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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC., Plaintiff, v. ASCENT PHARMACEUTICALS, INC., Defendant.	Case No. 3-23-cv-04015 **DEFENDANT ASCENT PHARMACEUTICAL'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S COMPLAINT**

Defendant Ascent Pharmaceuticals, Inc., ("Defendant" or "Ascent"), by and through the undersigned attorney, responds by way of its Answer and Affirmative Defenses to the Complaint (D.I. 1; "Complaint") of Plaintiff, Supernus Pharmaceuticals, Inc. ("Plaintiff" or "Supernus").

GENERAL DENIAL

Ascent denies all allegations of the Complaint not specifically admitted herein. Unless Ascent explicitly admits a statement of the Complaint, that allegation is denied. Ascent answers herewith stating its specific responses below, paragraph-by-paragraph, to the allegations of the Complaint.

To the extent that any allegation seeks information from Camber or Hetero, Ascent lacks knowledge or information to inform a belief as to the truth of the allegations of any sections directed to Camber or Hetero, and on that basis, denies them.

SPECIFIC ADMISSIONS AND DENIALS

NATURE OF THE ACTION[1]

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").

[1] To the extent that the headings used in the Complaint purport to make factual allegations to which a response is required, Ascent denies such allegations. The reproduction of such headings herein is done solely for the purposes of readability and convenience and shall not be construed as an admission.

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.

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

3. Upon information and belief, Defendant Ascent Pharmaceuticals Inc. is a corporation organized and existing under the laws of New York, having its principal place of business at 400 South Technology Drive, Central Islip, New York 11722.

ANSWER: Admitted.

4. Upon information and belief, Defendant Camber Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1031 Centennial Avenue, Piscataway, New Jersey 08854.

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

5. Upon information and belief, Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

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).

ANSWER: Ascent, responding only on behalf of Ascent, does not contest this Court's jurisdiction over the subject matter for purposes of this action only.

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).

ANSWER: Ascent, responding only on behalf of Ascent, does not contest this Court's personal jurisdiction over it 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. On or about June 15, 2023, Ascent sent a letter pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 regarding the Ascent ANDA Products and the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents (the "June 15 Notice Letter") to Supernus at 9715 Key West Avenue, Rockville, Maryland 20850.

ANSWER: Admitted.

9. The June 15 Notice Letter was signed by H. Keeto Sabharwal, Husch Blackwell LLP, for Ascent Pharmaceuticals Inc., who stated that he is its "agent authorized to accept service of process for Ascent."

ANSWER: Admitted.

10. According to the June 15 Notice Letter, Ascent filed Abbreviated New Drug Application No. 217443 ("the Ascent ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, and/or

sale in, and/or importation into, the United States of generic topiramate extended-release capsules, containing 25 mg, 50 mg, 100 mg, and 200 mg of topiramate ("Ascent ANDA Products").

ANSWER: Admitted.

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

ANSWER: Ascent, responding only on behalf of Ascent, admits that it is in the business of the development and manufacture of general pharmaceutical products for sale throughout the United States. Ascent denies any remaining allegations of this paragraph.

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

ANSWER: Denied.

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

ANSWER: Denied.

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.

ANSWER: Denied.

15. Upon information and belief, Hetero is the parent company, directly or indirectly, of both Ascent and Camber.

ANSWER: Denied.

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

ANSWER: Denied.

17. Upon information and belief, Ascent, directly or indirectly, develops, manufactures, imports, markets, and distributes, and/or sells pharmaceutical products, including at least 32 generic drug 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.

ANSWER: Admitted.

18. Upon information and belief, "[t]o keep up with growing demand, Hetero formed Ascent Pharmaceuticals in Central Islip, NY, in 2012 to further support product development and production," and "Ascent produces approximately 20 percent of the generic products offered by Camber Pharmaceuticals."

ANSWER: Admitted.

19. Upon information and belief, Ascent "manufactures generic pharmaceuticals for its customer, Camber Pharmaceuticals, Inc.," and "Camber sells generic pharmaceutical products manufactured by Ascent in the United States."

ANSWER: Admitted.

