IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SUPERNUS PHARMACEUTICALS, INC., Plaintiff, v. CREEKWOOD PHARMACEUTICALS, LLC, Defendant.	Civil Action No. _____

Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendant Creekwood Pharmaceuticals, LLC ("Creekwood" or "Defendant"), 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. 9,358,204 ("the '204 patent"); 9,603,853 ("the '853 patent"); 9,662,338 ("the '338 patent"); 11,324,753 ("the '753 patent"); 11,458,143 ("the '143 patent"); and 12,121,523 ("the '523 patent"), attached hereto as Exhibits A–F (collectively, "the patents-in-suit").

THE PARTIES

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

3. Upon information and belief, defendant Creekwood is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1130 Route 46 W, Suite 21, Parsippany, New Jersey 07054.

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

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

6. Upon information and belief, Creekwood is registered with the State of Delaware Department of State: Division of Corporations as a business operating in Delaware and having File Number 4555803.

7. Upon information and belief, Creekwood filed Abbreviated New Drug Application ("ANDA") No. 220277 ("Defendant's ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of generic viloxazine extended-release oral capsules, containing 100 mg and 200 mg of viloxazine ("Defendant's ANDA Products").

JURISDICTION AND VENUE

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

9. This Court has personal jurisdiction over Defendant under Fed. R. Civ. P. 4(k)(1).

10. This Court has personal jurisdiction over Creekwood at least because, upon information and belief: (i) Creekwood is a Delaware limited liability company; (ii) Creekwood, itself and through related entities and agents, regularly transacts and solicits business, performs work, and contracts to supply goods and services in Delaware and/or derives substantial revenue

from goods or services used or consumed in Delaware and thus maintains continuous and systematic contacts with this Judicial District; (iii) Creekwood, itself and through related entities and agents, is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of Delaware; (iv) Creekwood has consented and submitted to this Court's jurisdiction in prior civil actions and has invoked the benefits and protections of this Court by asserting counterclaims in prior civil actions;[1] (v) Creekwood, itself and through related entities and agents, will commit, induce, and/or contribute to acts of patent infringement in Delaware; (vi) Creekwood is registered with the State of Delaware Department of State: Division of Corporations as a business operating in Delaware and having File Number 4555803; (vii) Creekwood, itself and through related entities and agents, has purposefully availed itself of the rights, benefits, and privileges of Delaware's laws by continuously and systematically placing goods in the stream of commerce for importation, use, sale, offer for sale, and/or distribution throughout the United States, including the State of Delaware; (viii) Creekwood's website states that "[t]he company operates through its own development and manufacturing hub in India and Co-development/in-licensing partnerships across the globe" (*see* https://creekwoodpharma.com/about-us/ (last visited July 7, 2025)); (ix) Creekwood has purposefully directed its activities at residents and corporate entities within the state of Delaware; (x) Creekwood's contacts with this Judicial District—e.g., the manufacturing, importation, use, sale, offer for sale, and/or distribution of generic pharmaceutical products (including the accused products at issue in this action)—give rise to and/or are related to Plaintiff's claims; (xi) it is reasonable and fair for this Court to exercise personal jurisdiction

[1] *See, e.g.*, *Astellas Pharma Inc. v. Creekwood Pharmaceuticals LLC*, No. 1:25-cv-00045-JFB-EGT, D.I. 9 (D. Del.) (not contesting personal jurisdiction and asserting counterclaims).

over Creekwood; and (xii) if Defendant's ANDA receives final approval, Defendant's ANDA Products will be marketed and distributed by Creekwood in the State of Delaware, prescribed by physicians practicing in the State of Delaware, dispensed by pharmacies located within the State of Delaware, and used by patients in the State of Delaware.

11. Upon information and belief, pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), Defendant has prepared, submitted, and filed with FDA, and FDA has received, Defendant's ANDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Defendant's ANDA Products before the expiration of the patents-in-suit throughout the United States, including in this Judicial District.

12. This Court has personal jurisdiction over Defendant at least because, upon information and belief, if Defendant's ANDA receives final approval, Defendant's ANDA Products will be manufactured, sold, distributed, and/or used by Defendant in Delaware, prescribed by physicians practicing in Delaware, and/or administered to patients in Delaware.

