William C. Baton
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING LLP
One Riverfront Plaza
1037 Raymond Blvd., Suite 1520
Newark, NJ 07102
wbaton@saul.com

Attorneys for Plaintiff
Supernus Pharmaceuticals, Inc.

OF COUNSEL:

Edgar H. Haug
Nicholas F. Giove
Andrew S. Roper
Andrew Wasson
HAUG PARTNERS LLP
745 Fifth Avenue
New York, NY 10151

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC., **Plaintiff,** **v.** **AUROBINDO PHARMA LTD. and AUROBINDO PHARMA 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 Aurobindo Pharma Ltd. ("Aurobindo Ltd.") and Aurobindo Pharma USA, Inc. ("Aurobindo USA") (collectively, "Aurobindo" 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 No. 7,722,898 ("the '898 patent"), United States Patent No. 7,910,131 ("the '131 patent"), United States Patent No.

8,617,600 ("the '600 patent"), United States Patent No. 8,821,930 ("the '930 patent"), United States Patent No. 9,119,791 ("the '791 patent"), United States Patent No. 9,351,975 ("the '975 patent"), United States Patent No. 9,370,525 ("the '525 patent"), United States Patent No. 9,855,278 ("the '278 patent"), and United States Patent No. 10,220,042 ("the '042 patent"), United States Patent No. 11,166,960 ("the '960 patent") and United States Patent No. 11,896,599 ("the '599 patent") attached hereto as Exhibits A–K (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, Aurobindo USA is a corporation organized under the laws of Delaware and operating a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

4. Upon information and belief, Aurobindo USA is in the business of, *inter alia*, developing, manufacturing, marketing, distributing, and directly and/or indirectly selling generic pharmaceutical products throughout the United States (including in the State of New Jersey), and importing generic pharmaceutical products into the United States (including into the State of New Jersey).

5. Upon information and belief, Aurobindo USA, either directly or through one or more of its affiliates and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic pharmaceutical products, including in the State of New Jersey.

6. Upon information and belief, Aurobindo USA is registered with the State of New Jersey's Department of Health as a drug "wholesale[r]" with Registration Nos 5003120 and

5006312.[1] Aurobindo USA has, therefore, purposefully availed itself of the rights, benefits, and privileges of the laws of the State of New Jersey.

7. Upon information and belief, Aurobindo Ltd. is a corporation organized under the laws of India, having a principal place of business at Galaxy Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Pamkaktha, Ranga Reddy District, Hyderabad, Telangana, India, 500032.

8. Upon information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Ltd.

9. Upon information and belief, Aurobindo USA acts at the direction and for the benefit of Aurobindo Ltd. and is controlled and/or dominated by Aurobindo Ltd.

10. Upon information and belief, Aurobindo Ltd. and Aurobindo USA collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products.

11. Upon information and belief, Aurobindo Ltd. and Aurobindo USA are agents of each other and/or operate in concert as integrated parts of the same business group and enter into agreements with each other that are nearer than arm's length.

12. Upon information and belief, Aurobindo Ltd. is in the business of, *inter alia*, developing, manufacturing, marketing, distributing, and/or selling generic pharmaceutical products throughout the United States (including in the State of New Jersey), and importing generic pharmaceutical products into the United States (including into the State of New Jersey).

13. Upon information and belief, Aurobindo Ltd. and Aurobindo USA filed Abbreviated New Drug Application ("ANDA") No. 219241 ("the Aurobindo ANDA") with the

[1] New Jersey Department of Health Website, https://healthapps.state.nj.us/fooddrug/fdList.aspx (search company name field for "Aurobindo") (last visited Sep. 23, 2024).

FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of generic oxcarbazepine extended-release tablets, containing 150 mg, 300 mg, and 600 mg of oxcarbazepine ("the Aurobindo Product").

JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331,1338(a), 2201, and 2202.

15. 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).

16. 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. Aurobindo is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Aurobindo USA directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and in this Judicial District. On information and belief, Aurobindo USA has purposefully conducted and continues to conduct business in this Judicial District, and this Judicial District is a likely destination for Aurobindo's generic products upon approval of Aurobindo's ANDA.

17. On information and belief, Aurobindo USA is a subsidiary of Aurobindo Ltd. and is controlled and dominated by Aurobindo Ltd. On information and belief, Aurobindo Ltd. and Aurobindo USA operate as part of a single, integrated generic pharmaceutical manufacturer with Aurobindo Ltd. as the ultimate parent.

18. Upon information and belief, Aurobindo USA is registered with the State of New Jersey's Department of Health as a drug "wholesale[r]" with Registration Nos 5003120 and

5006312.[2] Aurobindo USA has, therefore, purposefully availed itself of the rights, benefits, and privileges of the laws of the State of New Jersey.