20. Upon information and belief, "Camber Pharmaceuticals was established in 2007 as the sales and marketing entity for Hetero's prescription products in the US market.

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

21. Upon information and belief, Camber is a "100% subsidiary" of Hetero.

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

22. Upon information and belief, "Ascent Pharmaceuticals, Inc. of Central Islip, New York, [is] Camber's sister company."

ANSWER: Denied.

23. Ascent is featured on Hetero's corporate website as one of Hetero's "strategically located[] manufacturing facilities," stating that the Ascent Central Islip, New York, manufacturing facility is one of Hetero's "state-of-the-art facilities." This demonstrates that Hetero and Ascent have not maintained corporate separateness, and that Hetero ratifies Ascent's places of business.

ANSWER: Ascent admits that it is featured on Hetero's corporate website as one of Hetero's "state-of-the-art factiles." Ascent denies any remaining allegations of this paragraph.

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

ANSWER: Admitted.

25. Upon information and belief, Defendants are acting cooperatively with respect to the preparation and submission of the Ascent ANDA.

ANSWER: Denied.

26. Upon information and belief, Ascent manufactures twenty-eight of its thirty-two currently listed products for marketing, distribution, and/or sale by Camber, including "Topiramate Tablets."

ANSWER: Admitted.

27. According to Camber, "Hetero is one of the world's largest producers of Active Pharmaceutical Ingredients (APIs) and offers over 300 finished dose pharmaceutical products globally."

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

28. Thus, upon information and belief, Ascent uses API supplied by its parent company, Hetero, to develop its ANDA Products and prepare its ANDA filings, and also uses Hetero API for the manufacture of its marketed products, including the topiramate API that Ascent uses for the Topiramate Tablets that are marketed, distributed, and/or sold by Camber, and it may also use topiramate API supplied by Hetero for the development of the Ascent ANDA Products, preparation of the Ascent ANDA, and manufacture of the Ascent ANDA Products that are to be marketed, distributed, and/or sold by Camber.

ANSWER: Denied.

29. Upon information and belief, Defendants and/or their affiliates, directly or indirectly, manufacture and/or direct the manufacture of generic pharmaceutical products for

which Ascent is the named ANDA applicant. Upon information and belief, Defendants, directly or indirectly, derive substantial revenue from the sales of such generic pharmaceutical products.

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

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

ANSWER: Denied.

31. 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.

ANSWER: Denied.

32. Upon information and belief, Ascent "develops and manufactures generic pharmaceutical products, which then are sold in the United States by independent marketing groups, the locations of which are in, among other places, New Jersey."

ANSWER: Admitted.

33. Upon information and belief, Ascent is registered with the State of New Jersey's Department of Health as a drug and medical device "[m]anufacturer and [w]holesale[r]" with Registration Number 5005459. Ascent has, therefore, purposefully availed itself of the rights, benefits, and privileges of New Jersey's laws

ANSWER: Denied.

34. This Court has personal jurisdiction over Ascent at least because, upon information and belief: (i) Ascent is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District, including by working in concert with Hetero and Camber; (ii) Ascent has purposefully directed its activities at residents and corporate entities within the State of New Jersey, including by working in concert with Hetero and Camber; (iii) Ascent 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 Hetero and Camber; (iv) Ascent has committed, induced, and/or contributed to acts of patent infringement in New Jersey, including by working in concert with Hetero and Camber; (v) the claims set forth herein against Ascent arise out of or relate to those activities; (vi) it is reasonable and fair for this Court to exercise personal jurisdiction over Ascent; and (vii) Ascent has previously submitted to the jurisdiction of this Court, has availed itself of New Jersey's legal protections in prior litigations, and previously consented to personal jurisdiction in this Judicial District.

ANSWER: Ascent does not contest that this Court has personal jurisdiction over Ascent for purposes of this action only. Ascent denies the remaining allegations in this paragraph.

35. Upon information and belief, the tortious acts of Ascent of (i) preparing and filing the Ascent 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 Ascent 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 Ascent 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, Ascent should reasonably anticipate being sued in New Jersey.

ANSWER: Denied.