13. Upon information and belief, Defendant's acts of preparing and filing Defendant's ANDA and directing notice of its ANDA submission to Plaintiff are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial importation, manufacture, use, and/or sale of Defendant's ANDA Products before the expiration of the patents-in-suit throughout the United States, including in this Judicial District. Because defending against an infringement lawsuit such as this one is an essential and expected part of an ANDA filer's business, Defendant reasonably anticipates being sued in Delaware.

14. Defendant's ANDA filing implicating the patents-in-suit directly relates to this litigation and is substantially connected with this Judicial District because it reliably and non-speculatively predicts Defendant's intent to market and sell Defendant's ANDA Products in this Judicial District.

15. Defendant has taken the significant step of applying to FDA for approval to engage in future activities—including the marketing of Defendant's ANDA Products—which, upon information and belief, will be purposefully directed at this Judicial District.

16. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), 1391(c), and/or 1400(b).

FACTS COMMON TO ALL COUNTS

17. Upon information and belief, on or about June 4, 2025, Defendant sent a letter pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95) regarding the paragraph IV certification that Defendant submitted in Defendant's ANDA and the patents-in-suit (the "Notice Letter") to Supernus at 9715 Key West Avenue, Rockville, Maryland 20850.

18. The Notice Letter included an Offer of Confidential Access ("OCA") to unspecified portions of Defendant's ANDA, purportedly pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

19. Defendant's OCA accompanying the Notice Letter contained numerous unreasonable and overly restrictive provisions. Plaintiff proposed revisions that comport with restrictions that "would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." *See* 21 U.S.C. § 355. Plaintiff and Defendant did not reach agreement on the terms of an Offer of Confidential Access and, to date, Defendant has not produced a copy of Defendant's ANDA to Plaintiff.

20. According to the Notice Letter, Defendant filed Defendant's ANDA with FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Defendant's ANDA Products.

21. Upon information and belief, Defendant is 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 Delaware, and importing generic pharmaceutical products into the United States, including throughout the State of Delaware; (ii) the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of Delaware; and (iii) the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

22. Upon information and belief, Defendant filed Defendant's ANDA and stands to benefit from its approval.

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

24. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 C.F.R. § 314.95(c)(7) requires that such a letter include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and

"(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)-(ii).

25. Upon information and belief, as of the date of the Notice Letter, Defendant 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).

26. Upon information and belief, the Notice Letter does not disclose any invalidity contentions or opinions specifically directed to: (i) any claims of the '204 patent; (ii) any claims of the '853 patent; or (iii) any claims of the '338 patent. Accordingly, upon information and belief, Defendant acknowledges and admits that the '204 patent, the '853 patent, and the '338 patent are not invalid.

27. Upon information and belief, the Notice Letter does not disclose any indirect infringement contentions specifically related to: (i) any claims of the '204 patent; or (ii) any claims of the '338 patent. Accordingly, upon information and belief, Defendant acknowledges and admits that it indirectly infringes the claims of the '204 patent and the '338 patent.

28. Upon information and belief, the Notice Letter does not disclose any unenforceability contentions for the patents-in-suit.

29. Supernus's Qelbree® is sold and marketed under New Drug Application ("NDA") No. 211964, which was approved by FDA for the manufacture and sale of viloxazine extended-release capsules 100 mg, 150 mg and 200 mg.

30. Qelbree® is a selective norepinephrine reuptake inhibitor indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older.

31. Qelbree®'s recommended dosage is as follows:

- Pediatric patients 6 to 11 years of age: Recommended starting dosage is 100 mg once daily. May titrate in increments of 100 mg weekly to the maximum recommended dosage of 400 mg once daily

- Pediatric patients 12 to 17 years of age: Recommended starting dosage is 200 mg once daily. May titrate after 1 week, by an increment of 200mg, to the maximum recommended dosage of 400 mg once daily

- Adult patients: Recommended starting dosage is 200 mg once daily. May titrate in increments of 200 mg weekly, to maximum recommended dosage of 600 mg once daily

- Capsules may be swallowed whole or opened and the entire contents sprinkled onto applesauce or pudding

- Severe Renal Impairment: Initial dosage is 100 mg once daily. Titrate in weekly increments of 50 mg to 100 mg to a maximum recommended dosage of 200 mg once daily

See, e.g., http://www.accessdata.fda.gov/drugsatfda_docs/label/2025/211964s013lbl.pdf#page=1 (last visited July 1, 2025).