19. Upon information and belief, Aurobindo USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100921223. Aurobindo USA has, therefore, purposefully availed itself of the rights, benefits, and privileges of New Jersey's laws.

20. On information and belief, Aurobindo USA and Aurobindo Ltd. have been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of the Aurobindo ANDA.

21. This Court has personal jurisdiction over Defendants because, *inter alia*: (i) Aurobindo Ltd., together with Aurobindo USA, has committed, induced, or contributed to acts of patent infringement in New Jersey; (ii) Defendants are doing business in New Jersey and maintain continuous and systematic contacts with this Judicial District; (iii) Defendants directly or indirectly through agents regularly do or solicit business in New Jersey and/or derive substantial revenue from services or things used or consumed in New Jersey; (iv) Defendants transact business, perform work, and contract to supply services or products in New Jersey; (v) Defendants have availed themselves of the rights, benefits, and privileges of this Court by asserting counterclaims in multiple New Jersey actions; and (vi) Aurobindo USA is registered as a wholesale drug distributor in the State of New Jersey under Registration Nos. 5003120 and 5006312.

22. Aurobindo USA and Aurobindo Ltd.'s tortious acts of (i) preparing and filing ANDA No. 219241 with a paragraph IV certification to the patents in suit for the purpose of

[2] New Jersey Department of Health Website, https://healthapps.state.nj.us/fooddrug/fdList.aspx (search company name field for "Aurobindo") (last visited Sep. 23, 2024).

obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product before the expiration of the patents in suit; and (ii) directing notice of its ANDA submission to Plaintiff Supernus, are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, and/or sale of the Aurobindo Product 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, Aurobindo USA and Aurobindo Ltd. should reasonably anticipate being sued in New Jersey.

23. This Court also has personal jurisdiction over Aurobindo Ltd. and Aurobindo USA because Aurobindo Ltd. and Aurobindo USA have previously submitted to the jurisdiction of this Court and have previously availed themselves of the rights, benefits, and privileges of this Court by initiating lawsuits, consenting to this Court's jurisdiction, and asserting counterclaims in other civil actions initiated in this Judicial District. *See, e.g.*, *Theravance Biopharma R&D IP, LLC, et al. v. Eugia Pharma Specialities Limited, et al.*, Civil Action No. 1:23-cv-00926 (Aurobindo Pharma USA, Inc., Aurobindo Pharma Limited); *Forest Lab'ys, LLC, et al. v. Aurobindo Pharma USA, Inc., et al.*, Civil Action No. 2:17-cv-11679 (Aurobindo Pharma USA, Inc., Aurobindo Pharma Limited); *Boehringer Ingelheim Pharms., Inc., et al. v. Aurobindo Pharma USA, Inc., et al.*, Civil Action No. 3:17-cv-07887 (Aurobindo Pharma USA, Inc.); *Mitsubishi Tanabe Pharma Corp., et al. v. Aurobindo Pharma USA, Inc., et al.*, Civil Action No. 1:17-cv-05005 (Aurobindo Pharma USA, Inc.).

24. In the alternative, this Court has jurisdiction over Aurobindo Ltd. under Fed. R. Civ. P. 4(k)(2)(A) because: (a) Supernus's claims arise under federal law; (b) Aurobindo Ltd. is a

foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Aurobindo Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Aurobindo Ltd. satisfies due process.

25. Upon information and belief, if ANDA No. 219241 is approved, the Aurobindo Product will be marketed and distributed by Defendants in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey.

26. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and 1391(c), and § 1400(b).

27. Aurobindo has a principal place of business in New Jersey at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Aurobindo Ltd. is incorporated in the Republic of India and may be sued in any Judicial District in the United States.

28. Venue is proper for Aurobindo Ltd. under 28 U.S.C. §§ 1391 and/or 1400(b), because, *inter alia*, Aurobindo Ltd. is subject to personal jurisdiction in this Judicial District, as set forth above, has committed an act of infringement and will commit further acts of infringement in this Judicial District, as set forth above, and/or continuously transacts business in this Judicial District, as set forth above.

29. Venue is proper for Aurobindo USA under 28 U.S.C. §§ 1391 and/or 1400(b). As set forth above, Aurobindo USA has committed and will commit further acts of infringement in this Judicial District. In addition, Aurobindo USA does business in this Judicial District through a permanent and continuous presence in the State of New Jersey. For example, Aurobindo USA

is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration Nos. 5003120 and 5006312 and continuously sells its products in this Judicial District. Upon information and belief, Aurobindo USA employs a salesforce that includes personnel that regularly and continuously work in this Judicial District and, if Aurobindo USA succeeds in obtaining FDA approval, Aurobindo USA will use its salesforce to sell the Aurobindo Product in the State of New Jersey.