36. This Court has personal jurisdiction over Ascent at least because, upon information and belief, if the Ascent ANDA is approved, the Ascent ANDA Products will be marketed, distributed, and/or sold, directly or indirectly, by Ascent 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. Specifically, upon information and belief, if Ascent succeeds in obtaining FDA approval, Ascent will, directly or indirectly, market, distribute, and/or sell the Ascent ANDA Products in the State of New Jersey, including by working in concert with Camber.

ANSWER: Ascent does not contest that this Court has personal jurisdiction over Ascent for purposes of this action only. Ascent denies the remaining allegations in this paragraph.

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

ANSWER: Admitted.

38. Upon information and belief, Camber "has its principal place of business at 1031 Centennial Avenue, Piscataway, NJ 08854." Moreover, upon information and belief, in 2020, Camber was "rapidly outgrowing its existing headquarters and warehouses," and thus, "a second location in Piscataway, NJ was acquired in 2021 . . . ."

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

39. Upon information and belief, "Camber sells generic pharmaceuticals throughout the United States, including New Jersey."

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

40. Upon information and belief, Camber is registered with the State of New Jersey's Department of Health as a drug and medical device "[m]anufacturer and [w]holesale[r]" with Registration Number 5003516. Camber has, therefore, purposefully availed itself of the rights, benefits, and privileges of New Jersey's laws.

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

41. This Court has personal jurisdiction over Camber at least because, upon information and belief: (i) Camber maintains a principal place of business in New Jersey located at 1031 Centennial Avenue, Piscataway, New Jersey 08854; (ii) Camber is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District, including by working in concert with Hetero and Ascent; (iii) Camber 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 Hetero and Ascent; (iv) Camber has committed, induced, and/or contributed to acts of patent infringement in New Jersey, including by working in concert with Hetero and Ascent; (v) the claims set forth herein against Camber arise out of or relate to those activities; (vi) it is reasonable and fair for this Court to exercise personal jurisdiction over Camber; and (vii) Camber has previously submitted to the jurisdiction of this Court, has availed itself of New Jersey's legal protections in prior litigations, and previously consented to personal jurisdiction and venue in this Judicial District.

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

42. Upon information and belief, Hetero has engaged in systematic and continuous business contacts within the State of New Jersey. For example, Hetero's website states that Hetero established its sole North America marketing office in New Jersey, located at 1035 Centennial Avenue, Piscataway, New Jersey 08854, which is the same address as one of Camber's addresses. Upon information and belief, Hetero also has an office at 1031 Centennial Avenue, Piscataway, New Jersey 08854, which is the same address as Camber's principal place of business. The co-existence of Hetero and Camber offices demonstrates that Hetero and Camber have not maintained corporate separateness and Hetero ratifies Camber's places of business.

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

43. Upon information and belief, Hetero actively works with Ascent and Camber to develop, manufacture, import, market, distribute, offer for sale, and/or sell generic drugs throughout the United States, including New Jersey.

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

44. This Court has personal jurisdiction over Hetero at least because, upon information and belief: (i) Hetero maintains its sole U.S. marketing office in New Jersey, located at 1035 Centennial Avenue, Piscataway, New Jersey 08854; (ii) Hetero is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District, including by working in concert with Ascent and Camber; (iii) Hetero 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 Ascent and Camber; (iv) Hetero has committed, induced, and/or contributed to acts of patent infringement in New Jersey, including by working in concert with Ascent and Camber; (v) the claims set forth herein against Hetero arise out of or relate to those activities; (vi) it is reasonable and fair for this Court to exercise personal jurisdiction over Hetero; and (vii) Hetero has previously submitted to the jurisdiction of this Court, has availed itself of New Jersey's legal protections in prior litigations, and previously consented to personal jurisdiction and venue in this Judicial District.