32. FDA's publication, titled, "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book"), lists six (6) patents, specifically the patents-in-suit, as covering Supernus's Qelbree®. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), the patents-in-suit were submitted to FDA with or after the approval of NDA No. 211964. The patents-in-suit are listed in the Orange Book as covering Qelbree®.

33. The '204 patent, titled, "Formulations of Viloxazine," was duly and legally issued by the United States Patent and Trademark Office on June 7, 2016, to Supernus upon assignment from inventors Michael Vieira, Austin B. Huang, and Padmanabh P. Bhatt. Supernus owns all rights, title, and interest in the '204 patent.

34. The '853 patent, titled, "Formulations of Viloxazine," was duly and legally issued by the United States Patent and Trademark Office on March 28, 2017, to Supernus upon

assignment from inventors Michael Vieira, Austin B. Huang, and Padmanabh P. Bhatt. Supernus owns all rights, title, and interest in the '853 patent.

35. The '338 patent, titled, "Formulations of Viloxazine," was duly and legally issued by the United States Patent and Trademark Office on May 30, 2017, to Supernus upon assignment from inventors Michael Vieira, Austin B. Huang, and Padmanabh P. Bhatt. Supernus owns all rights, title, and interest in the '338 patent.

36. The '753 patent, titled, "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)," was duly and legally issued by the United States Patent and Trademark Office on May 10, 2022, to Supernus upon assignment from inventor Christopher D. Breder. Supernus owns all rights, title, and interest in the '753 patent.

37. The '143 patent, titled, "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)," was duly and legally issued by the United States Patent and Trademark Office on October 4, 2022, to Supernus upon assignment from inventor Christopher D. Breder. Supernus owns all rights, title, and interest in the '143 patent.

38. The '523 patent, titled, "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)," was duly and legally issued by the United States Patent and Trademark Office on October 22, 2024, to Supernus upon assignment from inventor Christopher D. Breder. Supernus owns all rights, title, and interest in the '523 patent.

39. Upon information and belief, Defendant's ANDA is based upon Qelbree® (viloxazine extended-release capsules), 100 mg and 200 mg, as its reference listed drug.

40. Upon information and belief, Defendant's ANDA Products are viloxazine extended-release capsules, 100 mg and 200 mg.

41. Upon information and belief, Defendant has represented to FDA in Defendant's ANDA that Defendant's ANDA Products are bioequivalent to Qelbree®.

42. 21 U.S.C. § 355(j)(2)(A)(i) requires that an ANDA contain "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7)." In addition, 21 U.S.C. § 355(j)(2)(A)(v) provides that an ANDA must contain "information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers."

43. The Notice Letter does not indicate that Defendant intends to market Defendant's ANDA Products with labeling that materially differs from the Qelbree® label, including, for example, in terms of indications and usage, dosage and administration, dosage forms and strengths, contraindications, warnings and precautions, adverse reactions, drug interactions, use in specific populations, overdosage, description, clinical pharmacology, nonclinical toxicology, clinical studies, how supplied/storage and handling, patient counseling information, or composition of Defendant's ANDA Products. *See, e.g.,* https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/211964s013lbl.pdf#page=21 (last visited June 25, 2025).

44. Upon information and belief, the proposed prescribing information for Defendant's ANDA Products includes a section titled, "Indication and Usage" stating that Defendant's ANDA Products are "indicated for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older."

45. Upon information and belief, the proposed prescribing information for Defendant's ANDA Products includes a section titled, "Dosage and Administration," containing information about the recommended dosage for adult and pediatric patients. Upon information and belief, the proposed prescribing information for Defendant's ANDA Products recommends: (i) administering 100 mg orally once daily as the recommended starting dosage for pediatric patients 6 to 11 years of age, which may be titrated in increments of 100 mg at weekly intervals to a maximum recommended dose of 400 mg once daily, depending on response and tolerability, (ii) administering 200 mg orally once daily as the recommended starting dosage for pediatric patients 12 to 17 years of age, which may be titrated in increments of 200 mg after one week to the maximum recommended dosage of 400 mg once daily, depending on response and tolerability; and (iii) administering 200 mg orally once daily as the recommended starting dosage for adults, which may be titrated in increments of 200 mg weekly to the maximum recommended dosage of 600 mg once daily, depending on response and tolerability.

