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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC., Plaintiff, v. MACLEODS PHARMACEUTICALS LTD. and MACLEODS PHARMA USA, INC., Defendants.	Honorable Michael E. Farbiarz, U.S.D.J. Civil Action No. 25 CV 15399 (MEF)(MAH) **DEFENDANTS MACLEODS PHARMACEUTICALS LTD. AND MACLEODS PHARMA USA, INC.'S ANSWER TO THE COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendants Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. ("Macleods" or "Defendants"), by their undersigned attorneys, for their Answer to the Complaint for Patent Infringement filed by Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff"), state as follows. Pursuant to Fed R. Civ. P. 8(b)(3), Macleods denies all allegations in Plaintiff's Complaint except those expressly admitted below.

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").

ANSWER: Paragraph 1 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods admits that Plaintiff's Complaint purports to assert an action for patent infringement based on Macleods' filing of an Abbreviated New Drug Application ("ANDA") seeking approval from the U.S. Food and Drug Administration ("FDA") to commercially market a generic version of Qelbree® prior to the expiration of U.S. Patent Nos. 9,358,204, 9,603,853, 9,662,338, 11,324,753, 11,458,143, and 12,121,523. Macleods is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of Paragraph 1 of the Complaint and therefore denies them.

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.

ANSWER: Macleods is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 2 of the Complaint and, therefore, denies all allegations.

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.

ANSWER: Admitted.

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.

ANSWER: Admitted.

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

ANSWER: Admitted.

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).

ANSWER: Macleods admits that the following language appears on its website: "The formation of Macleods Pharma USA, Inc. in 2011, marked the commencement of our pharmaceutical business operations in the United States." Macleods denies all remaining allegations of Paragraph 6.

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 New Jersey), and importing generic pharmaceutical products into the United States (including into the State of New Jersey).

ANSWER: Macleods admits that Macleods USA is a generic pharmaceutical company. Macleods denies all remaining allegations of Paragraph 7.

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 New Jersey.

ANSWER: Macleods admits that Macleods USA is a generic pharmaceutical company. Macleods denies all remaining allegations of Paragraph 8.

9. Upon information and belief, Macleods USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0101021236.

ANSWER: Admitted.

10. Upon information and belief, Macleods USA is registered with the State of New Jersey's Department of Health as a drug and medical device "manufacturer and wholesaler" with Registration Number 5004370.

ANSWER: Admitted.

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

ANSWER: Admitted.

12. 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.

ANSWER: Macleods admits that Macleods USA is a subsidiary of Macleods Ltd. Macleods denies all remaining allegations of Paragraph 12.

13. 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.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required, and on that basis, Macleods denies the allegations of Paragraph 13.

14. 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 New Jersey), and importing generic pharmaceutical products into the United States (including into the State of New Jersey).

ANSWER: Macleods admit that Macleods Ltd. and Macleods USA are generic pharmaceutical companies. Macleods denies all remaining allegations of Paragraph 14.

15. 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").

ANSWER: Admitted.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required, and on that basis, Macleods denies the allegations of Paragraph 16.

17. This Court has personal jurisdiction over Defendants under: (i) Fed. R. Civ. P. 4(k)(1) and N.J. Ct. R. 4:4-4; and/or (ii) Fed. R. Civ. P. 4(k)(2).

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer may be required, and solely to conserve the resources of the parties and the Court, Macleods does not contest personal jurisdiction solely for the limited purpose of this action only. Macleods denies all remaining allegations of Paragraph 17.

18. This Court has personal jurisdiction over Macleods USA at least because, upon information and belief: (i) Macleods USA maintains a principal place of business in New Jersey located at 500 College Road East, STE 250, Princeton, NJ 08540; (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 New Jersey and/or derives substantial revenue from goods or services used or consumed in New Jersey 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 New Jersey; (iv) Macleods USA has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (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 New Jersey's Department of Health as a drug and medical device "manufacturer and wholesaler" with Registration Number 5004370; (vii) Macleods USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0101021236; (viii) Macleods USA, itself and through related entities and agents, has purposefully availed itself of the rights, benefits, and privileges of New Jersey'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 New Jersey; (ix) 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; (x) Macleods USA, itself and through related entities and agents, has committed, induced, and/or contributed to acts of patent infringement in New Jersey; and (xi) if Defendants' ANDA receives final approval, Defendants' ANDA Products will be marketed and distributed by Macleods USA in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Macleods does not contest personal jurisdiction solely for the limited purpose of this action only. Macleods denies all remaining allegations of Paragraph 18.