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

45. Venue is proper pursuant to §§ 1391(b) and (c) and/or § 1400(b), because upon information and belief, Camber has a principal place of business in New Jersey, and Ascent and Camber operate as an integrated business and are intimately connected sister companies, with Ascent manufacturing products for Camber to market, distribute, and/or sell in New Jersey, and Camber and Ascent have and will continue to engage in infringing activities in New Jersey. Upon information and belief, Ascent, Camber, and Hetero (and/or employees of Ascent, Camber, and Hetero) share a common address and/or utilize shared or common office space at 1035 Centennial Avenue, Piscataway, New Jersey 08854 and 1031 Centennial Avenue, Piscataway, New Jersey 08854. By virtue of this integrated and intimate corporate relationship, the lack of corporate separateness between and among Hetero, Camber, and Ascent, and Hetero's ratification of Ascent's and Camber's places of business, venue is proper in this Judicial District. In addition, Camber and Ascent have previously consented to venue in this Judicial District.

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

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

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

47. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because, upon information and belief, Hetero 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, Hetero maintains its sole U.S. marketing office in New Jersey, and Hetero has and will continue to engage in infringing activities in New Jersey.

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

FACTS AS TO ALL COUNTS

48. 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.

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

49. 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 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.

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

50. 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.

ANSWER: Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

51. FDA's publication, titled, "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book"), lists ten (10) patents, specifically the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents, as covering Supernus's Trokendi XR®. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), these ten (10) patents were submitted to the FDA with or after the approval of NDA No. 201635. These ten (10) patents are listed in the Orange Book as covering Trokendi XR®.

ANSWER: Ascent admits that the Orange Book lists the foregoing ten (10) patents with respect to the Trokendi XR® product. Ascent lacks knowledge or information sufficient to form

a belief as to the truth of the remaining allegations of this paragraph and, on that basis, denies them.

52. 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.

ANSWER: Ascent admits that the ‘576 patent, on its face, states that it issued on October 30, 2012, and that it bears the title “Sustained-Release Formulations of Topiramate.” Ascent denies any remaining allegations of this paragraph.

53. 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.

ANSWER: Ascent admits that the ‘580 patent, on its face, states that it issued on October 30, 2012, and that it bears the title “Sustained-Release Formulations of Topiramate.” Ascent denies any remaining allegations of this paragraph.

54. 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.

ANSWER: Ascent admits that the ‘683 patent, on its face, states that it issued on March 4, 2014, and that it bears the title “Sustained-Release Formulations of Topiramate.” Ascent denies any remaining allegations of this paragraph.

55. 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.

ANSWER: Ascent admits that the ‘248 patent, on its face, states that it issued on November 4, 2014, and that it bears the title “Sustained-Release Formulations of Topiramate.” Ascent denies any remaining allegations of this paragraph.

56. 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.

ANSWER: Ascent admits that the ‘191 patent, on its face, states that it issued on November 18, 2014, and that it bears the title “Sustained-Release Formulations of Topiramate.” Ascent denies any remaining allegations of this paragraph.

57. 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.

ANSWER: Ascent admits that the ‘989 patent, on its face, states that it issued on March 13, 2015, and that it bears the title “Sustained-Release Formulations of Topiramate.” Ascent denies any remaining allegations of this paragraph.

58. 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, 16 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.

ANSWER: Ascent admits that the ‘940 patent, on its face, states that it issued on January 24, 2017, and that it bears the title “Sustained-Release Formulations of Topiramate.” Ascent denies any remaining allegations of this paragraph.

59. 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.

ANSWER: Ascent admits that the ‘004 patent, on its face, states that it issued on January 31, 2017, and that it bears the title “Sustained-Release Formulations of Topiramate.” Ascent denies any remaining allegations of this paragraph.

60. 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.

ANSWER: Ascent admits that the ‘983 patent, on its face, states that it issued on April 18, 2017, and that it bears the title “Sustained-Release Formulations of Topiramate.” Ascent denies any remaining allegations of this paragraph.

61. 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.

ANSWER: Ascent admits that the '790 patent, on its face, states that it issued on June 11, 2019, and that it bears the title "Sustained-Release Formulations of Topiramate." Ascent denies any remaining allegations of this paragraph.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

64. Upon information and belief, the proposed prescribing information for the Ascent ANDA Products includes a header, titled, "Indications and Usage," and states that the Ascent 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.

ANSWER: Ascent admits that the proposed prescribing information for its ANDA Products states as such in-part. Ascent denies any remaining allegations of this paragraph.