46. Upon information and belief, the proposed prescribing information for Defendant's ANDA Products includes a section titled, "Mechanism of Action," stating that "[t]he mechanism of action of viloxazine in the treatment of ADHD is unclear; however, it is thought to be through inhibiting the reuptake of norepinephrine."

47. Upon information and belief, the proposed prescribing information for Defendant's ANDA Products includes a section titled, "Pharmacodynamics," stating that Defendant's ANDA Products also "bind[] to and inhibit[] the norepinephrine transporter (Ki=0.13 μM)" and "bind[] to and exhibit[] partial agonist activity at the serotonin 5-HT2C receptor (Ki=0.66 μM)."

48. Upon information and belief, Defendant's ANDA Products will have labeling that instruct patients to call their healthcare provider or get emergency help if they experience "new or worse depression" or "new or worse anxiety."

FIRST COUNT
(Defendant's Infringement of the '204 Patent)

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

50. Upon information and belief, Defendant submitted Defendant's ANDA to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendant's ANDA Products prior to the expiration of the '204 patent.

51. Upon information and belief, Defendant submitted Defendant's ANDA with a paragraph IV certification to the '204 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Defendant's ANDA Products before the expiration of the '204 patent.

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

53. Defendant sent the Notice Letter to Supernus purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

54. Under 35 U.S.C. § 271(e)(2)(A), the submission of Defendant's ANDA with a paragraph IV certification to the '204 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendant's ANDA Products before the expiration of the '204 patent is itself an act of infringement of the '204 patent.

55. Upon information and belief, Defendant will commercially manufacture, use, offer to sell, sell within the United States, and/or import into the United States Defendant's ANDA Products upon receiving final FDA approval.

56. Upon information and belief, Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendant's ANDA Products would infringe, directly and/or indirectly, one or more claims of the '204 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

57. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Defendant's ANDA Products prior to the expiration of the '204 patent will directly infringe the '204 patent under 35 U.S.C. § 271(a), will actively induce another's infringement of the '204 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '204 patent under 35 U.S.C. § 271(c).

58. Upon information and belief, Defendant's ANDA Products will be marketed with labeling that substantially copies the labeling for Qelbree®.

59. Upon information and belief, the label for Defendant's ANDA Products that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of Defendant's ANDA will encourage such third parties to infringe one or more of the claims of the '204 patent.

60. Upon information and belief, the use of Defendant's ANDA Products by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of

Defendant's ANDA Products will constitute an act of direct infringement of one or more of the claims of the '204 patent.

61. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendant's ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the '204 patent.

62. Upon information and belief, Defendant intends such infringement by third parties, as Defendant is in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendant knows that its actions will induce acts that constitute direct infringement of claims of the '204 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

63. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendant's ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant will contribute to the infringement of the '204 patent by third parties because: (i) Defendant's ANDA Products constitute a material part of the formulations claimed in the '204 patent; (ii) Defendant knows or should know that Defendant's ANDA Products will be made for uses that directly infringe the formulations claimed in the '204 patent; and (iii) Defendant's ANDA Products are not staple articles or commodities of commerce suitable for substantial noninfringing uses.

64. Upon information and belief, Defendant has acted with full knowledge of the '204 patent and its claims and without a reasonable basis for believing that Defendant would not be liable for infringement of the '204 patent. Defendant knew of the existence of the '204 patent, as evidenced by Defendant's filing of Defendant's ANDA with a paragraph IV certification specifically referencing the '204 patent. Notwithstanding this knowledge, Defendant has continued to signal its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Defendant's ANDA Products before the expiration of the patents-in-suit. Upon information and belief, through such activities, Defendant specifically intends infringement of the '204 patent.

65. Upon information and belief, the actions described herein relating to Defendant's ANDA and Defendant's ANDA Products were done by and for the benefit of Defendant.

66. This case is "exceptional," and Supernus is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

67. Unless Defendant is permanently enjoined by this Court, the acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law.

SECOND COUNT
(Defendant's Infringement of the '853 Patent)

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

69. Upon information and belief, Defendant submitted Defendant's ANDA to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendant's ANDA Products prior to the expiration of the '853 patent.

70. Upon information and belief, Defendant submitted Defendant's ANDA with a paragraph IV certification to the '853 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Defendant's ANDA Products before the expiration of the '853 patent.

