IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

SUPERNUS PHARMACEUTICALS, INC., Plaintiff, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED, Defendants.	Civil Case No. _____ (Filed Electronically)

COMPLAINT

Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Cadila Healthcare Limited ("Zydus Cadila") (collectively, "Zydus" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

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

THE PARTIES

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

3. Upon information and belief, Defendant Zydus USA is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 73 Route 31 North, Pennington, NJ 08534. Upon information and belief, Zydus USA is a wholly-owned subsidiary, directly or indirectly, of Defendant Zydus Cadila. Upon information and belief, Zydus USA acts at the direction of, under the control of, and for the direct benefit of Zydus Cadila and is controlled and/or dominated by Zydus Cadila.

4. Upon information and belief, Defendant Zydus Cadila is a corporation operating and existing under the laws of India, with its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad, Gujarat, 382481, India.

5. Upon information and belief, Defendants filed Abbreviated New Drug Application ("ANDA") No. 216167 ("the Zydus ANDA") with the 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 200 mg of topiramate ("the Zydus ANDA Product").

6. Upon information and belief, Zydus Cadila and Zydus USA are acting cooperatively with respect to the Zydus ANDA.

7. Upon information and belief, Zydus Cadila and Zydus USA collaborate to develop, manufacture, import, market, and distribute, and/or sell pharmaceutical products, including generic drug products (e.g., Donepezil Hydrochloride Tablets (5 mg and10 mg),

Divalproex Sodium Capsules (125 mg), and Gabapentin Tablets (600 mg and 800 mg)), that will be manufactured and sold pursuant to an ANDA throughout the United States, including throughout the State of New York.

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

9. Upon information and belief, Defendants will market the Zydus ANDA Product throughout the United States, including in New York, upon approval of the Zydus ANDA.

JURISDICTION AND VENUE

10. This is a civil action for patent infringement under 35 U.S.C. § 271. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq*. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. 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).

12. Zydus USA and Zydus Cadila expressly consented and submitted themselves to venue and personal jurisdiction in this Judicial District in Section 11.7 of a License Agreement (defined hereunder) entered into by the parties in the Prior Lawsuit (defined hereunder). *See* https://www.sec.gov/Archives/edgar/data/1356576/000110465917031191/a17-10293_1ex10d1.htm (accessed September 17, 2021) (attached hereto as Exhibit K). Section 11.7 states,

> **11.7 Governing Law**. The Settlement Documents shall be governed by the/ Laws of the State of New York without regard to the conflicts of law provisions thereof. The Parties irrevocably agree that the United States District Court for the Southern District of New York shall have exclusive jurisdiction to deal with any disputes arising out of or in connection with the Settlement Documents and that, accordingly, any proceedings arising out of or in connection with the Settlement Documents shall be brought in the United States District Court for the Southern District of New York. Notwithstanding the foregoing, if there is any dispute for which the United States District Court for the Southern District of New York does not have subject matter jurisdiction, the state courts in the county and state of New York shall have jurisdiction. In connection with any dispute arising out of or in connection with the Settlement Documents, each Party (i) hereby expressly consents and submits to the personal jurisdiction of the federal and state courts in the State of New York and (ii) hereby irrevocably waives any right to a trial by jury.

See Exhibit K.

13. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because, upon information and belief, Zydus Cadila 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.

14. Upon information and belief, Zydus USA holds a current and valid "Wholesaler" license from the New York State Board of Pharmacy under Registration No. 031649.

15. Upon information and belief, Zydus Cadila and Zydus USA (1) engage in and maintain systematic and continuous business contacts throughout the United States, including in this Judicial District, (2) have purposefully availed themselves of the benefits and protections of the laws of New York, and (3) derive substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredients throughout the United States, including in this Judicial District.

16. Upon information and belief, if the Zydus ANDA is approved, the Zydus ANDA Product will be marketed and distributed by Zydus USA at the direction and control of Zydus Cadila in the State of New York, prescribed by physicians practicing in the State of New York, dispensed by pharmacies located within the State of New York, and used by patients in the State of New York.

17. According to Defendants' website and Annual Report 2020-21, Zydus USA is a wholly owned subsidiary of Zydus Cadila. Zydus Website, https://zydususa.com/overview/ (accessed September 17, 2021); Zydus Annual Report 2020-21 at 83, https://www.zyduscadila.com/public/pdf/financial/annual/Annual-Report-2020-2021.pdf (accessed September 17, 2021).

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

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

20. Upon information and belief, Zydus USA acts at the direction, and for the benefit, of Zydus Cadila and is controlled and/or dominated by Zydus Cadila.

