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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC., **Plaintiff,** **v.** **MICRO LABS LTD. and MICRO LABS USA, INC.,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendants Micro Labs Ltd. and Micro Labs USA, Inc. (collectively, "Micro Labs" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 8,298,576 ("the '576 patent"), 8,298,580 ("the '580 patent"), 8,663,683 ("the '683 patent"), 8,877,248 ("the '248 patent"), 8,889,191 ("the '191 patent"), 8,992,989 ("the '989 patent"), 9,549,940 ("the '940

patent"), 9,555,004 ("the '004 patent"), 9,622,983 ("the '983 patent"), and 10,314,790 ("the '790 patent") attached hereto as Exhibits A–J (collectively, "the patents-in-suit").

THE PARTIES

2. Plaintiff Supernus is a corporation organized and existing under the laws of Delaware, having its principal place of business at 9715 Key West Avenue, Rockville, Maryland 20850.

3. Upon information and belief, Defendant Micro Labs Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 31, Race Course Road, Bangalore, India 560 001.

4. Upon information and belief, Defendant Micro Labs USA, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 220 Davidson Avenue, Suite 402, Somerset, New Jersey 08873.

5. Upon information and belief, Defendant Micro Labs USA, Inc. is, directly or indirectly, a wholly owned affiliate or subsidiary of Defendant Micro Labs Ltd. Upon information and belief, Defendant Micro Labs USA, Inc. is affiliated with and/or under the control of Defendant Micro Labs Ltd., and both entities conduct business under the trade name "Micro Labs." Upon information and belief, Defendant Micro Labs Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Defendant Micro Labs USA, Inc., throughout the United States, including in the State of New Jersey.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Defendants under: (i) Fed. R. Civ. P. 4(k)(1) and N.J. Ct. R. 4:4-4; and/or (ii) Fed. R. Civ. P. 4(k)(2).

8. Upon information and belief, on or about August 13, 2024, Micro Labs sent a letter pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95) regarding the paragraph IV certification that Micro Labs submitted in Abbreviated New Drug Application No. 219183 ("the Micro Labs ANDA") and the patents-in-suit (the "August 13 Notice Letter") to Supernus at 9715 Key West Avenue, Rockville, Maryland 20850.

9. The August 13 Notice Letter was signed by Kevin M. Nelson, ArentFox Schiff LLP, who stated that he is "authorized to accept service of process on behalf of Micro Labs Ltd. in connection with its ANDA No. 219183, relating to Micro Labs Ltd.'s topiramate product."

10. According to the August 13 Notice Letter, Micro Labs filed the Micro Labs ANDA with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of generic topiramate extended-release capsules, containing 25mg, 50mg, 100 mg, and 200mg of topiramate ("the Micro Labs ANDA Products").

11. Upon information and belief, Defendants are in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey, and importing generic pharmaceutical products into the United States, including throughout the State of New Jersey; (ii) the preparation, submission, and filing of Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to market generic drugs throughout the United States, including throughout the

State of New Jersey; and (iii) the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

12. Upon information and belief, Defendants were all actively involved in filing the Micro Labs ANDA and all stand to benefit from its approval.

13. Upon information and belief, Defendants collaborate to develop, manufacture, import, market, distribute, and/or sell pharmaceutical products, including generic drug products such as the Micro Labs ANDA Products that will be manufactured and sold pursuant to an ANDA, throughout the United States, including throughout the State of New Jersey.

14. Upon information and belief, Defendants derive substantial revenue from directly or indirectly selling generic pharmaceutical products throughout the United States, including in this Judicial District.

15. Upon information and belief, Micro Labs Ltd. is the parent company of Micro Labs USA, Inc.

16. Upon information and belief, Micro Labs Ltd. and Micro Labs USA, Inc. are intimately connected and operate as a unitary business, including in connection with the preparation and submission of the Micro Labs ANDA and the manufacture, use, offer for sale, sale, and/or importation into the United States of the Micro Labs ANDA Products.

17. Upon information and belief, Micro Labs Ltd. directly or indirectly develops, manufactures, imports, markets, and/or distributes, and/or sells pharmaceutical products, that are and/or will be manufactured and sold, pursuant to an ANDA, throughout the United States, including throughout the State of New Jersey.