19. 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 New Jersey 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 New Jersey; (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 New Jersey and/or derives substantial revenue from goods or services used or consumed in New Jersey (*see* https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/macleodspharmaceuticals-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 New Jersey; (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, has committed, induced, and/or contributed to acts of patent infringement in New Jersey; and (vii) if Defendants' ANDA receives final approval, Defendants'

ANDA Products will be marketed and distributed by Macleods Ltd. in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Macleods does not contest personal jurisdiction solely for the limited purpose of this action only. Macleods denies all remaining allegations of Paragraph 19.

20. 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.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Macleods does not contest personal jurisdiction solely for the limited purpose of this action only. Macleods denies all remaining allegations of Paragraph 20.

21. 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.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Macleods does not contest personal jurisdiction solely for the limited purpose of this action only. Macleods denies all remaining allegations of Paragraph 21.

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

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Macleods does not contest personal jurisdiction solely for the limited purpose of this action only. Macleods denies all remaining allegations of Paragraph 22.

23. 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 New Jersey, prescribed by physicians practicing in New Jersey, and/or administered to patients in New Jersey.

ANSWER: Paragraph 23 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Macleods does not contest personal jurisdiction solely for the limited purpose of this action only. Macleods denies all remaining allegations of Paragraph 23.

24. 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 New Jersey.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Macleods does not contest personal jurisdiction solely for the limited purpose of this action only. Macleods denies all remaining allegations of Paragraph 24.

25. 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.

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Macleods does not contest personal jurisdiction solely for the limited purpose of this action only. Macleods denies all remaining allegations of Paragraph 25.

26. 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.

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Macleods does not contest personal jurisdiction solely for the limited purpose of this action only. Macleods denies all remaining allegations of Paragraph 26.

27. 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.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Macleods does not contest personal jurisdiction solely for the limited purpose of this action only. Macleods denies all remaining allegations of Paragraph 27.

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

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Macleods does not contest the propriety of venue in this District. Macleods denies all remaining allegations of Paragraph 28.

FACTS COMMON TO ALL COUNTS

29. 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.

ANSWER: Macleods admits that on or about August 1, 2025, it sent Supernus a Notice of Certification under 21 U.S.C. § 355(j)(2)(B) of the Federal Food, Drug & Cosmetic Act, and under 21 C.F.R. § 314.95. Macleods denies all remaining allegations of Paragraph 29.

30. 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).

ANSWER: Macleods admits that its Notice Letter speaks for itself. Macleods denies all remaining allegations of Paragraph 30.

31. 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.

ANSWER: Macleods admits that its Notice Letter speaks for itself. Macleods denies all remaining allegations of Paragraph 31.

32. 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.

ANSWER: Macleods admits that its Notice Letter speaks for itself. Macleods denies all remaining allegations of Paragraph 32.

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

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

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Macleods does not contest personal jurisdiction solely for the limited purpose of this action only. Macleods denies all remaining allegations of Paragraph 33.

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

ANSWER: Denied.

35. 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 New Jersey.

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Macleods does not contest personal jurisdiction solely for the limited purpose of this action only. Macleods denies all remaining allegations of Paragraph 35.

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

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court,

Macleods does not contest personal jurisdiction solely for the limited purpose of this action only. Macleods denies all remaining allegations of Paragraph 36.

37. 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).

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) limit the defenses that may be presented in litigation. Macleods denies all remaining allegations of Paragraph 37.

38. 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).

ANSWER: Paragraph 38 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) limit the defenses that may be presented in litigation. Macleods denies all remaining allegations of Paragraph 38.

39. 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.

ANSWER: Paragraph 39 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies the allegations of Paragraph 39.

40. 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.

ANSWER: Paragraph 40 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies the allegations of Paragraph 40.

41. 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.

ANSWER: Paragraph 41 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies the allegations of Paragraph 41.

42. 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.

ANSWER: Upon information and belief, Macleods admits that Supernus is identified by the electronic version of the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book") as the holder of New Drug Application ("NDA") No. 211964 by which the FDA granted approval for the manufacture and sale of viloxazine extended-release capsules 100 mg, 150 mg and 200 mg.

43. 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.

ANSWER: Macleods admits that the FDA-approved labeling for Qelbree® states the full and complete FDA-approved indications of Qelbree® and that the labeling speaks for itself. Macleods denies all remaining allegations of Paragraph 43.

44. 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

ANSWER: Macleods admits that the FDA-approved labeling for Qelbree® states the full and complete FDA-approved indications of Qelbree® and that the labeling speaks for itself. Macleods denies all remaining allegations of Paragraph 44.

45. 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®.