21. Upon information and belief, Zydus USA and Zydus Cadila act, operate, and/or hold themselves out to the public as a single, fully integrated business.

FACTS AS TO ALL COUNTS

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

23. 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.

24. 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, or 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.

25. 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 FDA with or after the approval of NDA No. 201635.

26. 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.

27. 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.

28. 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.

29. 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.

30. 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.

31. 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.

32. 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.

33. 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.

34. 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.

35. 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.

36. In 2014, Zydus submitted ANDA No. 207382 seeking approval from the FDA to engage in the commercial use, manufacture, sale, offer for sale, or importation of generic 25 mg, 50 mg, and 100 mg topiramate extended-release capsules (“Zydus Products”)—a generic version of Trokendi XR®. *See Supernus Pharm., Inc. v. Zydus Pharm. (USA) Inc.*, No. 14-7272 (SDW)(SCM) (D.N.J.) (“Prior Lawsuit”), ECF No. 1. Supernus sued Zydus in the District of New Jersey asserting that the Zydus Products, if sold and marketed, would infringe certain patents. *See* Prior Lawsuit, ECF No. 1. The Prior Lawsuit against Zydus settled, and the parties

entered into settlement and license agreements (referred herein separately as "Settlement Agreement" and "License Agreement") that permitted Zydus to launch the Zydus Products on January 1, 2023, or earlier under certain circumstances. *See* https://ir.supernus.com/news-releases/news-release-details/supernus-announces-settlement-zydus-trokendi-xrr-patent (accessed September 17, 2021); Exhibit K.

37. On or about August 5, 2021, Zydus sent a letter purportedly pursuant to 21 U.S.C. § 355(j)(2)(B) and Section 505(j)(2)(B) of the Food, Drug, and Cosmetic Act ("FDCA") regarding the Zydus ANDA Product and the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents (the "August 5 Notice Letter") to Supernus at 9715 Key West Ave., Rockville, MD 20850.

38. The August 5 Notice Letter was signed by Brij Khera, Ph.D., Executive Vice President and Chief Legal Officer of Zydus USA.

39. Upon information and belief, the Zydus ANDA identifies Trokendi XR® (topiramate extended-release capsules), 200 mg as the reference listed drug.

40. Upon information and belief, the Zydus ANDA Product is topiramate extended-release capsules, 200 mg.

41. Upon information and belief, the proposed prescribing information for the Zydus ANDA Product includes a header titled "Indications and Usage" and states that the Zydus ANDA Product is 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.

42. Upon information and belief, the proposed prescribing information for the Zydus ANDA Product 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.

43. Upon information and belief, the proposed prescribing information for the Zydus ANDA Product will also state under the header "Dosage and Administration" that the Zydus ANDA Product can be taken without regard to meals, should be swallowed whole and intact, and should not be sprinkled on food, chewed, or crushed.

44. Upon information and belief, Zydus Cadila and Zydus USA acted in concert to develop the Zydus ANDA Product and/or seek approval from the FDA to sell the Zydus ANDA Product throughout the United States, including within this Judicial District.

45. Upon information and belief, both Zydus Cadila and Zydus USA participated in the preparation and/or filing of the Zydus ANDA.

46. Upon information and belief, Zydus manufactured the Zydus ANDA Product for development and use in preparing and filing the Zydus ANDA.

47. 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).

48. Upon information and belief, as of the date of the August 5 Notice Letter, Zydus 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).

49. Contrary to Defendants' contentions in the August 5 Notice Letter, the License Agreement does not authorize or under any circumstances grant Zydus permission to manufacture, have manufactured, import, use, or market in, into or for the United States the Zydus ANDA Product. *See* Exhibit K.

50. The August 5 Notice Letter alleges that all of the patents in suit are invalid. The Settlement Agreement and License Agreement specifically prohibit Defendants from challenging the validity or enforceability of most of the patents in suit. *See* Exhibit K.

51. Supernus and Zydus did not reach agreement on mutually acceptable terms for an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8). As of the filing of this Complaint, Zydus has not produced the Zydus ANDA to Supernus.

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

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

53. Upon information and belief, Zydus's submission and filing of the Zydus 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 Zydus ANDA Product before the expiration of the '576 patent is an act of infringement of the '576 patent by Zydus of one or more claims of the '576 patent under 35 U.S.C. § 271(e)(2)(A).

54. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

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

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

57. Upon information and belief, the factual and legal bases in the August 5 Notice Letter regarding the '576 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).

58. Zydus acted without a reasonable basis for believing that it 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.

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

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

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

61. Upon information and belief, Zydus's submission and filing of the Zydus 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 Zydus ANDA Product before the expiration of the '580 patent is an act of infringement of the '580 patent by Zydus of one or more claims of the '580 patent under 35 U.S.C. § 271(e)(2)(A).

62. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

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

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

65. Upon information and belief, the factual and legal bases in the August 5 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).

66. Zydus acted without a reasonable basis for believing that it 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.

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

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

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

69. Upon information and belief, Zydus's submission and filing of the Zydus 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 Zydus ANDA Product before the expiration of the '683 patent is an act of infringement of the '683 patent by Zydus of one or more claims of the '683 patent under 35 U.S.C. § 271(e)(2)(A).

70. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

71. Upon information and belief, Zydus's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Zydus ANDA Product will infringe, directly and/or indirectly, one or more claims of the '683 patent under 35 U.S.C. § 271.

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

73. Upon information and belief, the factual and legal bases in the August 5 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).

74. Zydus acted without a reasonable basis for believing that it 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.

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

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

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

77. Upon information and belief, Zydus's submission and filing of the Zydus 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 Zydus ANDA Product before the expiration of the '248 patent is an act of infringement of the '248 patent by Zydus of one or more claims of the '248 patent under 35 U.S.C. § 271(e)(2)(A).

78. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of ANDA No. 216167.

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

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

81. Upon information and belief, the factual and legal bases in the August 5 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).

82. Zydus acted without a reasonable basis for believing that it 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.

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

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

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

85. Upon information and belief, Zydus's submission and filing of the Zydus 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 Zydus ANDA Product before the expiration of the '191 patent is an act of infringement of the '191 patent by Zydus of one or more claims of the '191 patent under 35 U.S.C. § 271(e)(2)(A).

86. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

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

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

89. Upon information and belief, the factual and legal bases in the August 5 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).

90. Zydus acted without a reasonable basis for believing that it 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.

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

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

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

93. Upon information and belief, Zydus's submission and filing of the Zydus 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 Zydus ANDA Product before the expiration of the '989 patent is an act of infringement of the '989 patent by Zydus of one or more claims of the '989 patent under 35 U.S.C. § 271(e)(2)(A).

94. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

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

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

97. Upon information and belief, the factual and legal bases in the August 5 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).

98. Zydus acted without a reasonable basis for believing that it 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.

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

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

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

101. Upon information and belief, Zydus's submission and filing of the Zydus 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 Zydus ANDA Product before the expiration of the '940 patent is an act of infringement of the '940 patent by Zydus of one or more claims of the '940 patent under 35 U.S.C. § 271(e)(2)(A).

102. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

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

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

105. Upon information and belief, the factual and legal bases in the August 5 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).

106. Zydus acted without a reasonable basis for believing that it 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.

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

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

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

109. Upon information and belief, Zydus's submission and filing of the Zydus 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 Zydus ANDA Product before the expiration of the '004 patent is an act of infringement of the '004 patent by Zydus of one or more claims of the '004 patent under 35 U.S.C. § 271(e)(2)(A).

110. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

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

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

113. Upon information and belief, the factual and legal bases in the August 5 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).

114. Zydus acted without a reasonable basis for believing that it 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.

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

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

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

117. Upon information and belief, Zydus's submission and filing of the Zydus 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 Zydus ANDA Product before the expiration of the '983 patent is an act of infringement of the '983 patent by Zydus of one or more claims of the '983 patent under 35 U.S.C. § 271(e)(2)(A).

118. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

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

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

121. Upon information and belief, the factual and legal bases in the August 5 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).

122. Zydus acted without a reasonable basis for believing that it 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.

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

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

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

125. Upon information and belief, Zydus's submission and filing of the Zydus 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 Zydus ANDA Product before the expiration of the '790 patent is an act of infringement of the '790 patent by Zydus of one or more claims of the '790 patent under 35 U.S.C. § 271(e)(2)(A).

126. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

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

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

129. Upon information and belief, the factual and legal bases in the August 5 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).

130. Zydus acted without a reasonable basis for believing that it 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.

131. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Zydus is 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. 216167 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 Zydus ANDA Product 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 Zydus ANDA Product 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 Zydus ANDA Product 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 Zydus ANDA Product 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. 216167 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. 216167 that infringes the patents in suit (including any regulatory extensions);

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

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

Dated: September 17, 2021

By: s/ Edgar Haug

Edgar H. Haug
Nicholas F. Giove
Richard F. Kurz
HAUG PARTNERS LLP
745 Fifth Avenue
New York, New York 10151
(212) 588-0800
ehaug@haugpartners.com
ngiove@haugpartners.com
rkurz@haugpartners.com

Attorneys for Plaintiff
Supernus Pharmaceuticals, Inc.