18. Upon information and belief, Micro Labs Ltd. "markets and develops generic pharmaceutical products that are distributed and sold in the United States, including in the state of New Jersey."[1]

19. Upon information and belief, Micro Labs USA, Inc. "currently has more than 40 FDA approved generic products and has filed more than twenty-five ANDA's that are with the FDA at various stages of review," and "is planning to file ten to fifteen ANDA's annually" in the United States.[2]

20. Upon information and belief, Micro Labs USA, Inc. products are manufactured in "three state-of-the-art USFDA approved facilities, one in Goa and two in Bangalore, India focusing on oral solid tablets & capsules . . . ."[3]

21. Upon information and belief, Micro Labs USA, Inc. is a wholly owned subsidiary of Micro Labs Ltd.[4]

22. Upon information and belief, Micro Labs USA, Inc. is the United States headquarters of Micro Labs Ltd.[5]

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[1] Answer at 4, *Allergan Sales LLC v. Micro Labs Ltd.*, No. 19-9759, ECF No. 10 (D.N.J. June 3, 2019).
[2] Micro Labs USA, Inc. Website, About Us, https://www.microlabsusa.com/about-us/ (last visited Sep. 18, 2024).
[3] *Id.*
[4] *Id.* ("Micro Labs USA, Inc. is a wholly owned subsidiary of Micro Labs Limited, India . . . ."); Answer at 3, *Esperion Therapeutics, Inc. v. Micro Labs USA, Inc.*, No. 24-5921, ECF No. 22 (D.N.J. July 12. 2024) ("Micro Labs Ltd. admits that Micro Labs USA, Inc. is a subsidiary of Micro Labs Ltd."); Answer at 4, *Aerie Pharms., Inc. v. Micro Labs Ltd.*, No. 22-1365, ECF No. 28 (D.N.J. July 18, 2022) ("Micro Labs admits that Micro Labs USA Inc. in a wholly-owned subsidiary of Micro Labs Ltd.").
[5] Micro Labs USA, Inc. Website, About Us, https://www.microlabsusa.com/about-us/ (last visited Sep. 23, 2024) (referring to Micro Labs USA, Inc. as "the US headquarter [sic]" for Micro Labs Ltd.).

23. Upon information and belief, Micro Labs USA, Inc. is registered with the State of New Jersey's Department of Health as a drug "manufacturer and wholesale[r]" with Registration Number 5004479.[6] Micro Labs USA, Inc. has, therefore, purposefully availed itself of the rights, benefits, and privileges of the laws of the State of New Jersey.

24. Upon information and belief, Micro Labs USA, Inc. is registered with the New Jersey Department of Treasury as a business entity with Entity ID 0400404035.[7] Micro Labs USA, Inc. has, therefore, purposefully availed itself of the rights, benefits, and privileges of the laws of the State of New Jersey.

25. Upon information and belief, Micro Labs Ltd. and Micro Labs USA, Inc. have filed five answers in concert in the District of New Jersey. All five answers set forth responses on behalf of a self-referred-to single entity "Micro Labs," which includes both Micro Labs Ltd. and Micro Labs USA, Inc.[8]

26. Upon information and belief, Defendants, directly or indirectly, work in concert to develop, manufacture, import, market, distribute, and/or sell pharmaceutical products, pursuant to ANDAs, throughout the United States, including the State of New Jersey.

27. Upon information and belief, Defendants have been and are acting cooperatively with respect to the preparation, submission, and maintenance of the Micro Labs ANDA.

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[6] New Jersey Department of Health Website, https://healthapps.state.nj.us/fooddrug/fdList.aspx (search company name field for "Micro Labs") (last visited Sep. 18, 2024).
[7] New Jersey Department of Treasury Website, Business Record Service, https://www.njportal.com/DOR/businessrecords/EntityDocs/BusinessStatCopies.aspx (search business name field for "Micro Labs") (last visited Sep. 18, 2024).
[8] Answer at 1, *Esperion Therapeutics, Inc. v. Micro Labs USA, Inc.*, No. 24-5921, ECF No. 22 (D.N.J. July 12, 2024); Answer at 1, *Aerie Pharms, Inc. v. Micro Labs Ltd.*, No. 22-1365, ECF No. 28, (D.N.J. July 18, 2022); Answer at 1, *Allergan Sales, LLC v. Micro Labs Ltd.,* No. 19-9759, ECF No. 10 (D.N.J. June 3, 2019); Answer at 1, *AstraZeneca AB v. Micro Labs Ltd.*, No. 15-3376, ECF No. 11 (D.N.J. July 20, 2015).

28. Upon information and belief, Defendants and/or their affiliates, directly or indirectly, manufacture and/or direct the manufacture of generic pharmaceutical products for which Micro Labs is the named ANDA applicant. Upon information and belief, Defendants, directly or indirectly, derive substantial revenue from the sales of such generic pharmaceutical products.

29. Upon information and belief, Defendants will, directly or indirectly, market the Micro Labs ANDA Products throughout the United States, including in the State of New Jersey, upon approval of the Micro Labs ANDA.