ANSWER: Upon information and belief, Macleods admits that FDA's Orange Book lists the patents-in-suit as covering Supernus's Qelbree®. Macleods lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 45 and, therefore, denies those allegations.

46. 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.

ANSWER: Paragraph 46 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods admits that the '204 patent is entitled "Formulations of Viloxazine"; and that according to the electronic assignment database of the USPTO website, Supernus is identified as the assignee of the '204 patent. Macleods denies that the '204 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 46.

47. 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.

ANSWER: Paragraph 47 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods admits that the ‘853 patent is entitled “Formulations of Viloxazine”; and that according to the electronic assignment database of the USPTO website, Supernus is identified as the assignee of the ‘853 patent. Macleods denies that the ‘853 patent was “duly and lawfully issued,” and further denies any remaining allegations of Paragraph 47.

48. 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.

ANSWER: Paragraph 48 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods admits that the ‘338 patent is entitled “Formulations of Viloxazine”; and that according to the electronic assignment database of the USPTO website, Supernus is identified as the assignee of the ‘338 patent. Macleods denies that the ‘338 patent was “duly and lawfully issued,” and further denies any remaining allegations of Paragraph 48.

49. 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.

ANSWER: Paragraph 49 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods admits that the ‘753 patent is entitled “Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)”; and that according to the

electronic assignment database of the USPTO website, Supernus is identified as the assignee of the '753 patent. Macleods denies that the '753 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 49.

50. 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.

ANSWER: Paragraph 50 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods admits that the '143 patent is entitled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)"; and that according to the electronic assignment database of the USPTO website, Supernus is identified as the assignee of the '143 patent. Macleods denies that the '143 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 50.

51. 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.

ANSWER: Paragraph 51 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods admits that the '523 patent is entitled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)"; and that according to the electronic assignment database of the USPTO website, Supernus is identified as the assignee of the '523 patent. Macleods denies that the '523 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 51.

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

ANSWER: Macleods admits that the Macleods ANDA references Qelbree® (viloxazine extended-release capsules) as the reference listed drug. Macleods denies any remaining allegations of Paragraph 52.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

55. 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."

ANSWER: Paragraph 55 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods admits that 21 U.S.C. § 355(j)(2)(A)(i) and (v) speak for themselves. Macleods denies all remaining allegations of Paragraph 55.

56. 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).

ANSWER: Paragraph 56 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies the allegations of Paragraph 56.

57. 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."

ANSWER: Macleods admits that its proposed prescribing information speaks for itself. Macleods denies all remaining allegations of Paragraph 57.

58. 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.

ANSWER: Macleods admits that its proposed prescribing information speaks for itself. Macleods denies all remaining allegations of Paragraph 58.

59. 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."

ANSWER: Macleods admits that its proposed prescribing information speaks for itself. Macleods denies all remaining allegations of Paragraph 59.

60. 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)."

ANSWER: Macleods admits that its proposed prescribing information speaks for itself. Macleods denies all remaining allegations of Paragraph 60.

61. 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."

ANSWER: Macleods admits that its proposed labeling speaks for itself. Macleods denies all remaining allegations of Paragraph 61.

62. 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.

ANSWER: Paragraph 62 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Macleods does not contest personal jurisdiction solely for the limited purpose of this action only. Macleods denies all remaining allegations of Paragraph 62.

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

ANSWER: Paragraph 63 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies the allegations of Paragraph 63.

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

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

ANSWER: Macleods incorporates its answers to the preceding paragraphs as if fully set forth herein.

65. 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.

ANSWER: Denied.

66. 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.

ANSWER: Denied.

67. 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.

ANSWER: Denied.

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

ANSWER: Denied.

69. 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.

ANSWER: Denied.

70. 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).

ANSWER: Paragraph 70 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) limit the defenses that may be presented in litigation. Macleods denies all remaining allegations of Paragraph 70.

71. 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).

ANSWER: Paragraph 71 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) limit the defenses that may be presented in litigation. Macleods denies all remaining allegations of Paragraph 71.

72. 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.

ANSWER: Denied.

73. 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.

ANSWER: Denied

74. 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).

ANSWER: Denied.

75. 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).

ANSWER: Denied.

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

ANSWER: Denied.

77. 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.

ANSWER: Denied.

78. 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.

ANSWER: Denied.

79. 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.

ANSWER: Denied.

80. 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.

ANSWER: Denied.

81. 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.

ANSWER: Denied.

82. 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.

ANSWER: Denied.

83. 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.

ANSWER: Denied.

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

ANSWER: Denied.

85. 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.

ANSWER: Denied.