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

72. Defendant sent the Notice Letter to Supernus purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

73. Under 35 U.S.C. § 271(e)(2)(A), the submission of Defendant's ANDA with a paragraph IV certification to the '853 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendant's ANDA Products before the expiration of the '853 patent is itself an act of infringement of the '853 patent.

74. Upon information and belief, Defendant will commercially manufacture, use, offer to sell, sell within the United States, and/or import into the United States Defendant's ANDA Products upon receiving final FDA approval.

75. Upon information and belief, Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendant's ANDA Products would infringe, directly and/or indirectly, one or more claims of the '853 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

76. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Defendant's ANDA Products prior to the expiration of the '853 patent will directly infringe the '853 patent under 35 U.S.C. § 271(a), will actively induce another's infringement of

the ’853 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the ’853 patent under 35 U.S.C. § 271(c).

77. Upon information and belief, Defendant’s ANDA Products will be marketed with labeling that substantially copies the labeling for Qelbree®.

78. Upon information and belief, the label for Defendant’s ANDA Products that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of Defendant’s ANDA will encourage such third parties to perform one or more of the methods claimed in the ’853 patent.

79. Upon information and belief, the use of Defendant’s ANDA Products by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of Defendant’s ANDA Products will constitute an act of direct infringement of one or more of the methods claimed in the ’853 patent.

80. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendant’s ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the ’853 patent.

81. Upon information and belief, Defendant intends such infringement by third parties, as Defendant is in the business of developing, manufacturing, marketing, selling, and

distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendant knows that its actions will induce acts that constitute direct infringement of claims of the '853 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

82. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendant's ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant will contribute to the infringement of the '853 patent by third parties because: (i) Defendant's ANDA Products constitute a material part of the methods of treatment claimed in the '853 patent; (ii) Defendant knows or should know that Defendant's ANDA Products will be made for uses that directly infringe the methods of treatment claimed in the '853 patent; and (iii) Defendant's ANDA Products are not staple articles or commodities of commerce suitable for substantial noninfringing uses.

83. Upon information and belief, Defendant has acted with full knowledge of the '853 patent and its claims and without a reasonable basis for believing that Defendant would not be liable for infringement of the '853 patent. Defendant knew of the existence of the '853 patent, as evidenced by Defendant's filing of Defendant's ANDA with a paragraph IV certification specifically referencing the '853 patent. Notwithstanding this knowledge, Defendant has continued to signal its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Defendant's ANDA Products before the expiration of the patents-in-suit. Upon information and belief, through such activities, Defendant specifically intends infringement of the '853 patent.

84. Upon information and belief, the actions described herein relating to Defendant's ANDA and Defendant's ANDA Products were done by and for the benefit of Defendant.

85. This case is "exceptional," and Supernus is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

86. Unless Defendant is permanently enjoined by this Court, the acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law.

THIRD COUNT
(Defendant's Infringement of the '338 Patent)

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

88. Upon information and belief, Defendant submitted Defendant's ANDA to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendant's ANDA Products prior to the expiration of the '338 patent.

89. Upon information and belief, Defendant submitted Defendant's ANDA with a paragraph IV certification to the '338 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Defendant's ANDA Products before the expiration of the '338 patent.

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

91. Defendant sent the Notice Letter to Supernus purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

92. Under 35 U.S.C. § 271(e)(2)(A), the submission of Defendant's ANDA with a paragraph IV certification to the '338 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendant's ANDA Products before the expiration of the '338 patent is itself an act of infringement of the '338 patent.

93. Upon information and belief, Defendant will commercially manufacture, use, offer to sell, sell within the United States, and/or import into the United States Defendant's ANDA Products upon receiving final FDA approval.

94. Upon information and belief, Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendant's ANDA Products would infringe, directly and/or indirectly, one or more claims of the '338 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

95. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Defendant's ANDA Products prior to the expiration of the '338 patent will directly infringe the '338 patent under 35 U.S.C. § 271(a), will actively induce another's infringement of the '338 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '338 patent under 35 U.S.C. § 271(c).

96. Upon information and belief, Defendant's ANDA Products will be marketed with labeling that substantially copies the labeling for Qelbree®.

97. Upon information and belief, the label for Defendant's ANDA Products that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of Defendant's ANDA will encourage such third parties to infringe one or more of the claims of the '338 patent.

