UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
CENTRAL ISLIP

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SUPERNUS PHARMACEUTICALS, INC.,

Plaintiff,

v.

ASCENT PHARMACEUTICALS INC., CAMBER PHARMACEUTICALS, INC., AND HETERO LABS LIMITED,

Defendants.

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Civil Action No.

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COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendant Ascent Pharmaceuticals Inc. ("Ascent"), Defendant Camber Pharmaceuticals, Inc. ("Camber"), and Defendant Hetero Labs Limited ("Hetero") (collectively, Ascent, Camber, and Hetero are "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 8,298,576 ("the '576 patent"), 8,298,580 ("the '580 patent"), 8,663,683 ("the '683 patent"), 8,877,248 ("the '248 patent"), 8,889,191 ("the '191 patent"), 8,992,989 ("the '989 patent"), 9,549,940 ("the '940 patent"), 9,555,004 ("the '004 patent"), 9,622,983 ("the '983 patent"), and 10,314,790 ("the '790 patent") attached hereto as Exhibits A–J (collectively, "the patents-in-suit").

THE PARTIES

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

3. Upon information and belief, Defendant 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.

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.

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.

JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over Defendants under: (i) Fed. R. Civ. P. 4(k)(1); and/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.

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."

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").

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 York and this Judicial District, and importing generic pharmaceutical products into the United States, including throughout the State of New York and this Judicial District; (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 York and this Judicial District; and (iii) the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New York and this Judicial District.

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

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 (*see infra*) 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 York and this Judicial District.

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

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

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.

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[1] that are and/or will be manufactured and sold, pursuant to an ANDA, throughout the United States, including throughout the State of New York and this Judicial District.

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

[1] Ascent Website, Product List, https://ascentpharm.com/products-page-1/ (last visited July 28, 2023); Ascent Website, Product List, https://ascentpharm.com/products-page2/ (last visited July 28, 2023); Ascent Website, Product List, https://ascentpharm.com/products-page-3/ (last visited July 28, 2023); Ascent Website, Product List, https://ascentpharm.com/products-page-4/ (last visited July 28, 2023).

production," and "Ascent produces approximately 20 percent of the generic products offered by Camber Pharmaceuticals."[2]

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,"[3] including in New York and this Judicial District.

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."[4]

21. Upon information and belief, Camber is a "100% subsidiary" of Hetero.[5]

22. Upon information and belief, "Ascent Pharmaceuticals, Inc. of Central Islip, New York, [is] Camber's sister company."[6]

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,"[7] which demonstrates that

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[2] Camber Website, *Camber Celebrates 15 Years of Success* (September 30, 2022), https://www.camberpharma.com/15-years-success/ (last visited July 28, 2023).

[3] Answer at 9, *Vifor Pharma, Inc. v. Alkem Lab'ys Ltd.*, No. 20-106 (D. Del. Dec. 23, 2021), ECF No. 10; First Amended Answer at 5, *Relypsa, Inc. v. Alkem Lab'ys*, No. 20-106 (D. Del. Mar. 31, 2021), ECF No. 12.

[4] Camber Website, *Camber Celebrates 15 Years of Success* (September 30, 2022), https://www.camberpharma.com/15-years-success/ (last visited July 28, 2023).

[5] Hetero Website, Presence, https://www.hetero.com/presence (last visited July 28, 2023); *see also* Camber Website, *Camber Celebrates 15 Years of Success* (September 30, 2022), https://www.camberpharma.com/15-years-success/ (last visited July 28, 2023).

[6] Camber Website, *Camber Launches Generic Percocet* (June 12, 2017), https://www.camberpharma.com/camber-launches-generic-percocet/ (last visited July 28, 2023).

[7] Hetero Website, Expertise – Global Manufacturing Facilities, https://www.hetero.com/global-manufacturing-facilities (last visited July 28, 2023).

Hetero and Ascent have not maintained corporate separateness and that Hetero ratifies Ascent's places of business.

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 York and this Judicial District.

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

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."[8]

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."[9]

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,

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[8] Ascent Website, Product List, https://ascentpharm.com/products-page-1/ (last visited July 28, 2023); Ascent Website, Product List, https://ascentpharm.com/products-page2/ (last visited July 28, 2023); Ascent Website, Product List, https://ascentpharm.com/products-page-3/ (last visited July 28, 2023); Ascent Website, Product List, https://ascentpharm.com/products-page-4/ (last visited July 28, 2023) (expand "Topiramate Tablets").