30. Upon information and belief, Defendants have purposefully availed themselves of the privilege of doing business in the State of New Jersey by continuously and systematically placing goods in the stream of commerce for distribution and sale throughout the United States, including the State of New Jersey.

31. This Court has personal jurisdiction over Micro Labs Ltd. at least because, upon information and belief: (i) Micro Labs Ltd. has its United States headquarters in the State of New Jersey; (ii) Micro Labs Ltd. is doing business in the State of New Jersey and maintains continuous and systematic contacts with this Judicial District, including by working in concert with Micro Labs USA, Inc.; (iii) Micro Labs Ltd. has purposefully directed its activities at residents and corporate entities within the State of New Jersey, including by working in concert with Micro Labs USA, Inc.; (iv) Micro Labs Ltd. is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey, including by working in concert with Micro Labs USA, Inc.; (v) Micro Labs Ltd. has committed, induced, and/or contributed to acts of patent infringement in the State of New Jersey, including by working in concert with Micro Labs USA, Inc.; (vi) the claims set

forth herein against Micro Labs Ltd. arise out of or relate to those activities; (vii) it is reasonable and fair for this Court to exercise personal jurisdiction over Micro Labs Ltd.; and (viii) Micro Labs Ltd. has previously submitted to the jurisdiction of this Court, has availed itself of the State of New Jersey's legal protections in prior litigations, and previously consented to personal jurisdiction in this Judicial District.[9]

32. Upon information and belief, the tortious acts of Micro Labs Ltd. of (i) preparing and filing the Micro Labs ANDA with a paragraph IV certification to the patents-in-suit for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, and/or sale within the United States, and/or importation into the United States, of the Micro Labs ANDA Products before the expiration of the patents-in-suit, and (ii) directing notice of its ANDA submission to Supernus, are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, offer to sell, and/or sale of the Micro Labs ANDA Products by Defendants before the expiration of the patents-in-suit throughout the United States, including in this Judicial District. Because defending against an infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, Micro Labs Ltd. should reasonably anticipate being sued in the State of New Jersey.

33. This Court has personal jurisdiction over Micro Labs Ltd. at least because, upon information and belief, if the Micro Labs ANDA is approved, the Micro Labs ANDA Products will be marketed, distributed, and/or sold, directly or indirectly, by Micro Labs Ltd. in the State

[9] Answer at 5-6, *Esperion Therapeutics, Inc. v. Micro Labs USA, Inc.*, No. 24-5921, ECF No. 22 (D.N.J. July 12, 2024); Answer at 7, *Aerie Pharms, Inc. v. Micro Labs Ltd.*, No. 22-1365, ECF No. X, (D.N.J. July 18, 2022); Answer at 5, *Allergan Sales, LLC v. Micro Labs Ltd.,* No. 19-9759, ECF No. 10 (D.N.J. June 3, 2019); Answer at 5, *AstraZeneca AB v. Micro Labs Ltd.*, No. 15-3376, ECF No. 11 (D.N.J. July 20, 2015).

of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey. Specifically, upon information and belief, if Micro Labs Ltd. succeeds in obtaining FDA approval, Micro Labs Ltd. will, directly or indirectly, market, distribute, and/or sell the Micro Labs ANDA Products in the State of New Jersey, including by working in concert with Micro Labs USA, Inc.

34. Upon information and belief, Micro Labs Ltd. intends to benefit directly if the Micro Labs ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of the Micro Labs ANDA.

35. This Court has personal jurisdiction over Micro Labs USA, Inc., at least because, upon information and belief: (i) Micro Labs USA, Inc. is incorporated in the State of New Jersey; (ii) Micro Labs USA, Inc. maintains a principal place of business in the State of New Jersey located at 220 Davidson Avenue, Suite 402, Somerset, NJ 08873; (iii) Micro Labs USA Inc. is doing business in the State of New Jersey and maintains continuous and systematic contacts with this Judicial District, including by working in concert with Micro Labs Ltd.; (iv) Micro Labs USA, Inc. is in the business of developing and manufacturing generic pharmaceutical products, directly or indirectly, for importation, sale, and/or distribution in the State of New Jersey, including by working in concert with Micro Labs Ltd.; (v) Micro Labs USA, Inc. has committed, induced, and/or contributed to acts of patent infringement in the State of New Jersey, including by working in concert with Micro Labs Ltd.; (vi) Micro Labs USA, Inc. has purposefully directed its activities at residents and corporate entities within the State of New Jersey, including by working in concert with Micro Labs Ltd.; (vii) the claims set forth herein against Micro Labs USA, Inc. arise out of or relate to those activities; (viii) it is reasonable and fair for this Court to exercise personal jurisdiction over Micro Labs USA, Inc.; and (ix) Micro

Labs USA, Inc. has previously submitted to the jurisdiction of this Court, has availed itself of the State of New Jersey's legal protections in prior litigations, and previously consented to personal jurisdiction in this Judicial District.[10]

36. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because, upon information and belief, Micro Labs USA, Inc. has a principal place of business in the State of New Jersey and has and will continue to engage in infringing activities in the State of New Jersey.

37. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because, upon information and belief, Micro Labs Ltd. is incorporated in India and may be sued in any judicial district in the United States in which the Defendant is subject to the court's personal jurisdiction, Micro Labs Ltd. maintains United States headquarters in the State of New Jersey, and Micro Labs Ltd. has and will continue to engage in infringing activities in the State of New Jersey.

FACTS AS TO ALL COUNTS

38. Supernus's Trokendi XR® is sold and marketed under New Drug Application ("NDA") No. 201635, which was approved by the FDA for the manufacture and sale of topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg.

39. Trokendi XR® is an antiepileptic drug indicated: (i) as an initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older; (ii) as an adjunctive therapy for the treatment of partial-onset seizures, primary

[10] Answer at 5, *Esperion Therapeutics, Inc. v. Micro Labs USA, Inc.*, No. 24-5921, ECF No. 22 (D.N.J. July 12, 2024); Answer at 8, *Aerie Pharms, Inc. v. Micro Labs Ltd.*, No. 22-1365, ECF No. 28, (D.N.J. July 18, 2022); Answer at 5, *Allergan Sales, LLC v. Micro Labs Ltd.,* No. 19-9759, ECF No. 10 (D.N.J. June 3, 2019); Answer at 5, *AstraZeneca AB v. Micro Labs Ltd.*, No. 15-3376, ECF No. 11 (D.N.J. July 20, 2015).

generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older; and (iii) for the preventive treatment of migraine in patients 12 years of age and older.

40. Trokendi XR®'s recommended dosage: (i) for monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily, and in patients 6 to 9 years of age is based on weight; (ii) for adjunctive therapy in adults with partial-onset seizures or Lennox-Gastaut syndrome is 200 mg to 400 mg orally once daily and with primary generalized tonic-clonic seizures is 400 mg orally once daily, and for adjunctive therapy for patients 6 to 16 years of age with partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome is approximately 5 mg/kg to 9 mg/kg orally once daily; and (iii) for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

41. FDA's publication, titled, "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book"), lists ten (10) patents, specifically the patents-in-suit, as covering Supernus's Trokendi XR®. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), the patents-in-suit were submitted to the FDA with or after the approval of NDA No. 201635. The patents-in-suit are listed in the Orange Book as covering Trokendi XR®.

42. The '576 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '576 patent.

43. The ’580 patent, titled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’580 patent.

44. The ’683 patent, titled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on March 4, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’683 patent.

45. The ’248 patent, titled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on November 4, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’248 patent.

46. The ’191 patent, titled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on November 18, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’191 patent.

47. The ’989 patent, titled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on March 31, 2015, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’989 patent.

48. The ’940 patent, titled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on January 24, 2017,

to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '940 patent.

49. The '004 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on January 31, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '004 patent.

50. The '983 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on April 18, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '983 patent.

51. The '790 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on June 11, 2019, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '790 patent.

52. Upon information and belief, the Micro Labs ANDA is based upon Trokendi XR® (topiramate extended-release capsules), 25 mg, 50 mg, 100 mg, and 200 mg, as its reference listed drug.

53. Upon information and belief, the Micro Labs ANDA Products are topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg.

54. Upon information and belief, Defendants have represented to FDA in ANDA No. 219183 that the Micro Labs ANDA Products are bioequivalent to Trokendi XR®.

55. 21 U.S.C. § 355(j)(2)(A)(i) requires that an ANDA contain, "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the

new drug have been previously approved for a drug listed under paragraph (7)." In addition, 21 U.S.C. § 355(j)(2)(A)(v) provides that an ANDA must contain "information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers." The August 13 Notice Letter Notice Letter does not indicate that Defendants intend to market the Micro Labs ANDA Products with labeling that differs from the Trokendi XR® label in terms of conditions of use, including the indications, usage, dosage, administration, or composition of Defendants' ANDA Product.

56. Upon information and belief, the proposed prescribing information for the Micro Labs ANDA Products includes a section titled, "Indications and Usage," and states that the Micro Labs ANDA Products are indicated: (i) as an initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older; (ii) as an adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older; and (iii) for the preventive treatment of migraine in patients 12 years of age and older.