SECOND COUNT
(Defendants' Infringement of the '853 Patent)

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

ANSWER: Macleods incorporates its answers to the preceding paragraphs as if fully set forth herein.

87. 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.

ANSWER: Denied.

88. 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.

ANSWER: Denied.

89. 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.

ANSWER: Denied.

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

ANSWER: Denied.

91. 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.

ANSWER: Denied.

92. 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).

ANSWER: Paragraph 92 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) limit the defenses that may be presented in litigation. Macleods denies all remaining allegations of Paragraph 92.

93. 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).

ANSWER: Paragraph 93 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) limit the defenses that may be presented in litigation. Macleods denies all remaining allegations of Paragraph 93.

94. 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.

ANSWER: Denied.

95. 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.

ANSWER: Denied.

96. 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).

ANSWER: Denied.

97. 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).

ANSWER: Denied.

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

ANSWER: Denied.

99. 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.

ANSWER: Denied.

100. 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.

ANSWER: Denied.

101. 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.

ANSWER: Denied.

102. 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.

ANSWER: Denied.

103. 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.

ANSWER: Denied.

104. 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.

ANSWER: Denied.

105. 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.

ANSWER: Denied.

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

ANSWER: Denied.

107. 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.

ANSWER: Denied.

THIRD COUNT
(Defendants' Infringement of the '338 Patent)

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

ANSWER: Macleods incorporates its answers to the preceding paragraphs as if fully set forth herein.

109. 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.

ANSWER: Denied.

110. 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.

ANSWER: Denied.

111. 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.

ANSWER: Denied.

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

ANSWER: Denied.

113. 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.

ANSWER: Denied.

114. 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).

ANSWER: Paragraph 114 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) limit the defenses that may be presented in litigation. Macleods denies all remaining allegations of Paragraph 114.

115. 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).

ANSWER: Paragraph 115 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) limit the defenses that may be presented in litigation. Macleods denies all remaining allegations of Paragraph 115.

116. 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.

ANSWER: Denied.

117. 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.

ANSWER: Denied.

118. 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).

ANSWER: Denied.

119. 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).

ANSWER: Denied.

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

ANSWER: Denied.

121. 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.

ANSWER: Denied.

122. 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.

ANSWER: Denied.

123. 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.

ANSWER: Denied.

124. 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.

ANSWER: Denied.

125. 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.

ANSWER: Denied.

126. 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.

ANSWER: Denied.

127. 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.

ANSWER: Denied.

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

ANSWER: Denied.

129. 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.

ANSWER: Denied.

FOURTH COUNT
(Defendants' Infringement of the '753 Patent)

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

ANSWER: Macleods incorporates its answers to the preceding paragraphs as if full set forth herein.

131. 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.

ANSWER: Denied.

132. 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.

ANSWER: Denied.

133. 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.

ANSWER: Denied.

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

ANSWER: Denied.

135. 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.

ANSWER: Denied.

136. 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).

ANSWER: Paragraph 136 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) limit the defenses that may be presented in litigation. Macleods denies all remaining allegations of Paragraph 136.

137. 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).

ANSWER: Paragraph 137 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) limit the defenses that may be presented in litigation. Macleods denies all remaining allegations of Paragraph 137.

138. 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.

ANSWER: Denied.

139. 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.

ANSWER: Denied.

140. 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).

ANSWER: Denied.

141. 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).

ANSWER: Denied.

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

ANSWER: Denied.

143. 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.

ANSWER: Denied.

144. 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.

ANSWER: Denied.

145. 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.

ANSWER: Denied.

146. 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.

ANSWER: Denied.

147. 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.

ANSWER: Denied.

148. 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.

ANSWER: Denied

149. 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.

ANSWER: Denied.

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

ANSWER: Denied.

151. 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.

ANSWER: Denied.

FIFTH COUNT
(Defendants' Infringement of the '143 Patent)

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

ANSWER: Macleods incorporates by reference the preceding paragraphs as if fully set forth herein.

153. 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.

ANSWER: Denied.

154. 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.

ANSWER: Denied.

155. 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.

ANSWER: Denied.

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

ANSWER: Denied.

157. 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.

ANSWER: Denied.

158. 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).

ANSWER: Paragraph 158 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) limit the defenses that may be presented in litigation. Macleods denies all remaining allegations of Paragraph 158.

159. 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).

ANSWER: Paragraph 159 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21

C.F.R. § 314.95(c)(7) limit the defenses that may be presented in litigation. Macleods denies all remaining allegations of Paragraph 159.

160. 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.

ANSWER: Denied.

161. 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.

ANSWER: Denied.

162. 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).

ANSWER: Denied.