[9] Camber Website, *Camber Celebrates 15 Years of Success* (September 30, 2022), https://www.camberpharma.com/15-years-success/ (last visited July 28, 2023).

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.

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.

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

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

32. Upon information and belief, Ascent "develops and manufactures generic pharmaceutical products, which then are sold in the United States," including in New York and in this Judicial District, "by independent marketing groups . . . ."[10]

33. Upon information and belief, Ascent is registered with New York's Department of State, Division of Corporations as a domestic business corporation operating in New York with Department of State (DOS) Identification Number 4136894.[11] Upon information and

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[10] Answer at 4, *Tris Pharma, Inc. v. Ascent Pharm., Inc.*, No. 21-12867 (D.N.J. June 21, 2021), ECF No. 38.

[11] New York's Department of State, Division of Corporations Website, https://apps.dos.ny.gov/publicInquiry/#search (select "Entity type" and choose "Active," select

belief, Ascent is registered with the State of New York's Department of Health as a currently licensed entity "acting as a manufacturer, distributor, importer, exporter, institutional dispenser or institutional dispenser limited of controlled substances, or conducting research, instructional activities or chemical analysis with controlled substances in New York State."[12] Ascent has, therefore, purposefully availed itself of the rights, benefits, and privileges of New York's laws.

34. Upon information and belief, Ascent has purposefully availed itself of the privilege of doing business in the State of New York and this Judicial District by continuously and systematically placing goods in the stream of commerce for distribution and sale throughout the United States, including the State of New York and this Judicial District. For example, on its website, Ascent states that "Ascent Pharmaceuticals, Inc., with Corporate Head Quarters in Central Islip, New York is a leading generic pharmaceutical company," and further states, "Ascent Pharmaceutical is a specialist pharmaceutical company dedicated to making effective treatments and tests available to healthcare professionals and consumers."[13]

35. This Court has personal jurisdiction over Ascent, at least because, upon information and belief: (i) Ascent is incorporated in New York; (ii) Ascent maintains a principal place of business in New York located at 400 S. Technology Drive, Central Islip, New York 11722; (iii) Ascent is doing business in New York and this Judicial District and maintains

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"Corporation" in the "Entity list" field, and enter into the "EntityName" field "Ascent Pharmaceuticals Inc." and select "Search the Database") (last visited July 28, 2023).

[12] New York's Department of Health Website, Licensing and Certification, https://www.health.ny.gov/professionals/narcotic/licensing_and_certification/ (select "This Microsoft Excel file" hyperlink under "Listing of Currently Licensed Entities" and search the Excel file for "Ascent") (last visited July 28, 2023).

[13] Ascent Pharmaceuticals, Inc. Website, "Products," https://ascentpharm.com (last visited July 28, 2023).

continuous and systematic contacts with New York and this Judicial District, including by working in concert with Hetero and Camber; (iv) Ascent is in the business of developing and manufacturing generic pharmaceutical products, directly or indirectly, for importation, sale, and/or distribution in the State of New York and in this Judicial District, including by working in concert with Hetero and Camber; (v) Ascent has committed, induced, and/or contributed to acts of patent infringement in New York and this Judicial District, including by working in concert with Hetero and Camber; (vi) Ascent has purposefully directed its activities at residents and corporate entities within the State of New York and this Judicial District, including by working in concert with Hetero and Camber; (vii) the claims set forth herein against Ascent arise out of or relate to those activities; and (viii) it is reasonable and fair for this Court to exercise personal jurisdiction over Ascent.

36. 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 New York and 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 this Judicial District.

37. 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 York and this Judicial District, dispensed by pharmacies located within the State of New York and this Judicial District, and used by patients in the State of New York and this Judicial District. 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 York, including by working in concert with Camber and Hetero.

38. 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.

39. Upon information and belief, "Camber sells generic pharmaceuticals throughout the United States,"[14] including in New York and in this Judicial District. Camber has, therefore, purposefully availed itself of the rights, benefits, and privileges of New York's laws.