FACTS AS TO ALL COUNTS

30. Supernus owns New Drug Application ("NDA") No. 202810, which was approved by the FDA for the manufacture and sale of oxcarbazepine extended-release tablets, 150 mg, 300 mg, and 600 mg, which Supernus markets under the name Oxtellar XR®.

31. Oxtellar XR® "is indicated for the treatment of partial-onset seizures in patients 6 years of age and older."

32. The '898 patent, entitled, "Modified-Release Preparations Containing Oxcarbazepine and Derivatives Thereof" was duly and legally issued by the United States Patent and Trademark Office on May 25, 2010, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '898 patent.

33. The '131 patent, entitled, "Method of Treating Seizures Using Modified Release Formulations of Oxcarbazepine" was duly and legally issued by the United States Patent and Trademark Office on March 22, 2011, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '131 patent.

34. The '600 patent, entitled, "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof" was duly and legally issued by the United States Patent

and Trademark Office on December 31, 2013, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '600 patent.

35. The '930 patent, entitled, "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof" was duly and legally issued by the United States Patent and Trademark Office on September 2, 2014, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '930 patent.

36. The '791 patent, entitled, "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof" was duly and legally issued by the United States Patent and Trademark Office on September 1, 2015, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '791 patent.

37. The '975 patent, entitled, "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof" was duly and legally issued by the United States Patent and Trademark Office on May 31, 2016, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '975 patent.

38. The '525 patent, entitled, "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof" was duly and legally issued by the United States Patent and Trademark Office on June 21, 2016, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '525 patent.

39. The ’278 patent, entitled, “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof” was duly and legally issued by the United States Patent and Trademark Office on January 2, 2018, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the ’278 patent.

40. The ’042 patent, entitled, “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof” was duly and legally issued by the United States Patent and Trademark Office on March 5, 2019, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the ’042 patent.

41. The ’960 patent, entitled, “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof” was duly and legally issued by the United States Patent and Trademark Office on November 9, 2021, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the ’960 patent.

42. The ’599 patent, entitled, “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof” was duly and legally issued by the United States Patent and Trademark Office on February 13, 2024, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the ’599 patent.

43. Pursuant to 21 U.S.C. § 355(b)(1), the patents in suit are listed in FDA’s publication titled, “Approved Drug Products with Therapeutic Equivalence Evaluations”

(commonly known as the "Orange Book") in connection with Oxtellar XR®. Supernus submitted the patents in suit to FDA to be listed in the Orange Book for NDA No. 202810.

44. Upon information and belief, Defendants worked in concert to prepare, submit, and file the Aurobindo ANDA with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Aurobindo Product and included a "paragraph IV" certification seeking approval before the expiration of patents in suit.

45. Upon information and belief, the Aurobindo ANDA is based upon Oxtellar XR® (oxcarbazepine) extended-release tablets, 150 mg, 300 mg, and 600 mg, as its reference listed drug.

46. Upon information and belief, the Aurobindo Product is oxcarbazepine extended-release tablets, 150 mg, 300 mg, and 600 mg.

47. Upon information and belief, Defendants have represented to FDA in the Aurobindo ANDA that the Aurobindo Product is bioequivalent to Oxtellar XR®.

48. 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 9 Notice Letter does not indicate that

Defendants intend to market the Aurobindo Product with labeling that differs from the Oxtellar XR® label in terms of conditions of use, including the indications, usage, dosage, administration, or composition of the Aurobindo Product.

49. Upon information and belief, the proposed prescribing information for the Aurobindo Product includes a section titled, "Indications and Usage," and states that the Aurobindo Product "is indicated for the treatment of partial-onset seizures in patients 6 years of age and older."

50. Upon information and belief, the proposed prescribing information for the Aurobindo Product includes a section titled, "Dosage and Administration," and states that:

> Administer [the Aurobindo Product] as a single daily dose taken on an empty stomach (at least 1 hour before or at least 2 hours after meals) [see Clinical Pharmacology (12.3)]. If [the Aurobindo Product] is taken with food, adverse reactions are more likely to occur because of increased peak levels [see Clinical Pharmacology (12.3)].
>
> Swallow [the Aurobindo Product] tablets whole. Do not cut, crush, or chew the tablets. For ease of swallowing in pediatric patients or patients with difficulty swallowing, achieve daily dosages with multiples of appropriate lower strength tablets (e.g., 150 mg tablets).

51. Upon information and belief, the proposed prescribing information for the Aurobindo Product includes a section titled, "Description." The August 9 Notice Letter does not indicate that Defendants intend to market the Aurobindo Product with labeling that differs from the Oxtellar XR® label with respect to the section titled, "Description."

52. Upon information and belief, the proposed prescribing information for the Aurobindo Product includes a sections titled, "Clinical Pharmacology" and "Clinical Studies." The August 9 Notice Letter does not indicate that Defendants intend to market the Aurobindo

Product with labeling that differs from the Oxtellar XR® label with respect to the sections titled, "Clinical Pharmacology" and "Clinical Studies."