65. Upon information and belief, the proposed prescribing information for the Ascent ANDA Products includes a header, 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.

ANSWER: Ascent admits that the proposed prescribing information for its ANDA Products states as such in-part. Ascent denies any remaining allegations of this paragraph.

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

ANSWER: Admitted.

67. Upon information and belief, Ascent Pharmaceuticals Inc. developed the Ascent ANDA Products and/or sought approval from the FDA to sell the Ascent ANDA Products throughout the United States, including within this Judicial District.

ANSWER: Admitted.

68. Upon information and belief, Ascent Pharmaceuticals Inc. participated in the preparation and/or filing of the Ascent ANDA.

ANSWER: Admitted.

69. 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).

ANSWER: Admitted.

70. Upon information and belief, as of the date of the June 15 Notice Letter, Ascent 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).

ANSWER: Admitted.

71. Upon information and belief, the Ascent Notice Letter does not disclose any noninfringement contentions or opinions for the '683 patent claims 1, 6-16, 18-20, and 23-24, the '248 patent claim 14 and 18-20, the '191 patent claims 1-24, the '989 patent claims 14 and 18- 20, the '940 patent claims 14 and 18-20, the '983 patent claims 13 and 17-29, and the '790 patent claims 1-10 and 12-24, and accordingly, upon information and belief, Ascent acknowledges that the Ascent ANDA and the Ascent ANDA Products infringe the '683 patent claims 1, 6-16, 18- 20, and 23-24, the '248 patent claims 14 and 18-20, the '191 patent claims 1-24, the '989 patent 19 claims 14 and 18-20, the '940 patent claims 14 and 18-20, the '983 patent claims 13 and 17-29, and the '790 patent claims 1-10 and 12-24.

ANSWER: Denied.

72. Upon information and belief, the Ascent Notice Letter does not disclose any invalidity or unenforceability contentions or opinions for the '576 patent claims 1-30, the '580 patent claims 1-31, the '683 patent claims 2-5, the '248 patent claims 1-13 and 15-17, the '989 patent claims 1-13 and 15-17, and the '940 patent claims 1-13 and 15-17, and accordingly, upon information and belief, Ascent acknowledges that the '576 patent claims 1-30, the '580 patent claims 1-31, the '683 patent claims 2-5, the '248 patent claims 1-13 and 15-17, the '989 patent claims 1-13 and 15-17, and the '940 patent claims 1-13 and 15-17 are valid and enforceable.

ANSWER: Denied.

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

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

ANSWER: Ascent repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

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

ANSWER: Denied.

75. 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 Ascent ANDA Products upon, or in anticipation of, FDA approval of the Ascent ANDA.

ANSWER: Denied.

76. 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 20 Ascent ANDA Products will infringe, directly and/or indirectly, one or more claims of the '576 patent under 35 U.S.C. § 271.

ANSWER: Denied.

77. Upon information and belief, the commercial offering for sale and/or sale of the Ascent 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.

ANSWER: Denied.

78. Upon information and belief, the factual and legal bases in the June 15 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).

ANSWER: Denied.

79. 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.

ANSWER: Denied.

80. 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.

ANSWER: Denied.

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

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

ANSWER: Ascent repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

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

ANSWER: Denied.

83. 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 Ascent ANDA Products upon, or in anticipation of, FDA approval of the Ascent ANDA.

ANSWER: Denied.

84. 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 Ascent ANDA Products will infringe, directly and/or indirectly, one or more claims of the '580 patent under 35 U.S.C. § 271.

ANSWER: Denied.

85. Upon information and belief, the commercial offering for sale and/or sale of the Ascent 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.

ANSWER: Denied.

86. Upon information and belief, the factual and legal bases in the June 15 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).

ANSWER: Denied.

87. 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.

ANSWER: Denied.

88. 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.

ANSWER: Denied.

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

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

ANSWER: Ascent repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

90. Upon information and belief, Defendants' submission and filing of the Ascent ANDA with a paragraph IV certification to the '683 patent to obtain approval to engage in the

commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Ascent ANDA Products before the expiration of the '683 patent is an act of infringement of the '683 patent by Defendants of one or more claims of the '683 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

91. 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 Ascent ANDA Products upon, or in anticipation of, FDA approval of the Ascent ANDA.