40. This Court has personal jurisdiction over Camber at least because, upon information and belief: (i) Camber is doing business in New York and maintains continuous and systematic contacts with this Judicial District, including with working in concert with Hetero and Ascent; (ii) Camber has purposefully directed its activities at residents and corporate entities within the State of New York and 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 York and

[14] Answer at 2, *Roxane Lab'ys, Inc. v. Camber Pharm., Inc.*, No. 14-4042, ECF No. 130 (D.N.J. Sep. 19, 2014).

this Judicial District, including by working in concert with Hetero and Ascent; (iv) Camber has committed, induced, and/or contributed to acts of patent infringement in New York and this Judicial District, 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; and (vi) it is reasonable and fair for this Court to exercise personal jurisdiction over Camber.

41. Upon information and belief, Hetero has engaged in systematic and continuous business contacts within the State of New York and this Judicial District. For example, 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,"[15] which demonstrates that Hetero and Ascent have not maintained corporate separateness and Hetero ratifies Ascent's places of business.

42. 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 in New York and in this Judicial District.

43. This Court has personal jurisdiction over Hetero at least because, upon information and belief: (i) Hetero maintains as a place of business the Ascent Central Islip, New York, manufacturing facility, located at 400 South Technology Drive, Central Islip, New York 11722; (ii) Hetero is doing business in New York 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 York and in this Judicial District,

[15] Hetero Website, Expertise – Global Manufacturing Facilities, https://www.hetero.com/global-manufacturing-facilities (last visited July 28, 2023).

including by working in concert with Ascent and Camber; (iv) Hetero has committed, induced, and/or contributed to acts of patent infringement in New York and in this Judicial District, 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; and (vi) it is reasonable and fair for this Court to exercise personal jurisdiction over Hetero.

44. Venue is proper pursuant to §§ 1391(b) and (c) and/or § 1400(b), because upon information and belief, Ascent is incorporated in New York.

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

46. Venue is proper pursuant to §§ 1391(b) and (c) and/or § 1400(b), because upon information and belief, Ascent is incorporated in New York and in this Judicial District and has a principal place of business in New York and in this Judicial District, and Ascent and Camber operate as an integrated business and are intimately connected sister companies, with Ascent manufacturing products in New York and in this Judicial District for Camber to market, distribute, and/or sell throughout the United States, including in New York and in this Judicial District, and Ascent and Camber have and will continue to engage in infringing activities in New York and in this Judicial District. Upon information and belief, Ascent, Camber, and Hetero (and/or employees of Ascent, Camber, and Hetero) share a common manufacturing facility located at 400 South Technology Drive, Central Islip, New York 11722. 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.

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, and Hetero has and will continue to engage in infringing activities in New York and in this Judicial District.

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.

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.

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.

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®.

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.

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.

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.

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.

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.

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.

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, 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.

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.

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.

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.

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.

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

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.

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.

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.

67. Upon information and belief, Ascent 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.

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

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).

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).

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 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.

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.

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.

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).

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.

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

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.

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).

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.

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.

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.

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).

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.

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.

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.

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).

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.

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.

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.

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).

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.

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.

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.

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).

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.

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.

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.

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).

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.

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.

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.

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).

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.

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.

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.

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).

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.

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.

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.

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).

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.

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.

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.

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 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).

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.

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.

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.

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).

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.

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.

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.

122. 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).

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.

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.

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.

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).

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.

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.

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.

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).

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.

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.

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.

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).

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.

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.

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.

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).

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.

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.

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.

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).

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.

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.

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.

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).

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.

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.

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.

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).

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.

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.

PRAYER FOR RELIEF

WHEREFORE, Supernus respectfully requests the following relief:

i. A Judgment declaring that the patents-in-suit are valid and enforceable;

ii. A Judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that the submission to FDA and filing of ANDA No. 217443 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Ascent ANDA Products was an act of infringement of the patents-in-suit by Defendants;

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

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

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

vi. A Judgment, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, awarding Supernus damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 217443 that infringes the patents-in-suit;

vii. A Judgment, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, declaring that Defendants' infringement of the patents-in-suit is willful and awarding Supernus enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 217443 that infringes the patents-in-suit (including any regulatory extensions);

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

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

Dated: July 28, 2023

By: /s/ Nicholas F. Giove

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