53. 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." Likewise, 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).

54. On or about August 9, 2024, Aurobindo sent a letter purportedly pursuant to § 505(j)(2)(B)(iv) of the FDCA and 21 C.F.R. §§ 314.94, 314.95 regarding the Aurobindo Product and the '898 patent, the '131 patent, the '600 patent, the '930 patent, the '791 patent, the '975 patent, the '525 patent, the '278 patent, the '042 patent, the '960 patent, and the '599 patent (the "August 9 Notice Letter").

55. The August 9 Notice Letter does not include any specific noninfringement contentions for claims 1–6 and 12–19 of the '599 patent, i.e., the August 9 Notice Letter does not dispute that the '599 patent literally covers the Aurobindo Product.

56. The August 9 Notice Letter does not include any detailed statement of the factual and legal basis for Defendants' opinion that the patents in suit are unenforceable.

57. The August 9 Notice Letter purportedly included an Offer of Confidential Access to "certain [unspecified] information" from the Aurobindo ANDA, 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 the Aurobindo ANDA to Plaintiff.

FIRST COUNT
(Defendants' Infringement of the '898 Patent)

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

59. Upon information and belief, Defendants seek FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Aurobindo Product.

60. Upon information and belief, Defendants included a paragraph IV certification to the '898 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Aurobindo Product before the expiration of the '898 patent.

61. Upon information and belief, Defendants will commercially manufacture, use, sell, offer for sale, and/or import the Aurobindo Product upon, or in anticipation of, FDA approval.

62. The submission and filing of ANDA No. 219241 with a paragraph IV certification to the '898 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product before the expiration of the '898 patent is an act of infringement by Defendants of one or

more claims of the '898 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

63. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product that is the subject of ANDA No. 219241 will infringe, directly and/or indirectly, one or more claims of the '898 patent under 35 U.S.C. § 271 *et seq.,* including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

64. Upon information and belief, Defendants' offering for sale and/or sale of the Aurobindo Product will induce and/or contribute to third-party infringement of one or more claims of the '898 patent under 35 U.S.C. § 271.

65. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Aurobindo Product, and therefore will infringe at least one claim of the '898 patent.

66. Defendants have knowledge of the '898 patent and, upon information and belief, know or should know that the proposed labeling for the Aurobindo Product will induce direct infringement of at least one claim of the '898 patent, either literally or under the doctrine of equivalents.

67. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Aurobindo Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Aurobindo Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '898 patent.

68. Defendants' infringement of the '898 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court.

Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '898 patent.

69. As of the date of the August 9 Notice Letter, Defendants were aware of the existence of the '898 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '898 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

SECOND COUNT
(Defendants' Infringement of the '131 Patent)

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

71. Upon information and belief, Defendants included a paragraph IV certification to the '131 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Aurobindo Product before the expiration of the '131 patent.

72. The submission and filing of ANDA No. 219241 with a paragraph IV certification to the '131 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product before the expiration of the '131 patent is an act of infringement by Defendants of one or more claims of the '131 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

73. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product that is the subject of ANDA No. 219241 will infringe, directly or indirectly, one or more claims of the '131 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

74. Upon information and belief, Defendants' offering for sale and/or sale of the Aurobindo Product will induce and/or contribute to third-party infringement of one or more claims of the '131 patent under 35 U.S.C. § 271.

75. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Aurobindo Product, and therefore will infringe at least one claim of the '131 patent.

76. Defendants have knowledge of the '131 patent and, upon information and belief, know or should know that the proposed labeling for the Aurobindo Product will induce direct infringement of at least one claim of the '131 patent, either literally or under the doctrine of equivalents.

77. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Aurobindo Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Aurobindo Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '131 patent.

78. Defendants' infringement of the '131 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '131 patent.

79. As of the date of the August 9 Notice Letter, Defendants were aware of the existence of the '131 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that

they would not be liable for infringement of the '131 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

THIRD COUNT
(Defendants' Infringement of the '600 Patent)

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

81. Upon information and belief, Defendants included a paragraph IV certification to the '600 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Aurobindo Product before the expiration of the '600 patent.

82. The submission and filing of ANDA No. 219241 with a paragraph IV certification to the '600 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product before the expiration of the '600 patent is an act of infringement by Defendants of one or more claims of the '600 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

83. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product that is the subject of ANDA No. 219241 will infringe, directly or indirectly, one or more claims of the '600 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

84. Upon information and belief, Defendants' offering for sale and/or sale of the Aurobindo Product will induce and/or contribute to third-party infringement of one or more claims of the '600 patent under 35 U.S.C. § 271.

85. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Aurobindo Product, and therefore will infringe at least one claim of the '600 patent.

