IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SUPERNUS PHARMACEUTICALS, INC., **Plaintiff,** **v.** **MACLEODS PHARMACEUTICALS LTD. and MACLEODS PHARMA USA, INC.,** **Defendants.**	**Civil Action No. _____**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendants Macleods Pharmaceuticals Ltd. ("Macleods Ltd.") and Macleods Pharma USA, Inc. ("Macleods USA," and collectively with Macleods Ltd., "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. 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 Macleods Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Atlanta Arcade, Marol Church Rd., Andheri (East), Mumbai, 400059, India.

4. Upon information and belief, defendant Macleods USA is a corporation organized and existing under the laws of Delaware, having a principal place of business at 500 College Road East, STE 250, Princeton, NJ 08540.

5. Upon information and belief, Macleods USA is a wholly-owned subsidiary of Macleods Ltd.

6. Macleods Ltd.'s website states: "The formation of Macleods Pharma USA, Inc. in 2011, marked the commencement of our pharmaceutical business operations in the United States." https://www.macleodspharma.com/usa/#about (last visited on September 8, 2025).

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

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

9. Upon information and belief, Macleods USA is registered with the State of Delaware Department of State: Division of Corporations as a business operating in Delaware having File Number 5062107.

10. Upon information and belief, Macleods USA is a wholly owned subsidiary of Macleods Ltd.

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

12. Upon information and belief, Macleods Ltd. and Macleods USA collaborate with respect to the development, regulatory approval, manufacturing, importing, marketing, sale, and/or distribution of pharmaceutical products. Upon information and belief, Macleods Ltd. and Macleods USA are agents of each other and/or operate in concert as integrated parts of the same business group and enter into agreements with each other that are nearer than arm's length.

13. Upon information and belief, Macleods Ltd. and Macleods USA are in the business of, among other things, developing, manufacturing, importing, marketing, distributing, and/or 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).

14. Upon information and belief, Macleods Ltd. and Macleods USA filed Abbreviated New Drug Application ("ANDA") No. 220570 ("Defendants' 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 150 mg and 200 mg of viloxazine ("Defendants' ANDA Products").

JURISDICTION AND VENUE

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

16. 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).

17. This Court has personal jurisdiction over Macleods USA at least because, upon information and belief: (i) Macleods USA is a corporation organized under the laws of Delaware; (ii) Macleods USA, 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 (*see* https://economictimes.indiatimes.com/ industry/healthcare/biotech/pharmaceuticals/macleods-pharmaceuticals-recalls-products-in-us-for-manufacturing-issues/articleshow/90180546.cms?from=mdr (last visited on September 8, 2025)) ("Macleods [Ltd.] is also recalling a lot of Olanzapine tablets, used to treat schizophrenia, in the US market. The USFDA noted that [Macleods Ltd.] is recalling the affected lot also for eCGMP deviations. ***[Macleods Ltd.] had produced the affected lot at its Baddi plant and later marketed in the US market by Macleods Pharma USA Inc.***" (emphasis added)); (iii) Macleods USA is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of Delaware; (iv) Macleods USA, itself and through related entities and agents, will commit, induce, and/or contribute to acts of patent infringement in Delaware; (v) Macleods USA 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] (vi) Macleods USA is registered with the State of Delaware

[1] *See, e.g., ZS Pharma, Inc., et al. v. Macleods Pharms. Ltd., et al*., No. 1-23-cv-01190-JLH, D.I. 15 (D. Del.) (not contesting personal jurisdiction and asserting counterclaims); *Bayer Pharma AG, et al v. Macleods Pharms. Ltd., et al*, No. 1-23-cv-665-RGA, D.I. 13 (D. Del.) (same); *ZS*

Department of State: Division of Corporations as a business operating in Delaware having File Number 5062107; (vii) Macleods USA, 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) Macleods USA'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; (ix) Macleods USA's contacts with the state of Delaware (direct and/or indirect) are continuous and systematic; (x) it is reasonable and fair for this Court to exercise personal jurisdiction over Macleods USA; and (xi) if Defendants' ANDA receives final approval, Defendants' ANDA Products will be marketed and distributed by Macleods USA 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.