98. Upon information and belief, the use of Defendant's ANDA Products by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of Defendant's ANDA Products will constitute an act of direct infringement of one or more of the claims of the '338 patent.

99. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendant's ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the '338 patent.

100. Upon information and belief, Defendant intends such infringement by third parties, as Defendant is in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendant knows that its actions will induce acts that constitute direct infringement of claims of the '338 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

101. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendant's ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant will contribute to the infringement of the '338 patent by third parties because: (i) Defendant's ANDA Products constitute a material part of the formulations claimed in the '338 patent; (ii) Defendant knows or

should know that Defendant's ANDA Products will be made for uses that directly infringe the formulations claimed in the '338 patent; and (iii) Defendant's ANDA Products are not staple articles or commodities of commerce suitable for substantial noninfringing uses.

102. Upon information and belief, Defendant has acted with full knowledge of the '338 patent and its claims and without a reasonable basis for believing that Defendant would not be liable for infringement of the '338 patent. Defendant knew of the existence of the '338 patent, as evidenced by Defendant's filing of Defendant's ANDA with a paragraph IV certification specifically referencing the '338 patent. Notwithstanding this knowledge, Defendant has continued to signal its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Defendant's ANDA Products before the expiration of the patents-in-suit. Upon information and belief, through such activities, Defendant specifically intends infringement of the '338 patent.

103. Upon information and belief, the actions described herein relating to Defendant's ANDA and Defendant's ANDA Products were done by and for the benefit of Defendant.

104. This case is "exceptional," and Supernus is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

105. Unless Defendant is permanently enjoined by this Court, the acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law.

FOURTH COUNT
(Defendant's Infringement of the '753 Patent)

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

107. Upon information and belief, Defendant submitted Defendant's ANDA to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendant's ANDA Products prior to the expiration of the '753 patent.

108. Upon information and belief, Defendant submitted Defendant's ANDA with a paragraph IV certification to the '753 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Defendant's ANDA Products before the expiration of the '753 patent.

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

110. Defendant sent the Notice Letter to Supernus purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

111. Under 35 U.S.C. § 271(e)(2)(A), the submission of Defendant's ANDA with a paragraph IV certification to the '753 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendant's ANDA Products before the expiration of the '753 patent is itself an act of infringement of the '753 patent.

112. Upon information and belief, Defendant will commercially manufacture, use, offer to sell, sell within the United States, and/or import into the United States Defendant's ANDA Products upon receiving final FDA approval.

113. Upon information and belief, Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendant's ANDA Products would infringe, directly and/or indirectly, one or more claims of the '753 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

114. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Defendant's ANDA Products prior to the expiration of the '753 patent will directly infringe the '753 patent under 35 U.S.C. § 271(a), will actively induce another's infringement of the '753 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '753 patent under 35 U.S.C. § 271(c).

115. Upon information and belief, Defendant's ANDA Products will be marketed with labeling that substantially copies the labeling for Qelbree®.

116. Upon information and belief, the label for Defendant's ANDA Products that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of Defendant's ANDA will encourage such third parties to perform one or more of the methods claimed in the '753 patent.

117. Upon information and belief, the use of Defendant's ANDA Products by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of Defendant's ANDA Products will constitute an act of direct infringement of one or more of the methods claimed in the '753 patent.

118. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendant's ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or

pharmacists) to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the '753 patent.

119. Upon information and belief, Defendant intends such infringement by third parties, as Defendant is in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendant knows that its actions will induce acts that constitute direct infringement of claims of the '753 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

120. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendant's ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant will contribute to the infringement of the '753 patent by third parties because: (i) Defendant's ANDA Products constitute a material part of the methods claimed in the '753 patent; (ii) Defendant knows or should know that Defendant's ANDA Products will be made for uses that directly infringe the methods claimed in the '753 patent; and (iii) Defendant's ANDA Products are not staple articles or commodities of commerce suitable for substantial noninfringing uses.

121. Upon information and belief, Defendant has acted with full knowledge of the '753 patent and its claims and without a reasonable basis for believing that Defendant would not be liable for infringement of the '753 patent. Defendant knew of the existence of the '753 patent, as evidenced by Defendant's filing of Defendant's ANDA with a paragraph IV certification specifically referencing the '753 patent. Notwithstanding this knowledge, Defendant has continued to signal its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Defendant's ANDA Products before the expiration of the

patents-in-suit. Upon information and belief, through such activities, Defendant specifically intends infringement of the '753 patent.