86. Defendants have knowledge of the '600 patent and, upon information and belief, know or should know that the proposed labeling for the Aurobindo Product will induce direct infringement of at least one claim of the '600 patent, either literally or under the doctrine of equivalents.

87. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Aurobindo Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Aurobindo Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '600 patent.

88. Defendants' infringement of the '600 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '600 patent.

89. As of the date of the August 9 Notice Letter, Defendants were aware of the existence of the '600 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '600 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

FOURTH COUNT
(Defendants' Infringement of the '930 Patent)

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

91. Upon information and belief, Defendants included a paragraph IV certification to the '930 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Aurobindo Product before the expiration of the '930 patent.

92. The submission and filing of ANDA No. 219241 with a paragraph IV certification to the '930 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product before the expiration of the '930 patent is an act of infringement by Defendants of one or more claims of the '930 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

93. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product that is the subject of ANDA No. 219241 will infringe, directly or indirectly, one or more claims of the '930 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

94. Upon information and belief, Defendants' offering for sale and/or sale of the Aurobindo Product will induce and/or contribute to third-party infringement of one or more claims of the '930 patent under 35 U.S.C. § 271.

95. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Aurobindo Product, and therefore will infringe at least one claim of the '930 patent.

96. Defendants have knowledge of the '930 patent and, upon information and belief, know or should know that the proposed labeling for the Aurobindo Product will induce direct

infringement of at least one claim of the '930 patent, either literally or under the doctrine of equivalents.

97. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Aurobindo Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Aurobindo Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '930 patent.

98. Defendants' infringement of the '930 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '930 patent.

99. As of the date of the August 9 Notice Letter, Defendants were aware of the existence of the '930 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '930 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

FIFTH COUNT
(Defendants' Infringement of the '791 Patent)

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

101. Upon information and belief, Defendants included a paragraph IV certification to the '791 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Aurobindo Product before the expiration of the '791 patent.

102. The submission and filing of ANDA No. 219241 with a paragraph IV certification to the '791 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product before the expiration of the '791 patent is an act of infringement by Defendants of one or more claims of the '791 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

103. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product that is the subject of ANDA No. 219241 will infringe, directly or indirectly, one or more claims of the '791 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

104. Upon information and belief, Defendants' offering for sale and/or sale of the Aurobindo Product will induce and/or contribute to third-party infringement of one or more claims of the '791 patent under 35 U.S.C. § 271.

105. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Aurobindo Product, and therefore will infringe at least one claim of the '791 patent.

106. Defendants have knowledge of the '791 patent and, upon information and belief, know or should know that the proposed labeling for the Aurobindo Product will induce direct infringement of at least one claim of the '791 patent, either literally or under the doctrine of equivalents.

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

Aurobindo Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '791 patent.

108. Defendants' infringement of the '791 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '791 patent.

109. As of the date of the August 9 Notice Letter, Defendants were aware of the existence of the '791 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '791 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

SIXTH COUNT
(Defendants' Infringement of the '975 Patent)

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

111. Upon information and belief, Defendants included a paragraph IV certification to the '975 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Aurobindo Product before the expiration of the '975 patent.

112. The submission and filing of ANDA No. 219241 with a paragraph IV certification to the '975 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product before the expiration of the '975 patent is an act of infringement by Defendants of one or more claims of the '975 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(e)(2)(A).

113. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product that is the subject of ANDA No. 219241 will infringe, directly or indirectly, one or more claims of the '975 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

114. Upon information and belief, Defendants' offering for sale and/or sale of the Aurobindo Product will induce and/or contribute to third-party infringement of one or more claims of the '975 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 Aurobindo Product, and therefore will infringe at least one claim of the '975 patent.

116. Defendants have knowledge of the '975 patent and, upon information and belief, know or should know that the proposed labeling for the Aurobindo Product will induce direct infringement of at least one claim of the '975 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 Aurobindo Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Aurobindo Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '975 patent.

118. Defendants' infringement of the '975 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '975 patent.

119. As of the date of the August 9 Notice Letter, Defendants were aware of the existence of the '975 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '975 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

SEVENTH COUNT
(Defendants' Infringement of the '525 Patent)

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

121. Upon information and belief, Defendants included a paragraph IV certification to the '525 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Aurobindo Product before the expiration of the '525 patent.

122. The submission and filing of ANDA No. 219241 with a paragraph IV certification to the '525 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product before the expiration of the '525 patent is an act of infringement by Defendants of one or more claims of the '525 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

123. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product that is the subject of ANDA No. 219241 will infringe, directly or indirectly, one or more claims of the '525 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

124. Upon information and belief, Defendants' offering for sale and/or sale of the Aurobindo Product will induce and/or contribute to third-party infringement of one or more claims of the '525 patent under 35 U.S.C. § 271.

125. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Aurobindo Product, and therefore will infringe at least one claim of the '525 patent.