18. This Court has personal jurisdiction over Macleods Ltd. at least because, upon information and belief: (i) Macleods Ltd., itself and through its subsidiaries and agents, has purposefully availed itself of the privilege of doing business in the State of Delaware 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; (ii) Macleods Ltd., itself and through its subsidiaries and agents, regularly transacts or solicits business, performs work, and contracts to supply goods and services in Delaware and/or

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Pharma, Inc., et al. v. Macleods Pharms. Ltd., et al., No. 22-cv-01100-GBW, D.I. 18 (D. Del.) (same); *Anacor Pharms., Inc., et al v. Macleods Pharms. Ltd., et al*., No. 1-21-cv-01350-CFC, D.I. 14 (D. Del.) (same).

derives substantial revenue from goods or services used or consumed in Delaware (*see* https://economictimes.indiatimes.com/ industry/healthcare/biotech/pharmaceuticals/macleods-pharmaceuticals-recalls-products-in-us-for-manufacturing-issues/articleshow/90180546.cms?from=mdr (last visited on September 8, 2025)) ("Macleods [Ltd.] is also recalling a lot of Olanzapine tablets, used to treat schizophrenia, in the US market. The USFDA noted that [Macleods Ltd.] is recalling the affected lot also for eCGMP deviations. ***[Macleods Ltd.] had produced the affected lot at its Baddi plant and later marketed in the US market by Macleods Pharma USA Inc.***" (emphasis added)); (iii) Macleods Ltd., itself and through its subsidiaries and agents, is in the business of developing and manufacturing generic pharmaceutical products for importation, use, sale, offer for sale, and/or distribution throughout the United States, including in the State of Delaware; (iv) Macleods Ltd. 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;[2] (v) Macleods Ltd.'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; (vi) Macleods Ltd., itself and through its subsidiaries and agents, will commit, induce, and/or contribute to acts of patent infringement in Delaware; (vii) Macleods Ltd.'s contacts with the state of Delaware (direct and/or indirect) are continuous and systematic; (viii) it is reasonable and fair for this Court to

[2] *See, e.g., ZS Pharma, Inc., et al. v. Macleods Pharms. Ltd., et al*., No. 1-23-cv-01190-JLH, D.I. 15 (D. Del.) (not contesting personal jurisdiction and asserting counterclaims); *Bayer Pharma AG, et al v. Macleods Pharms. Ltd., et al*, No. 1-23-cv-665-RGA, D.I. 13 (D. Del.) (same); *ZS Pharma, Inc., et al. v. Macleods Pharms. Ltd., et al*., No. 22-cv-01100-GBW, D.I. 18 (D. Del.) (same); *Anacor Pharms., Inc., et al v. Macleods Pharms. Ltd., et al*., No. 1-21-cv-01350-CFC, D.I. 14 (D. Del.) (same).

exercise personal jurisdiction over Macleods Ltd.; and (ix) if Defendants' ANDA receives final approval, Defendants' ANDA Products will be marketed and distributed by Macleods Ltd. 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.

19. In the alternative, this Court has jurisdiction over Macleods Ltd. under Fed. R. Civ. P. 4(k)(2) because: (i) Supernus's claims arise under federal law; (ii) Macleods Ltd. is a foreign defendant not subject to jurisdiction in any state's courts of general jurisdiction; and (iii) Macleods Ltd. has sufficient contacts with the United States as a whole—including, but not limited to, preparing and submitting ANDAs to FDA and/or importing, manufacturing, using, selling, offering to sell, and distributing pharmaceutical products throughout the United States—such that this Court's exercise of jurisdiction over Macleods Ltd. satisfies due process and is otherwise consistent with the United States Constitution and laws.

20. 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)), Defendants have prepared, submitted, and filed with FDA, and FDA has received, Defendants' ANDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Defendants' ANDA Products before the expiration of the patents-in-suit throughout the United States, including in this Judicial District.

21. Upon information and belief, Defendants acted collaboratively in the preparation and submission of Defendants' ANDA to FDA.

22. This Court has personal jurisdiction over Defendants at least because, upon information and belief, if Defendants' ANDA receives final approval, Defendants' ANDA

Products will be manufactured, sold, distributed, and/or used by Defendants in Delaware, prescribed by physicians practicing in Delaware, and/or administered to patients in Delaware.

23. Upon information and belief, Defendants' acts of preparing and filing Defendants' ANDA and directing notice of their ANDA submission to Plaintiff are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, and/or sale of Defendants' 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, Defendants reasonably anticipate being sued in Delaware.

24. Defendants' 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 Defendants' intent to market and sell Defendants' ANDA Products in this Judicial District.

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

26. Upon information and belief, Defendants have been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of Defendants' ANDA and intend to benefit from Defendants' ANDA upon receiving final FDA approval.