122. Upon information and belief, the actions described herein relating to Defendant's ANDA and Defendant's ANDA Products were done by and for the benefit of Defendant.

123. This case is "exceptional," and Supernus is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

124. Unless Defendant is permanently enjoined by this Court, the acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law.

FIFTH COUNT
(Defendant's Infringement of the '143 Patent)

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

126. Upon information and belief, Defendant submitted Defendant's ANDA to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendant's ANDA Products prior to the expiration of the '143 patent.

127. Upon information and belief, Defendant submitted Defendant's ANDA with a paragraph IV certification to the '143 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Defendant's ANDA Products before the expiration of the '143 patent.

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

129. Defendant sent the Notice Letter to Supernus purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

130. Under 35 U.S.C. § 271(e)(2)(A), the submission of Defendant's ANDA with a paragraph IV certification to the '143 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendant's ANDA Products before the expiration of the '143 patent is itself an act of infringement of the '143 patent.

131. Upon information and belief, Defendant will commercially manufacture, use, offer to sell, sell within the United States, and/or import into the United States Defendant's ANDA Products upon receiving final FDA approval.

132. Upon information and belief, Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendant's ANDA Products would infringe, directly and/or indirectly, one or more claims of the '143 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

133. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Defendant's ANDA Products prior to the expiration of the '143 patent will directly infringe the '143 patent under 35 U.S.C. § 271(a), will actively induce another's infringement of the '143 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '143 patent under 35 U.S.C. § 271(c).

134. Upon information and belief, Defendant's ANDA Products will be marketed with labeling that substantially copies the labeling for Qelbree®.

135. Upon information and belief, the label for Defendant's ANDA Products that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of

Defendant's ANDA will encourage such third parties to perform one or more of the methods claimed in the '143 patent.

136. Upon information and belief, the use of Defendant's ANDA Products by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of Defendant's ANDA Products will constitute an act of direct infringement of one or more of the methods claimed in the '143 patent.

137. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendant's ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the '143 patent.

138. Upon information and belief, Defendant intends such infringement by third parties, as Defendant is in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendant knows that its actions will induce acts that constitute direct infringement of claims of the '143 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

139. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendant's ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant will contribute to the

infringement of the ’143 patent by third parties because: (i) Defendant’s ANDA Products constitute a material part of the methods of treatment claimed in the ’143 patent; (ii) Defendant knows or should know that Defendant’s ANDA Products will be made for uses that directly infringe the methods of treatment claimed in the ’143 patent; and (iii) Defendant’s ANDA Products are not staple articles or commodities of commerce suitable for substantial noninfringing uses.

140. Upon information and belief, Defendant has acted with full knowledge of the ’143 patent and its claims and without a reasonable basis for believing that Defendant would not be liable for infringement of the ’143 patent. Defendant knew of the existence of the ’143 patent, as evidenced by Defendant’s filing of Defendant’s ANDA with a paragraph IV certification specifically referencing the ’143 patent. Notwithstanding this knowledge, Defendant has continued to signal its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Defendant’s ANDA Products before the expiration of the patents-in-suit. Upon information and belief, through such activities, Defendant specifically intends infringement of the ’143 patent.

141. Upon information and belief, the actions described herein relating to Defendant’s ANDA and Defendant’s ANDA Products were done by and for the benefit of Defendant.

142. This case is “exceptional,” and Supernus is entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

143. Unless Defendant is permanently enjoined by this Court, the acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law.

SIXTH COUNT
(Defendant's Infringement of the '523 Patent)

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

145. Upon information and belief, Defendant submitted Defendant's ANDA to FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market Defendant's ANDA Products prior to the expiration of the '523 patent.

146. Upon information and belief, Defendant submitted Defendant's ANDA with a paragraph IV certification to the '523 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Defendant's ANDA Products before the expiration of the '523 patent.

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

148. Defendant sent the Notice Letter to Supernus purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

149. Under 35 U.S.C. § 271(e)(2)(A), the submission of Defendant's ANDA with a paragraph IV certification to the '523 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendant's ANDA Products before the expiration of the '523 patent is itself an act of infringement of the '523 patent.