57. Upon information and belief, the proposed prescribing information for the Micro Labs ANDA Products includes a section titled, "Dosage and Administration," and states that: (i) the recommended dose for monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily, and dosing in patients 6 to 9 years of age is based on weight; (ii) the recommended total daily dose as adjunctive therapy in adults with partial-onset seizures or Lennox-Gastaut syndrome is 200 mg to 400 mg orally once daily and with primary generalized tonic-clonic seizures is 400 mg orally once daily, and the recommended total daily

dose as adjunctive therapy for patients 6 to 16 years of age with partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome is approximately 5 mg/kg to 9 mg/kg orally once daily; and (iii) the recommended total daily dose as treatment for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

58. Upon information and belief, the proposed prescribing information for the Micro Labs ANDA Products also states under the section titled, "Dosage and Administration," that the Micro Labs ANDA Products can be taken without regard to meals, to swallow capsule whole and intact, and do not sprinkle on food, chew, or crush.

59. Upon information and belief, Micro Labs developed the Micro Labs ANDA Products and/or sought approval from the FDA to sell the Micro Labs ANDA Products throughout the United States, including within this Judicial District.

60. Upon information and belief, Micro Labs participated in the preparation, filing, and maintenance of the Micro Labs ANDA.

61. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 C.F.R. § 314.95(c)(7) requires that such a letter include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)-(ii).

62. Upon information and belief, as of the date of the August 13 Notice Letter, Micro Labs was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

63. Upon information and belief, the August 13 Notice Letter does not disclose any noninfringement contentions or opinions specifically directed to the '248 patent claims 14 and 18-20, the '989 patent claims 1-12 and 15-17, the '940 patent claims 1-12 and 15-17, and the '983 patent claims 1-11 and 14-16. Accordingly, upon information and belief, Micro Labs Ltd. acknowledges and admits that the Micro Labs ANDA and the Micro Labs ANDA Products infringe at least the '248 patent claims 14 and 18-20, the '989 patent claims 1-12 and 15-17, the '940 patent claims 1-12 and 15-17, and the '983 patent claims 1-11 and 14-16.

64. Upon information and belief, the August 13 Notice Letter does not disclose any unenforceability contentions or opinions for the patents-in-suit.

65. The August 13 Notice Letter purportedly included an Offer of Confidential Access to "certain [unspecified] information" from ANDA No. 219183, purportedly pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Defendants' Offer of Confidential Access contained numerous unreasonable and overly restrictive provisions. Plaintiff proposed revisions that comport with restrictions that "would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." See 21 U.S.C. § 355. Plaintiff and Defendants did not reach agreement on the terms of an Offer of Confidential Access and, to date, Defendants have not produced a copy of ANDA No. 219183 to Plaintiff.

FIRST COUNT
(Defendants' Infringement of the '576 Patent)

66. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

67. Upon information and belief, Defendants' submission and filing of the Micro Labs ANDA with a paragraph IV certification to the '576 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Micro Labs ANDA Products before the expiration of the '576 patent is an act of infringement by Defendants of one or more claims of the '576 patent under 35 U.S.C. § 271(e)(2)(A).

68. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Micro Labs ANDA Products upon, or in anticipation of, FDA approval of the Micro Labs ANDA.

69. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Micro Labs ANDA Products will infringe, directly and/or indirectly, one or more claims of the '576 patent under 35 U.S.C. § 271.

70. Upon information and belief, the commercial offering for sale and/or sale of the Micro Labs ANDA Products by Defendants will induce and/or contribute to third-party infringement of one or more claims of the '576 patent under 35 U.S.C. § 271.

71. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Micro Labs ANDA Products, and therefore will infringe at least one claim of the '576 patent.

72. Defendants have knowledge of the '576 patent and, upon information and belief, know or should know that the proposed labeling for the Micro Labs ANDA Products will induce direct infringement of at least one claim of the '576 patent, either literally or under the doctrine of equivalents.

73. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Micro Labs ANDA Products will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Micro Labs ANDA Products according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '576 patent.

74. Upon information and belief, the factual and legal bases in the August 13 Notice Letter regarding the '576 patent do not comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

75. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '576 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

76. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

SECOND COUNT
(Defendants' Infringement of the '580 Patent)

77. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

78. Upon information and belief, Defendants' submission and filing of the Micro Labs ANDA with a paragraph IV certification to the '580 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Micro Labs ANDA Products before the expiration of the '580 patent is an act of infringement by Defendants of one or more claims of the '580 patent under 35 U.S.C. § 271(e)(2)(A).

79. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Micro Labs ANDA Products upon, or in anticipation of, FDA approval of the Micro Labs ANDA.

80. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Micro Labs ANDA Products will infringe, directly and/or indirectly, one or more claims of the '580 patent under 35 U.S.C. § 271.