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

FACTS COMMON TO ALL COUNTS

28. Upon information and belief, on or about August 1, 2025, Defendants 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 Defendants submitted in Defendants' ANDA and the patents-in-suit (the "Notice Letter") to Supernus at 9715 Key West Avenue, Rockville, Maryland 20850 and 1550 East Gude Drive, Rockville, Maryland 20850.

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

30. Defendants' 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 Defendants did not reach agreement on the terms of an Offer of Confidential Access and, to date, Defendants have not produced a copy of Defendants' ANDA to Plaintiff.

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

32. Upon information and belief, Defendants are in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware, and importing generic pharmaceutical products into the United States, including throughout the State of Delaware; (ii) the preparation, submission, and filing of Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to market generic drugs throughout the United States, including throughout the State of

Delaware; and (iii) the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

33. Upon information and belief, Defendants were both actively involved in filing Defendants' ANDA and both stand to benefit from its approval.

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

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

36. 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).

37. Upon information and belief, as of the date of the Notice Letter, Defendants were 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).

38. 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, Defendants acknowledge and admit that the ’204 patent, the ’853 patent, and the ’338 patent are not invalid.

39. Upon information and belief, the Notice Letter does not disclose any noninfringement contentions or opinions specifically directed to any claims of the ’753 patent, any claims of the ’143 patent, or any claims of the ’523 patent. Accordingly, upon information and belief, Defendants acknowledge and admit infringement of the ’753 patent, the ’143 patent, and the ’523 patent.

40. Upon information and belief, the Notice Letter does not disclose any unenforceability contentions for the patents-in-suit. Accordingly, upon information and belief, Defendants acknowledge and admit that the patents-in-suit are not unenforceable.

41. 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.

42. 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.

43. 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

44. 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®.

45. 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.

46. 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.

47. 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.

48. 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.

49. 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.

50. 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.

51. Upon information and belief, Defendants’ ANDA is based upon Qelbree® (viloxazine extended-release capsules), 150 mg and 200 mg, as its reference listed drug.

52. Upon information and belief, Defendants’ ANDA Products are viloxazine extended-release capsules, 150 mg and 200 mg.

53. Upon information and belief, Defendants have represented to FDA in Defendants’ ANDA that Defendants’ ANDA Products are bioequivalent to Qelbree®.

54. 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."

55. The Notice Letter does not indicate that Defendants intend to market Defendants' 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 Defendants' ANDA Products. *See, e.g.,* https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/211964s013lbl.pdf#page=21 (last visited September 8, 2025).

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

57. Upon information and belief, the proposed prescribing information for Defendants' 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 Defendants' ANDA Products recommends, among other things: (i) 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 (ii) 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.

58. Upon information and belief, the proposed prescribing information for Defendants' 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."

59. Upon information and belief, the proposed prescribing information for Defendants' ANDA Products includes a section titled, "Pharmacodynamics," stating that Defendants' 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)."

60. Upon information and belief, Defendants' 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."

61. Upon information and belief, Defendants jointly developed Defendants' ANDA Products and jointly sought approval from FDA to sell Defendants' ANDA Products throughout the United States, including within this Judicial District.

62. Upon information and belief, Defendants jointly prepared and submitted Defendants' ANDA and are jointly prosecuting and maintaining Defendants' ANDA.

FIRST COUNT
(Defendants' Infringement of the '204 Patent)

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

64. Upon information and belief, Defendants submitted Defendants' 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 Defendants' ANDA Products prior to the expiration of the '204 patent.

65. Upon information and belief, Macleods USA provided, is providing, and will provide material and significant support, advice, aid, instruction, inducement, and encouragement to Macleods Ltd. in the preparation, filing, maintenance, and further prosecution of Defendants' ANDA.

66. Upon information and belief, Macleods Ltd. provided, is providing, and will provide material and significant support, advice, aid, instruction, inducement, and encouragement to Macleods USA in the preparation, filing, maintenance, and further prosecution of Defendants' ANDA.

67. Upon information and belief, Defendants are jointly and severally liable for Defendants' infringement of one or more claims of the '204 patent.

68. Upon information and belief, Defendants submitted Defendants' 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 Defendants' ANDA Products before the expiration of the '204 patent.

69. Upon information and belief, as of the date of the Notice Letter, Defendants were 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).

