug product 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.

69. 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.

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 Appco and Somerset's submission of ANDA No. 220327, 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 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride 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. 220327 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 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride 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 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride 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: June 13, 2025

s/ Keith J. Miller
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LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, this matter in controversy is the subject of, or related to, one other pending litigation in this District, which is captioned *Braintree Laboratories, Inc. et al. v. Lupin Limited et al.*, No. 2:23-cv-2853(CPO)(EAP)(D.N.J. May 25, 2023), and otherwise is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding in any court. I further certify, that to the best of my knowledge, there are no non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court and amended certification if there is a change in the facts stated in this original certification.

I certify under penalty of perjury, that the foregoing is true and correct.

Dated: June 13, 2025
Newark, NJ

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