126. Defendants have knowledge of the '525 patent and, upon information and belief, know or should know that the proposed labeling for the Aurobindo Product will induce direct infringement of at least one claim of the '525 patent, either literally or under the doctrine of equivalents.

127. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Aurobindo Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Aurobindo Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '525 patent.

128. Defendants' infringement of the '525 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '525 patent.

129. As of the date of the August 9 Notice Letter, Defendants were aware of the existence of the '525 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that

they would not be liable for infringement of the '525 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

EIGHTH COUNT
(Defendants' Infringement of the '278 Patent)

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

131. Upon information and belief, Defendants included a paragraph IV certification to the '278 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Aurobindo Product before the expiration of the '278 patent.

132. The submission and filing of ANDA No. 219241 with a paragraph IV certification to the '278 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product before the expiration of the '278 patent is an act of infringement by Defendants of one or more claims of the '278 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

133. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product that is the subject of ANDA No. 219241 will infringe, directly or indirectly, one or more claims of the '278 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

134. Upon information and belief, Defendants' offering for sale and/or sale of the Aurobindo Product will induce and/or contribute to third-party infringement of one or more claims of the '278 patent under 35 U.S.C. § 271.

135. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Aurobindo Product, and therefore will infringe at least one claim of the ’278 patent.

136. Defendants have knowledge of the ’278 patent and, upon information and belief, know or should know that the proposed labeling for the Aurobindo Product will induce direct infringement of at least one claim of the ’278 patent, either literally or under the doctrine of equivalents.

137. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Aurobindo Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Aurobindo Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the ’278 patent.

138. Defendants’ infringement of the ’278 patent has caused and will cause Supernus to suffer irreparable harm. Defendants’ infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the ’278 patent.

139. As of the date of the August 9 Notice Letter, Defendants were aware of the existence of the ’278 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the ’278 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

NINTH COUNT
(Defendants’ Infringement of the ’042 Patent)

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

141. Upon information and belief, Defendants included a paragraph IV certification to the '042 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Aurobindo Product before the expiration of the '042 patent.

142. The submission and filing of ANDA No. 219241 with a paragraph IV certification to the '042 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product before the expiration of the '042 patent is an act of infringement by Defendants of one or more claims of the '042 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

143. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product that is the subject of ANDA No. 219241 will infringe, directly or indirectly, one or more claims of the '042 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

144. Upon information and belief, Defendants' offering for sale and/or sale of the Aurobindo Product will induce and/or contribute to third-party infringement of one or more claims of the '042 patent under 35 U.S.C. § 271.

145. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Aurobindo Product, and therefore will infringe at least one claim of the '042 patent.

146. Defendants have knowledge of the '042 patent and, upon information and belief, know or should know that the proposed labeling for the Aurobindo Product will induce direct

infringement of at least one claim of the '042 patent, either literally or under the doctrine of equivalents.

147. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Aurobindo Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Aurobindo Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '042 patent.

148. Defendants' infringement of the '042 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '042 patent.

149. As of the date of the August 9 Notice Letter, Defendants were aware of the existence of the '042 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '042 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

TENTH COUNT
(Defendants' Infringement of the '960 Patent)

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

151. Upon information and belief, Defendants included a paragraph IV certification to the '960 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Aurobindo Product before the expiration of the '960 patent.

152. The submission and filing of ANDA No. 219241 with a paragraph IV certification to the '960 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product before the expiration of the '960 patent is an act of infringement by Defendants of one or more claims of the '960 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

153. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product that is the subject of ANDA No. 219241 will infringe, directly or indirectly, one or more claims of the '960 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

154. Upon information and belief, Defendants' offering for sale and/or sale of the Aurobindo Product will induce and/or contribute to third-party infringement of one or more claims of the '960 patent under 35 U.S.C. § 271.

155. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Aurobindo Product, and therefore will infringe at least one claim of the '960 patent.

156. Defendants have knowledge of the '960 patent and, upon information and belief, know or should know that the proposed labeling for the Aurobindo Product will induce direct infringement of at least one claim of the '960 patent, either literally or under the doctrine of equivalents.

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

Aurobindo Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '960 patent.

158. Defendants' infringement of the '960 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '960 patent.

159. As of the date of the August 9 Notice Letter, Defendants were aware of the existence of the '960 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '960 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

ELEVENTH COUNT
(Defendants' Infringement of the '599 Patent)

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

161. Upon information and belief, Defendants included a paragraph IV certification to the '599 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Aurobindo Product before the expiration of the '599 patent.

162. The submission and filing of ANDA No. 219241 with a paragraph IV certification to the '599 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product before the expiration of the '599 patent is an act of infringement by Defendants of one or more claims of the '599 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

163. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product that is the subject of ANDA No. 219241 will infringe, directly or indirectly, one or more claims of the '599 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

164. Upon information and belief, Defendants' offering for sale and/or sale of the Aurobindo Product will induce and/or contribute to third-party infringement of one or more claims of the '599 patent under 35 U.S.C. § 271.