70. Defendants 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).

71. Under 35 U.S.C. § 271(e)(2)(A), the submission of Defendants' 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 Defendants' ANDA Products before the expiration of the '204 patent is itself an act of infringement of the '204 patent.

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

73. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' 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).

74. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Defendants' 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).

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

76. Upon information and belief, the label for Defendants' 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

Defendants' ANDA will encourage such third parties to infringe one or more of the claims of the '204 patent.

77. Upon information and belief, the use of Defendants' 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 Defendants' ANDA Products will constitute an act of direct infringement of one or more of the claims of the '204 patent.

78. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendants' ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants 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.

79. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their 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.

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

the infringement of the ’204 patent by third parties because: (i) Defendants’ ANDA Products constitute a material part of the formulations claimed in the ’204 patent; (ii) Defendants know or should know that Defendants’ ANDA Products will be made for uses that directly infringe the formulations claimed in the ’204 patent; and (iii) Defendants’ ANDA Products are not staple articles or commodities of commerce suitable for substantial noninfringing uses.

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

82. Upon information and belief, the actions described herein relating to Defendants’ ANDA and Defendants’ ANDA Products were done by and for the benefit of all Defendants.

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

84. Unless Defendants are 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
(Defendants' Infringement of the '853 Patent)

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

86. Upon information and belief, Defendants submitted Defendants' 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 Defendants' ANDA Products prior to the expiration of the '853 patent.

87. Upon information and belief, Macleods USA provided, is providing, and will provide material and significant support, advice, aid, instruction, inducement, and encouragement to Macleods Ltd. in the preparation, filing, maintenance, and further prosecution of Defendants' ANDA.

88. Upon information and belief, Macleods Ltd. provided, is providing, and will provide material and significant support, advice, aid, instruction, inducement, and encouragement to Macleods USA in the preparation, filing, maintenance, and further prosecution of Defendants' ANDA.

89. Upon information and belief, Defendants are jointly and severally liable for Defendants' infringement of one or more claims of the '853 patent.

90. Upon information and belief, Defendants submitted Defendants' 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 Defendants' ANDA Products before the expiration of the '853 patent.

91. Upon information and belief, as of the date of the Notice Letter, Defendants were 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).

92. Defendants 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).

93. Under 35 U.S.C. § 271(e)(2)(A), the submission of Defendants' 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 Defendants' ANDA Products before the expiration of the '853 patent is itself an act of infringement of the '853 patent.

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

95. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' 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).

96. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Defendants' 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).

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

98. Upon information and belief, the label for Defendants' 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

Defendants' ANDA will encourage such third parties to perform one or more of the methods claimed in the '853 patent.

99. Upon information and belief, the use of Defendants' 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 Defendants' ANDA Products will constitute an act of direct infringement of one or more of the methods claimed in the '853 patent.

100. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendants' ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants 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.

101. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their 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.

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

the infringement of the ’853 patent by third parties because: (i) Defendants’ ANDA Products constitute a material part of the methods of treatment claimed in the ’853 patent; (ii) Defendants know or should know that Defendants’ ANDA Products will be made for uses that directly infringe the methods of treatment claimed in the ’853 patent; and (iii) Defendants’ ANDA Products are not staple articles or commodities of commerce suitable for substantial noninfringing uses.

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

104. Upon information and belief, the actions described herein relating to Defendants’ ANDA and Defendants’ ANDA Products were done by and for the benefit of all Defendants.

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

106. Unless Defendants are 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
(Defendants' Infringement of the '338 Patent)

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

108. Upon information and belief, Defendants submitted Defendants' 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 Defendants' ANDA Products prior to the expiration of the '338 patent.

109. Upon information and belief, Macleods USA provided, is providing, and will provide material and significant support, advice, aid, instruction, inducement, and encouragement to Macleods Ltd. in the preparation, filing, maintenance, and further prosecution of Defendants' ANDA.

110. Upon information and belief, Macleods Ltd. provided, is providing, and will provide material and significant support, advice, aid, instruction, inducement, and encouragement to Macleods USA in the preparation, filing, maintenance, and further prosecution of Defendants' ANDA.

111. Upon information and belief, Defendants are jointly and severally liable for Defendants' infringement of one or more claims of the '338 patent.

112. Upon information and belief, Defendants submitted Defendants' 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 Defendants' ANDA Products before the expiration of the '338 patent.

113. Upon information and belief, as of the date of the Notice Letter, Defendants were 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).