81. Upon information and belief, the commercial offering for sale and/or sale of the Micro Labs ANDA Products by Defendants will induce and/or contribute to third-party infringement of one or more claims of the '580 patent under 35 U.S.C. § 271.

82. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Micro Labs ANDA Products, and therefore will infringe at least one claim of the '580 patent.

83. Defendants have knowledge of the '580 patent and, upon information and belief, know or should know that the proposed labeling for the Micro Labs ANDA Products will induce direct infringement of at least one claim of the '580 patent, either literally or under the doctrine of equivalents.

84. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Micro Labs ANDA Products will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Micro Labs ANDA Products according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '580 patent.

85. Upon information and belief, the factual and legal bases in the August 13 Notice Letter regarding the '580 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

86. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '580 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

87. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

THIRD COUNT
(Defendants' Infringement of the '683 Patent)

88. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

89. Upon information and belief, Defendants' submission and filing of the Micro Labs ANDA with a paragraph IV certification to the '683 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Micro Labs ANDA Products before the expiration of the '683 patent is an act of infringement by Defendants of one or more claims of the '683 patent under 35 U.S.C. § 271(e)(2)(A).

90. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Micro Labs ANDA Products upon, or in anticipation of, FDA approval of the Micro Labs ANDA.

91. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the

Micro Labs ANDA Products will infringe, directly and/or indirectly, one or more claims of the '683 patent under 35 U.S.C. § 271.

92. Upon information and belief, the commercial offering for sale and/or sale of the Micro Labs ANDA Products by Defendants will induce and/or contribute to third-party infringement of one or more claims of the '683 patent under 35 U.S.C. § 271.

93. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Micro Labs ANDA Products, and therefore will infringe at least one claim of the '683 patent.

94. Defendants have knowledge of the '683 patent and, upon information and belief, know or should know that the proposed labeling for the Micro Labs ANDA Products will induce direct infringement of at least one claim of the '683 patent, either literally or under the doctrine of equivalents.

95. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Micro Labs ANDA Products will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Micro Labs ANDA Products according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '683 patent.

96. Upon information and belief, the factual and legal bases in the August 13 Notice Letter regarding the '683 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

97. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '683 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

98. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

FOURTH COUNT
(Defendants' Infringement of the '248 Patent)

99. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

100. Upon information and belief, Defendants' submission and filing of the Micro Labs ANDA with a paragraph IV certification to the '248 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Micro Labs ANDA Products before the expiration of the '248 patent is an act of infringement by Defendants of one or more claims of the '248 patent under 35 U.S.C. § 271(e)(2)(A).

101. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Micro Labs ANDA Products upon, or in anticipation of, FDA approval of the Micro Labs ANDA.

102. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Micro Labs ANDA Products will infringe, directly and/or indirectly, one or more claims of the '248 patent under 35 U.S.C. § 271.

103. Upon information and belief, the commercial offering for sale and/or sale of the Micro Labs ANDA Products by Defendants will induce and/or contribute to third-party infringement of one or more claims of the '248 patent under 35 U.S.C. § 271.

104. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Micro Labs ANDA Products, and therefore will infringe at least one claim of the '248 patent.

105. Defendants have knowledge of the '248 patent and, upon information and belief, know or should know that the proposed labeling for the Micro Labs ANDA Products will induce direct infringement of at least one claim of the '248 patent, either literally or under the doctrine of equivalents.

106. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Micro Labs ANDA Products will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Micro Labs ANDA Products according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '248 patent.

107. Upon information and belief, the factual and legal bases in the August 13 Notice Letter regarding the '248 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

108. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '248 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

109. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

FIFTH COUNT
(Defendants' Infringement of the '191 Patent)

110. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

111. Upon information and belief, Defendants' submission and filing of the Micro Labs ANDA with a paragraph IV certification to the '191 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Micro Labs ANDA Products before the expiration of the '191 patent is an act of infringement by Defendants of one or more claims of the '191 patent under 35 U.S.C. § 271(e)(2)(A).

112. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Micro Labs ANDA Products upon, or in anticipation of, FDA approval of the Micro Labs ANDA.

113. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Micro Labs ANDA Products will infringe, directly and/or indirectly, one or more claims of the '191 patent under 35 U.S.C. § 271.

114. Upon information and belief, the commercial offering for sale and/or sale of the Micro Labs ANDA Products by Defendants will induce and/or contribute to third-party infringement of one or more claims of the '191 patent under 35 U.S.C. § 271.

115. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Micro Labs ANDA Products, and therefore will infringe at least one claim of the '191 patent.

116. Defendants have knowledge of the '191 patent and, upon information and belief, know or should know that the proposed labeling for the Micro Labs ANDA Products will induce direct infringement of at least one claim of the '191 patent, either literally or under the doctrine of equivalents.

117. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Micro Labs ANDA Products will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Micro Labs ANDA Products according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '191 patent.

118. Upon information and belief, the factual and legal bases in the August 13 Notice Letter regarding the '191 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

119. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '191 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

120. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

SIXTH COUNT
(Defendants' Infringement of the '989 Patent)

121. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

122. Upon information and belief, Defendants' submission and filing of the Micro Labs ANDA with a paragraph IV certification to the '989 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Micro Labs ANDA Products before the expiration of the '989 patent is an act of infringement by Defendants of one or more claims of the '989 patent under 35 U.S.C. § 271(e)(2)(A).

123. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Micro Labs ANDA Products upon, or in anticipation of, FDA approval of the Micro Labs ANDA.

124. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Micro Labs ANDA Products will infringe, directly and/or indirectly, one or more claims of the '989 patent under 35 U.S.C. § 271.

125. Upon information and belief, the commercial offering for sale and/or sale of the Micro Labs ANDA Products by Defendants will induce and/or contribute to third-party infringement of one or more claims of the '989 patent under 35 U.S.C. § 271.

126. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Micro Labs ANDA Products, and therefore will infringe at least one claim of the '989 patent.

127. Defendants have knowledge of the '989 patent and, upon information and belief, know or should know that the proposed labeling for the Micro Labs ANDA Products will induce

direct infringement of at least one claim of the '989 patent, either literally or under the doctrine of equivalents.

128. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Micro Labs ANDA Products will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Micro Labs ANDA Products according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '989 patent.

129. Upon information and belief, the factual and legal bases in the August 13 Notice Letter regarding the '989 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

130. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '989 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

131. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

SEVENTH COUNT
(Defendants' Infringement of the '940 Patent)

132. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

133. Upon information and belief, Defendants' submission and filing of the Micro Labs ANDA with a paragraph IV certification to the '940 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of

the Micro Labs ANDA Products before the expiration of the '940 patent is an act of infringement by Defendants of one or more claims of the '940 patent under 35 U.S.C. § 271(e)(2)(A).

134. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Micro Labs ANDA Products upon, or in anticipation of, FDA approval of the Micro Labs ANDA.

135. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Micro Labs ANDA Products will infringe, directly and/or indirectly, one or more claims of the '940 patent under 35 U.S.C. § 271.

136. Upon information and belief, the commercial offering for sale and/or sale of the Micro Labs ANDA Products by Defendants will induce and/or contribute to third-party infringement of one or more claims of the '940 patent under 35 U.S.C. § 271.

137. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Micro Labs ANDA Products, and therefore will infringe at least one claim of the '940 patent.

138. Defendants have knowledge of the '940 patent and, upon information and belief, know or should know that the proposed labeling for the Micro Labs ANDA Products will induce direct infringement of at least one claim of the '940 patent, either literally or under the doctrine of equivalents.

139. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Micro Labs ANDA Products will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will

use the Micro Labs ANDA Products according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '940 patent.

140. Upon information and belief, the factual and legal bases in the August 13 Notice Letter regarding the '940 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

141. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '940 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

142. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

EIGHTH COUNT
(Defendants' Infringement of the '004 Patent)

143. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

144. Upon information and belief, Defendants' submission and filing of the Micro Labs ANDA with a paragraph IV certification to the '004 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Micro Labs ANDA Products before the expiration of the '004 patent is an act of infringement by Defendants of one or more claims of the '004 patent under 35 U.S.C. § 271(e)(2)(A).

145. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Micro Labs ANDA Products upon, or in anticipation of, FDA approval of the Micro Labs ANDA.

146. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Micro Labs ANDA Products will infringe, directly and/or indirectly, one or more claims of the '004 patent under 35 U.S.C. § 271.

147. Upon information and belief, the commercial offering for sale and/or sale of the Micro Labs ANDA Products by Defendants will induce and/or contribute to third-party infringement of one or more claims of the '004 patent under 35 U.S.C. § 271.

148. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Micro Labs ANDA Products, and therefore will infringe at least one claim of the '004 patent.

149. Defendants have knowledge of the '004 patent and, upon information and belief, know or should know that the proposed labeling for the Micro Labs ANDA Products will induce direct infringement of at least one claim of the '004 patent, either literally or under the doctrine of equivalents.

150. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Micro Labs ANDA Products will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Micro Labs ANDA Products according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '004 patent.

151. Upon information and belief, the factual and legal bases in the August 13 Notice Letter regarding the '004 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

152. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '004 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

153. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

NINTH COUNT
(Defendants' Infringement of the '983 Patent)

154. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

155. Upon information and belief, Defendants' submission and filing of the Micro Labs ANDA with a paragraph IV certification to the '983 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Micro Labs ANDA Products before the expiration of the '983 patent is an act of infringement by Defendants of one or more claims of the '983 patent under 35 U.S.C. § 271(e)(2)(A).

156. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Micro Labs ANDA Products upon, or in anticipation of, FDA approval of the Micro Labs ANDA.

157. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Micro Labs ANDA Products will infringe, directly and/or indirectly, one or more claims of the '983 patent under 35 U.S.C. § 271.

158. Upon information and belief, the commercial offering for sale and/or sale of the Micro Labs ANDA Products by Defendants will induce and/or contribute to third-party infringement of one or more claims of the '983 patent under 35 U.S.C. § 271.

159. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Micro Labs ANDA Products, and therefore will infringe at least one claim of the '983 patent.

160. Defendants have knowledge of the '983 patent and, upon information and belief, know or should know that the proposed labeling for the Micro Labs ANDA Products will induce direct infringement of at least one claim of the '983 patent, either literally or under the doctrine of equivalents.

161. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Micro Labs ANDA Products will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Micro Labs ANDA Products according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '983 patent.

162. Upon information and belief, the factual and legal bases in the August 13 Notice Letter regarding the '983 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

163. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '983 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

164. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

TENTH COUNT
(Defendants' Infringement of the '790 Patent)

165. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

166. Upon information and belief, Defendants' submission and filing of the Micro Labs ANDA with a paragraph IV certification to the '790 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Micro Labs ANDA Products before the expiration of the '790 patent is an act of infringement by Defendants of one or more claims of the '790 patent under 35 U.S.C. § 271(e)(2)(A).

167. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Micro Labs ANDA Products upon, or in anticipation of, FDA approval of the Micro Labs ANDA.

168. Upon information and belief, Defendants' commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Micro Labs ANDA Products will infringe, directly and/or indirectly, one or more claims of the '790 patent under 35 U.S.C. § 271.

169. Upon information and belief, the commercial offering for sale and/or sale of the Micro Labs ANDA Products by Defendants will induce and/or contribute to third-party infringement of one or more claims of the '790 patent under 35 U.S.C. § 271.

170. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Micro Labs ANDA Products, and therefore will infringe at least one claim of the '790 patent.

171. Defendants have knowledge of the '790 patent and, upon information and belief, know or should know that the proposed labeling for the Micro Labs ANDA Products will induce direct infringement of at least one claim of the '790 patent, either literally or under the doctrine of equivalents.

172. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Micro Labs ANDA Products will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Micro Labs ANDA Products according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '790 patent.

173. Upon information and belief, the factual and legal bases in the August 13 Notice Letter regarding the '790 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

174. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '790 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

175. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

Prayer for Relief

WHEREFORE, Supernus respectfully requests the following relief:

i. A Judgment declaring that the patents-in-suit are enforceable and not invalid;

ii. A Judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that the submission to FDA and filing of ANDA No. 219183 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Micro Labs ANDA Products was an act of infringement of the patents-in-suit by Defendants;

iii. A Judgment pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the Micro Labs ANDA Products before the expiration of the patents-in-suit (including any regulatory extensions) would directly and/or indirectly infringe the patents-in-suit;

iv. An Order, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, that the effective date of any approval of the Micro Labs ANDA Products shall be no earlier than the latest date on which the patents-in-suit expire (including any regulatory extensions);

v. An Order, pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees, and attorneys, and any person in active concert or participation or privity with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation in the United States of the Micro Labs ANDA Products until the expiration of the patents-in-suit (including any regulatory extensions);

vi. A Judgment, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, awarding Supernus damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or

sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 219183 that infringes the patents-in-suit;

vii. A Judgment, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, declaring that Defendants' infringement of the patents-in-suit is willful and awarding Supernus enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 219183 that infringes the patents-in-suit (including any regulatory extensions);

viii. A Judgment, pursuant to 35 U.S.C. § 285, declaring that this is an exceptional case and awarding Supernus its attorneys' fees and costs; and

ix. Such other and further relief as this Court may deem just and proper.

Dated: September 20, 2024

By: s/ William C. Baton

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that the matter in controversy involves the same plaintiff, same drug product, and same patents that are at issue in the matter captioned *Supernus Pharmaceuticals, Inc. v. Ajanta Pharma Ltd., et al.*, Appeal No. 24-1606 (Fed. Cir.), which was appealed from *Supernus Pharmaceuticals, Inc. v. Torrent Pharmaceuticals Ltd.*, C.A. Nos. 21-6964-GC-JTQ and 21-14268-GC-DEA (D.N.J.) (consolidated).

To the best of my knowledge, this matter is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: September 20, 2024

By: s/ William C. Baton

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