165. Upon information and belief, Defendants know, should know, and intend that caregivers will prescribe and patients will use the Aurobindo Product, and therefore will infringe at least one claim of the '599 patent.

166. Defendants have knowledge of the '599 patent and, upon information and belief, know or should know that the proposed labeling for the Aurobindo Product will induce direct infringement of at least one claim of the '599 patent, either literally or under the doctrine of equivalents.

167. Upon information and belief, Defendants know, should know, and intend that the proposed labeling for the Aurobindo Product will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because caregivers and/or patients will use the Aurobindo Product according to the instructions in the proposed labeling in a way that directly infringes at least one claim of the '599 patent.

168. Defendants' infringement of the '599 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '599 patent.

169. As of the date of the August 9 Notice Letter, Defendants were aware of the existence of the '599 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '599 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

i. A Judgment declaring that the '898 patent is valid and enforceable;

ii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 219241 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product was an act of infringement of the '898 patent by Defendants;

iii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product prior to the expiration of the '898 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

iv. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Aurobindo Product shall be no earlier than the date on which the '898 patent expires, including any regulatory extensions;

v. A Judgment 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 those persons in active concert or participation or privity with them or any

of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 219241 until the expiration of the '898 patent, including any regulatory extensions;

vi. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the '898 patent;

vii. A Judgment declaring that infringement of the '898 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the '898 patent;

viii. A Judgment declaring that the '131 patent is valid and enforceable;

ix. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 219241 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product was an act of infringement of the '131 patent by Defendants;

x. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product prior to the expiration of the '131 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

xi. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Aurobindo Product shall be no earlier than the date on which the '131 patent expires, including any regulatory extensions;

xii. A Judgment 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 those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 219241 until the expiration of the '131 patent, including any regulatory extensions;

xiii. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the '131 patent;

xiv. A Judgment declaring that infringement of the '131 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the '131 patent;

xv. A Judgment declaring that the '600 patent is valid and enforceable;

xvi. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 219241 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product was an act of infringement of the '600 patent by Defendants;

xvii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product prior to the expiration of the ’600 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

xviii. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Aurobindo Product shall be no earlier than the date on which the ’600 patent expires, including any regulatory extensions;

xix. A Judgment 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 those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 219241 until the expiration of the ’600 patent, including any regulatory extensions;

xx. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the ’600 patent;

xxi. A Judgment declaring that infringement of the ’600 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the ’600 patent;

xxii. A Judgment declaring that the ’930 patent is valid and enforceable;

xxiii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 219241 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product was an act of infringement of the '930 patent by Defendants;

xxiv. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product prior to the expiration of the '930 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

xxv. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Aurobindo Product shall be no earlier than the date on which the '930 patent expires, including any regulatory extensions;

xxvi. A Judgment 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 those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 219241 until the expiration of the '930 patent, including any regulatory extensions;

xxvii. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the '930 patent;

xxviii. A Judgment declaring that infringement of the ’930 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the ’930 patent;

xxix. A Judgment declaring that the ’791 patent is valid and enforceable;

xxx. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 219241 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product was an act of infringement of the ’791 patent by Defendants;

xxxi. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product prior to the expiration of the ’791 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

xxxii. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Aurobindo Product shall be no earlier than the date on which the ’791 patent expires, including any regulatory extensions;

xxxiii. A Judgment 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 those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 219241 until the expiration of the ’791 patent, including any regulatory extensions;

xxxiv. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the '791 patent;

xxxv. A Judgment declaring that infringement of the '791 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the '791 patent;

xxxvi. A Judgment declaring that the '975 patent is valid and enforceable;

xxxvii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 219241 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product was an act of infringement of the '975 patent by Defendants;

xxxviii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product prior to the expiration of the '975 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

xxxix. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Aurobindo Product shall be no earlier than the date on which the '975 patent expires, including any regulatory extensions;

xl. A Judgment 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 those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 219241 until the expiration of the '975 patent, including any regulatory extensions;

xli. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the '975 patent;

xlii. A Judgment declaring that infringement of the '975 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the '975 patent;

xliii. A Judgment declaring that the '525 patent is valid and enforceable;

xliv. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 219241 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product was an act of infringement of the '525 patent by Defendants;

xlv. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product prior to the expiration of the '525 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

xlvi. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Aurobindo Product shall be no earlier than the date on which the '525 patent expires, including any regulatory extensions;

xlvii. A Judgment 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 those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 219241 until the expiration of the '525 patent, including any regulatory extensions;

xlviii. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the '525 patent;

xlix. A Judgment declaring that infringement of the '525 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the '525 patent;

l. A Judgment declaring that the '278 patent is valid and enforceable;

li. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 219241 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product was an act of infringement of the '278 patent by Defendants;

lii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product prior to the expiration of the ’278 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

liii. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Aurobindo Product shall be no earlier than the date on which the ’278 patent expires, including any regulatory extensions;

liv. A Judgment 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 those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 219241 until the expiration of the ’278 patent, including any regulatory extensions;

lv. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the ’278 patent;

lvi. A Judgment declaring that infringement of the ’278 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the ’278 patent;

lvii. A Judgment declaring that the ’042 patent is valid and enforceable;

lviii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 219241 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product was an act of infringement of the '042 patent by Defendants;

lix. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product prior to the expiration of the '042 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

lx. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Aurobindo Product shall be no earlier than the date on which the '042 patent expires, including any regulatory extensions;

lxi. A Judgment 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 those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 219241 until the expiration of the '042 patent, including any regulatory extensions;

lxii. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the '042 patent;

lxiii. A Judgment declaring that infringement of the ’042 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the ’042 patent;

lxiv. A Judgment declaring that the ’960 patent is valid and enforceable;

lxv. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 219241 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product was an act of infringement of the ’960 patent by Defendants;

lxvi. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product prior to the expiration of the ’960 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

lxvii. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Aurobindo Product shall be no earlier than the date on which the ’960 patent expires, including any regulatory extensions;

lxviii. A Judgment 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 those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 219241 until the expiration of the ’960 patent, including any regulatory extensions;

lxix. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the '960 patent;

lxx. A Judgment declaring that infringement of the '960 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the '960 patent;

lxxi. A Judgment declaring that the '599 patent is valid and enforceable;

lxxii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 219241 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product was an act of infringement of the '599 patent by Defendants;

lxxiii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Aurobindo Product prior to the expiration of the '599 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

lxxiv. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Aurobindo Product shall be no earlier than the date on which the '599 patent expires, including any regulatory extensions;

lxxv. A Judgment 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 those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 219241 until the expiration of the ’599 patent, including any regulatory extensions;

lxxvi. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the ’599 patent;

lxxvii. A Judgment declaring that infringement of the ’599 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 219241 that infringes the ’599 patent;

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

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

Dated: September 23, 2024

Respectfully submitted,

By: s/ William C. Baton

William C. Baton
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING LLP
One Riverfront Plaza
1037 Raymond Blvd., Suite 1520
Newark, NJ 07102
wbaton@saul.com

OF COUNSEL:

Edgar H. Haug
Nicholas F. Giove
Andrew S. Roper
Andrew Wasson
HAUG PARTNERS LLP
745 Fifth Avenue
New York, New York 10151
(212) 588-0888
ehaug@haugpartners.com
ngiove@haugpartners.com
aroper@haugpartners.com

Attorneys for Plaintiff
Supernus Pharmaceuticals, Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding. This case involves the validity or infringement of patents involved in the following cases previously pending in this Court:

- *Supernus Pharmaceuticals, Inc. v. RiconPharma LLC et al.*, C.A. No. 22-6340 (KM)(MAH) (D.N.J.);
- *Supernus Pharmaceuticals, Inc. v. Apotex Inc. et al.*, C.A. No. 22-0322 (FLW)(TJB) (D.N.J.);
- *Supernus Pharmaceuticals, Inc. v. Riconpharma LLC et al.*, C.A. No. 21-12133 (MEF)(MAH) (D.N.J.);
- *Supernus Pharmaceuticals, Inc. v. Apotex Inc. et al.*, C.A. No. 20-7870 (MAS)(TJB) (D.N.J.);
- *Supernus Pharmaceuticals, Inc. v. TWi Pharmaceuticals, Inc. et al.*, C.A. No. 17-2164 (RMB)(JS) (D.N.J.);
- *Supernus Pharmaceuticals, Inc. v. Actavis, Inc. et al.*, C.A. No. 15-8342 (RMB)(JS) (D.N.J.);
- *Supernus Pharmaceuticals, Inc. v. Actavis Inc. et al.*, C.A. No. 15-2499 (RMB)(JS) (D.N.J.);
- *Supernus Pharmaceuticals, Inc. v. TWi Pharmaceuticals, Inc. et al.*, C.A. No. 15-0369 (RMB)(JS) (D.N.J.).

Dated: September 23, 2024

Respectfully submitted,

By: s/ William C. Baton

William C. Baton
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING LLP
One Riverfront Plaza
1037 Raymond Blvd., Suite 1520
Newark, NJ 07102
wbaton@saul.com

Attorneys for Plaintiff
Supernus Pharmaceuticals, Inc.

OF COUNSEL:
Edgar H. Haug
Nicholas F. Giove
Andrew S. Roper
Andrew Wasson
HAUG PARTNERS LLP
745 Fifth Avenue
New York, NY 10151