150. Upon information and belief, Defendant will commercially manufacture, use, offer to sell, sell within the United States, and/or import into the United States Defendant's ANDA Products upon receiving final FDA approval.

151. Upon information and belief, Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendant's ANDA Products would infringe, directly and/or indirectly, one or more claims of the '523 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

152. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Defendant's ANDA Products prior to the expiration of the '523 patent will directly infringe the '523 patent under 35 U.S.C. § 271(a), will actively induce another's infringement of the '523 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '523 patent under 35 U.S.C. § 271(c).

153. Upon information and belief, Defendant's ANDA Products will be marketed with labeling that substantially copies the labeling for Qelbree®.

154. Upon information and belief, the label for Defendant's ANDA Products that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of Defendant's ANDA will encourage such third parties to perform one or more of the methods claimed in the '523 patent.

155. Upon information and belief, the use of Defendant's ANDA Products by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of Defendant's ANDA Products will constitute an act of direct infringement of one or more of the methods claimed in the '523 patent.

156. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendant's ANDA Products and/or distributing the

corresponding labeling, package insert, and/or medication guide, Defendant will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the '523 patent.

157. Upon information and belief, Defendant intends such infringement by third parties, as Defendant is in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendant knows that its actions will induce acts that constitute direct infringement of claims of the '523 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

158. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendant's ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant will contribute to the infringement of the '523 patent by third parties because: (i) Defendant's ANDA Products constitute a material part of the methods of treatment claimed in the '523 patent; (ii) Defendant knows or should know that Defendant's ANDA Products will be made for uses that directly infringe the methods of treatment claimed in the '523 patent; and (iii) Defendant's ANDA Products are not staple articles or commodities of commerce suitable for substantial noninfringing uses.

159. Upon information and belief, Defendant has acted with full knowledge of the '523 patent and its claims and without a reasonable basis for believing that Defendant would not be liable for infringement of the '523 patent. Defendant knew of the existence of the '523 patent, as

evidenced by Defendant's filing of Defendant's ANDA with a paragraph IV certification specifically referencing the '523 patent. Notwithstanding this knowledge, Defendant has continued to signal its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Defendant's ANDA Products before the expiration of the patents-in-suit. Upon information and belief, through such activities, Defendant specifically intends infringement of the '523 patent.

160. Upon information and belief, the actions described herein relating to Defendant's ANDA and Defendant's ANDA Products were done by and for the benefit of Defendant.

161. This case is "exceptional," and Supernus is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

162. Unless Defendant is permanently enjoined by this Court, the acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law.

STATEMENT REGARDING PRIOR-FILED SUIT

163. Supernus previously filed an action in the District of New Jersey on July 11, 2025 asserting infringement of the same patents-in-suit based on the same ANDA No. 220277 in the instant action. That action has been assigned Civil Action No. 2:25-cv-13201-MEF-MAH ("the D.N.J. Action"). In the D.N.J. Action, Supernus alleged that venue was proper over Defendant. Judicial economy would be promoted, and Supernus's choice of forum respected, if the claims related to Supernus's action for infringement of the patents-in-suit are addressed by the District of New Jersey. Bringing this second-filed case in Delaware ensures that all statutory and/or regulatory periods arising under 35 U.S.C. § 355(j) due to the submission of Defendant's ANDA are maintained, notwithstanding any dismissal of the D.N.J. Action.

Prayer for Relief

WHEREFORE, Supernus respectfully requests the following relief:

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

ii. A Judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that the submission to FDA and filing of Defendant's ANDA with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Defendant's ANDA Products was an act of infringement of the patents-in-suit by Defendant;

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 Defendant's 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 Defendant's ANDA Products shall be no earlier than the latest date on which the patents-in-suit expire (including any regulatory extensions);

v. An Order, pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendant and its officers, agents, servants, employees, and attorneys, and any person in active concert or participation or privity with Defendant, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation in the United States, of Defendant's 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 Defendant commercially manufactures, uses, offers to sell, or

sells within the United States, and/or imports into the United States, any product that is the subject of Defendant's ANDA that infringes the patents-in-suit;

vii. A Judgment, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, declaring that Defendant's infringement of the patents-in-suit is willful and awarding Supernus enhanced damages if Defendant commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States, any product that is the subject of Defendant's ANDA 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.

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Dated: July 15, 2025

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