ANSWER: Denied.

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

ANSWER: Denied.

93. Upon information and belief, the commercial offering for sale and/or sale of the Ascent 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.

ANSWER: Denied.

94. Upon information and belief, the factual and legal bases in the June 15 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).

ANSWER: Denied.

95. 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.

ANSWER: Denied.

96. 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.

ANSWER: Denied.

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

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

ANSWER: Ascent repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

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

ANSWER: Denied.

99. 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 Ascent ANDA Products upon, or in anticipation of, FDA approval of the Ascent ANDA.

ANSWER: Denied.

100. 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 Ascent ANDA Products will infringe, directly and/or indirectly, one or more claims of the '248 patent under 35 U.S.C. § 271.

ANSWER: Denied.

101. Upon information and belief, the commercial offering for sale and/or sale of the Ascent 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.

ANSWER: Denied.

102. Upon information and belief, the factual and legal bases in the June 15 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).

ANSWER: Denied.

103. 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.

ANSWER: Denied.

104. 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.

ANSWER: Denied.

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

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

ANSWER: Ascent repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

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

ANSWER: Denied.

107. 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 Ascent ANDA Products upon, or in anticipation of, FDA approval of the Ascent ANDA.

ANSWER: Denied.

108. 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 Ascent ANDA Products will infringe, directly and/or indirectly, one or more claims of the '191 patent under 35 U.S.C. § 271.

ANSWER: Denied.

109. Upon information and belief, the commercial offering for sale and/or sale of the Ascent 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.

ANSWER: Denied.

110. Upon information and belief, the factual and legal bases in the June 15 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).

ANSWER: Denied.

111. 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.

ANSWER: Denied.

112. 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.

ANSWER: Denied.

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

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

ANSWER: Ascent repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

114. Upon information and belief, Defendants' submission and filing of the Ascent ANDA with a paragraph IV certification to the '989 patent to obtain approval to engage in the

commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United 26 States of the Ascent ANDA Products before the expiration of the '989 patent is an act of infringement of the '989 patent by Defendants of one or more claims of the '989 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

115. 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 Ascent ANDA Products upon, or in anticipation of, FDA approval of the Ascent ANDA.

ANSWER: Denied.

116. 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 Ascent ANDA Products will infringe, directly and/or indirectly, one or more claims of the '989 patent under 35 U.S.C. § 271.

ANSWER: Denied.

117. Upon information and belief, the commercial offering for sale and/or sale of the Ascent 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.

ANSWER: Denied.

118. Upon information and belief, the factual and legal bases in the June 15 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).

ANSWER: Denied.

119. 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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

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

ANSWER: Ascent repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

112. Upon information and belief, Defendants' submission and filing of the Ascent ANDA with a paragraph IV certification to the '940 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Ascent ANDA Products before the expiration of the '940 patent is an act of infringement of the '940 patent by Defendants of one or more claims of the '940 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

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 Ascent ANDA Products upon, or in anticipation of, FDA approval of the Ascent ANDA.

ANSWER: Denied.

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 Ascent ANDA Products will infringe, directly and/or indirectly, one or more claims of the '940 patent under 35 U.S.C. § 271.

ANSWER: Denied.

125. Upon information and belief, the commercial offering for sale and/or sale of the Ascent 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.

ANSWER: Denied.

126. Upon information and belief, the factual and legal bases in the June 15 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).

ANSWER: Denied.

127. 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.

ANSWER: Denied.

128. 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.

ANSWER: Denied.

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

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

ANSWER: Ascent repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

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

ANSWER: Denied.

131. 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 Ascent ANDA Products upon, or in anticipation of, FDA approval of the Ascent ANDA.

ANSWER: Denied.

132. 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 Ascent ANDA Products will infringe, directly and/or indirectly, one or more claims of the '004 patent under 35 U.S.C. § 271.

ANSWER: Denied.

133. Upon information and belief, the commercial offering for sale and/or sale of the Ascent 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.

ANSWER: Denied.