114. Defendants 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).

115. Under 35 U.S.C. § 271(e)(2)(A), the submission of Defendants' 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 Defendants' ANDA Products before the expiration of the '338 patent is itself an act of infringement of the '338 patent.

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

117. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' 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).

118. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Defendants' 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).

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

120. Upon information and belief, the label for Defendants' 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

Defendants' ANDA will encourage such third parties to infringe one or more of the claims of the '338 patent.

121. Upon information and belief, the use of Defendants' 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 Defendants' ANDA Products will constitute an act of direct infringement of one or more of the claims of the '338 patent.

122. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendants' ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants 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.

123. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their 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.

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

the infringement of the ’338 patent by third parties because: (i) Defendants’ ANDA Products constitute a material part of the formulations claimed in the ’338 patent; (ii) Defendants know or should know that Defendants’ ANDA Products will be made for uses that directly infringe the formulations claimed in the ’338 patent; and (iii) Defendants’ ANDA Products are not staple articles or commodities of commerce suitable for substantial noninfringing uses.

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

126. Upon information and belief, the actions described herein relating to Defendants’ ANDA and Defendants’ ANDA Products were done by and for the benefit of all Defendants.

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

128. Unless Defendants are 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
(Defendants' Infringement of the '753 Patent)

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

130. Upon information and belief, Defendants submitted Defendants' 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 Defendants' ANDA Products prior to the expiration of the '753 patent.

131. Upon information and belief, Macleods USA provided, is providing, and will provide material and significant support, advice, aid, instruction, inducement, and encouragement to Macleods Ltd. in the preparation, filing, maintenance, and further prosecution of Defendants' ANDA.

132. Upon information and belief, Macleods Ltd. provided, is providing, and will provide material and significant support, advice, aid, instruction, inducement, and encouragement to Macleods USA in the preparation, filing, maintenance, and further prosecution of Defendants' ANDA.

133. Upon information and belief, Defendants are jointly and severally liable for Defendants' infringement of one or more claims of the '753 patent.

134. Upon information and belief, Defendants submitted Defendants' 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 Defendants' ANDA Products before the expiration of the '753 patent.

135. Upon information and belief, as of the date of the Notice Letter, Defendants were 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).

136. Defendants 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).

137. Under 35 U.S.C. § 271(e)(2)(A), the submission of Defendants' 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 Defendants' ANDA Products before the expiration of the '753 patent is itself an act of infringement of the '753 patent.

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

139. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' 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).

140. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Defendants' 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).

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

142. Upon information and belief, the label for Defendants' 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

Defendants' ANDA will encourage such third parties to perform one or more of the methods claimed in the '753 patent.

143. Upon information and belief, the use of Defendants' 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 Defendants' ANDA Products will constitute an act of direct infringement of one or more of the methods claimed in the '753 patent.

144. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendants' ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants 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.

145. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their 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.

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

the infringement of the ’753 patent by third parties because: (i) Defendants’ ANDA Products constitute a material part of the methods claimed in the ’753 patent; (ii) Defendants know or should know that Defendants’ ANDA Products will be made for uses that directly infringe the methods claimed in the ’753 patent; and (iii) Defendants’ ANDA Products are not staple articles or commodities of commerce suitable for substantial noninfringing uses.

147. Upon information and belief, Defendants have acted with full knowledge of the ’753 patent and its claims and without a reasonable basis for believing that Defendants would not be liable for infringement of the ’753 patent. Defendants knew of the existence of the ’753 patent, as evidenced by Defendants’ filing of Defendants’ ANDA with a paragraph IV certification specifically referencing the ’753 patent. Notwithstanding this knowledge, Defendants have continued to signal their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Defendants’ ANDA Products before the expiration of the patents-in-suit. Upon information and belief, through such activities, Defendants specifically intend infringement of the ’753 patent.

148. Upon information and belief, the actions described herein relating to Defendants’ ANDA and Defendants’ ANDA Products were done by and for the benefit of all Defendants.

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

150. Unless Defendants are 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
(Defendants' Infringement of the '143 Patent)

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

152. Upon information and belief, Defendants submitted Defendants' 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 Defendants' ANDA Products prior to the expiration of the '143 patent.

153. Upon information and belief, Macleods USA provided, is providing, and will provide material and significant support, advice, aid, instruction, inducement, and encouragement to Macleods Ltd. in the preparation, filing, maintenance, and further prosecution of Defendants' ANDA.