134. Upon information and belief, the factual and legal bases in the June 15 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).

ANSWER: Denied.

135. 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.

ANSWER: Denied.

136. 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.

ANSWER: Denied.

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

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

ANSWER: Ascent repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

138. Upon information and belief, Defendants' submission and filing of the Ascent ANDA with a paragraph IV certification to the '983 patent to obtain approval to engage in the

commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Ascent ANDA Products before the expiration of the '983 patent is an act of infringement of the '983 patent by Defendants of one or more claims of the '983 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

139. 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 Ascent ANDA Products upon, or in anticipation of, FDA approval of the Ascent ANDA.

ANSWER: Denied.

140. 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 Ascent ANDA Products will infringe, directly and/or indirectly, one or more claims of the '983 patent under 35 U.S.C. § 271.

ANSWER: Denied.

141. Upon information and belief, the commercial offering for sale and/or sale of the Ascent 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.

ANSWER: Denied.

142. Upon information and belief, the factual and legal bases in the June 15 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).

ANSWER: Denied.

143. 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.

ANSWER: Denied.

144. 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.

ANSWER: Denied.

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

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

ANSWER: Ascent repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

146. Upon information and belief, Defendants' submission and filing of the Ascent ANDA with a paragraph IV certification to the '790 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Ascent ANDA Products before the expiration of the '790 patent is an act of

infringement of the '790 patent by Defendants of one or more claims of the '790 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

147. 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 Ascent ANDA Products upon, or in anticipation of, FDA approval of the Ascent ANDA.

ANSWER: Denied.

148. 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 Ascent ANDA Products will infringe, directly and/or indirectly, one or more claims of the '790 patent under 35 U.S.C. § 271.

ANSWER: Denied.

149. Upon information and belief, the commercial offering for sale and/or sale of the Ascent 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.

ANSWER: Denied.

150. Upon information and belief, the factual and legal bases in the June 15 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).

ANSWER: Denied.

151. 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.

ANSWER: Denied.

152. 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.

ANSWER: Denied.

AFFIRMATIVE DEFENSES

Further answering the Complaint, Ascent asserts the following defenses in response to the allegations of the Complaint, undertaking the burden of proof only as to those defenses required by law, regardless of how such defenses are denominated below. Ascent reserves the right to amend this Answer with additional defenses as further information is obtained.

FIRST AFFIRMATIVE DEFENSE

Plaintiff's Complaint fails to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

To the extent that Plaintiff alleges that submission of Ascent's ANDA makes this case an exceptional case under 35 U.S.C. § 285, the Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

The claims of the patents-in-suit are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of §§

101, 102, 103, 111, 112, 116, 135, 256, and 287, or other judicially-created bases for invalidation and unenforceability including, at least, non-statutory double patenting.

FOURTH AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale, or importation of Ascent's ANDA products will not infringe, directly or indirectly, any valid and/or enforceable claims of the patents-in suit, either literally or under the doctrine of equivalents.

FIFTH AFFIRMATIVE DEFENSE

Any claim of infringement of the patents-in-suit under the doctrine of equivalents would be precluded by prosecution history estoppel.

SIXTH AFFIRMATIVE DEFENSE

Ascent has not infringed, and is not infringing, directly or indirectly, any valid claim of the patents-in-suit, and all activities Ascent has performed or is performing in relation to the Ascent ANDA products have solely been for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

SEVENTH AFFIRMATIVE DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

RESERVATION OF RIGHTS

Ascent reserves the right to assert or plead any additional affirmative defenses, the availability of which may arise or become known throughout the course of this legal action.

Dated: October 10, 2023

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/s/ Karen A. Confoy

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Defendant Ascent Pharmaceuticals, Inc. ("Ascent") by its undersigned counsel, hereby certifies that, to the best of Ascent's knowledge, the claims asserted in this action are not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: October 10, 2023

/s/ Karen A. Confoy
Karen A. Confoy

CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on October 10, 2023, a true and correct copy of the foregoing document was filed with the Court and served electronically by the Court's CM/ECF System to all counsel of record and registered users.

Dated: October 10, 2023

/s/ Karen A. Confoy
Karen A. Confoy