154. Upon information and belief, Macleods Ltd. provided, is providing, and will provide material and significant support, advice, aid, instruction, inducement, and encouragement to Macleods USA in the preparation, filing, maintenance, and further prosecution of Defendants' ANDA.

155. Upon information and belief, Defendants are jointly and severally liable for Defendants' infringement of one or more claims of the '143 patent.

156. Upon information and belief, Defendants submitted Defendants' 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 Defendants' ANDA Products before the expiration of the '143 patent.

157. Upon information and belief, as of the date of the Notice Letter, Defendants were 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).

158. Defendants 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).

159. Under 35 U.S.C. § 271(e)(2)(A), the submission of Defendants' 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 Defendants' ANDA Products before the expiration of the '143 patent is itself an act of infringement of the '143 patent.

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

161. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' 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).

162. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Defendants' 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).

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

164. Upon information and belief, the label for Defendants' 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

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

165. Upon information and belief, the use of Defendants' 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 Defendants' ANDA Products will constitute an act of direct infringement of one or more of the methods claimed in the '143 patent.

166. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendants' ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants 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.

167. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their 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.

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

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

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

170. Upon information and belief, the actions described herein relating to Defendants’ ANDA and Defendants’ ANDA Products were done by and for the benefit of all Defendants.

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

172. Unless Defendants are 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
(Defendants' Infringement of the '523 Patent)

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

174. Upon information and belief, Defendants submitted Defendants' 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 Defendants' ANDA Products prior to the expiration of the '523 patent.

175. Upon information and belief, Macleods USA provided, is providing, and will provide material and significant support, advice, aid, instruction, inducement, and encouragement to Macleods Ltd. in the preparation, filing, maintenance, and further prosecution of Defendants' ANDA.

176. Upon information and belief, Macleods Ltd. provided, is providing, and will provide material and significant support, advice, aid, instruction, inducement, and encouragement to Macleods USA in the preparation, filing, maintenance, and further prosecution of Defendants' ANDA.

177. Upon information and belief, Defendants are jointly and severally liable for Defendants' infringement of one or more claims of the '523 patent.

178. Upon information and belief, Defendants submitted Defendants' 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 Defendants' ANDA Products before the expiration of the '523 patent.

179. Upon information and belief, as of the date of the Notice Letter, Defendants were 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).

180. Defendants 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).

181. Under 35 U.S.C. § 271(e)(2)(A), the submission of Defendants' 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 Defendants' ANDA Products before the expiration of the '523 patent is itself an act of infringement of the '523 patent.

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

183. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' 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).

184. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Defendants' 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).

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

186. Upon information and belief, the label for Defendants' 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

Defendants' ANDA will encourage such third parties to perform one or more of the methods claimed in the '523 patent.

187. Upon information and belief, the use of Defendants' 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 Defendants' ANDA Products will constitute an act of direct infringement of one or more of the methods claimed in the '523 patent.

188. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendants' ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants 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.

189. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their 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.

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

the infringement of the ’523 patent by third parties because: (i) Defendants’ ANDA Products constitute a material part of the methods of treatment claimed in the ’523 patent; (ii) Defendants know or should know that Defendants’ ANDA Products will be made for uses that directly infringe the methods of treatment claimed in the ’523 patent; and (iii) Defendants’ ANDA Products are not staple articles or commodities of commerce suitable for substantial noninfringing uses.

191. Upon information and belief, Defendants have acted with full knowledge of the ’523 patent and its claims and without a reasonable basis for believing that Defendants would not be liable for infringement of the ’523 patent. Defendants knew of the existence of the ’523 patent, as evidenced by Defendants’ filing of Defendants’ ANDA with a paragraph IV certification specifically referencing the ’523 patent. Notwithstanding this knowledge, Defendants have continued to signal their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Defendants’ ANDA Products before the expiration of the patents-in-suit. Upon information and belief, through such activities, Defendants specifically intend infringement of the ’523 patent.

192. Upon information and belief, the actions described herein relating to Defendants’ ANDA and Defendants’ ANDA Products were done by and for the benefit of all Defendants.

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

194. Unless Defendants are 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.

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 Defendants' 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 Defendants' ANDA Products was an act of infringement of the patents-in-suit by Defendants;

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

vi. A Judgment, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, awarding Supernus damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or

sell within the United States, and/or import into the United States, any product that is the subject of Defendants' ANDA 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 Defendants' 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.

Dated: September 15, 2025

By: s/ *Francis DiGiovanni*

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