163. 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).

ANSWER: Denied.

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

ANSWER: Denied.

165. 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.

ANSWER: Denied.

166. 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.

ANSWER: Denied.

167. 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.

ANSWER: Denied.

168. 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.

ANSWER: Denied.

169. 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.

ANSWER: Denied.

170. 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.

ANSWER: Denied.

171. 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.

ANSWER: Denied.

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

ANSWER:

173. 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.

ANSWER: Denied.

SIXTH COUNT
(Defendants' Infringement of the '523 Patent)

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

ANSWER: Macleods incorporates by reference the preceding paragraphs as if fully set forth herein.

175. 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.

ANSWER: Denied.

176. 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.

ANSWER: Denied.

177. 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.

ANSWER: Denied.

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

ANSWER: Denied.

179. 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.

ANSWER: Denied.

180. 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).

ANSWER: Paragraph 180 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) limit the defenses that may be presented in litigation. Macleods denies all remaining allegations of Paragraph 180.

181. 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).

ANSWER: Paragraph 181 contains legal conclusions to which no answer is required. To the extent an answer is required, Macleods denies that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) limit the defenses that may be presented in litigation. Macleods denies all remaining allegations of Paragraph 181.

182. 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.

ANSWER: Denied.

183. 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.

ANSWER: Denied.

184. 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).

ANSWER: Denied.

185. 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).

ANSWER: Denied.

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

ANSWER: Denied.

187. 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.

ANSWER: Denied.

188. 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.

ANSWER: Denied.

189. 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.

ANSWER: Denied.

190. 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.

ANSWER: Denied.

191. 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.

ANSWER: Denied.

192. 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.

ANSWER: Denied.

193. 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.

ANSWER: Denied.

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

ANSWER: Denied.

195. 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.

ANSWER: Denied.

GENERAL DENIAL AND RESPONSE TO PRAYER FOR RELIEF

To the extent not specifically admitted above, Macleods hereby denies all allegations in the Complaint. Macleods further denies that Plaintiff is entitled to any relief whatsoever. Macleods denies that Plaintiff is entitled to the judgment or other relief prayed for in Paragraphs i-ix of the Complaint under the heading Prayer for Relief.

MACLEODS'S DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiff, Macleods avers and asserts the following separate defenses to the Complaint:

FIRST SEPARATE DEFENSE
(INVALIDITY OF THE '204 PATENT)

One or more claims of the '204 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '204 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220570 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '204 Patent.

THIRD SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '204 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220570 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '204 Patent.

FOURTH SEPARATE DEFENSE
(INVALIDITY OF THE '853 PATENT)

One or more claims of the '853 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FIFTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '853 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220570 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '853 Patent.

SIXTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '853 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220570 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '853 Patent.

SEVENTH SEPARATE DEFENSE
(INVALIDITY OF THE '338 PATENT)

One or more claims of the '338 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

EIGHTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '338 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220570 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '338 Patent.

NINTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '338 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220570 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '338 Patent.

TENTH SEPARATE DEFENSE
(INVALIDITY OF THE '753 PATENT)

One or more claims of the '753 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

ELEVENTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '753 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220570 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '753 Patent.

TWELFTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '753 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220570 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '753 Patent.

THIRTEENTH SEPARATE DEFENSE
(INVALIDITY OF THE '143 PATENT)

One or more claims of the '143 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FOURTEENTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '143 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220570 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '143 Patent.

FIFTEENTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '143 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220570 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '143 Patent.

SIXTEENTH SEPARATE DEFENSE
(INVALIDITY OF THE '523 PATENT)

One or more claims of the '523 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SEVENTEENTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '523 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220570 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '523 Patent.

EIGHTEENTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '523 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220570 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '523 Patent.

NINETEENTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiff's Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

TWENTIETH SEPARATE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

Plaintiff's Complaint lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), and/or (c).

TWENTY-FIRST SEPARATE DEFENSE
(PROSECUTION HISTORY ESTOPPEL)

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the '204, '853, '338, '753, '143, and '523 patents, Plaintiff is estopped from maintaining that any valid or enforceable claim of the '204, '853, '338, '753, '143, and '523 patents is infringed by the product that is the subject of ANDA No. 220570.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Macleods reserves the right to plead additional separate defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

MACLEODS' COUNTERCLAIMS

For its counterclaims against Counterclaim-Defendant Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff"), Counterclaim-Plaintiffs Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (collectively, "Macleods" or "Counterclaim-Plaintiffs"), state as follows:

THE PARTIES

1. On information and belief, Counterclaim-Defendant Supernus is a corporation organized and existing under the laws of Delaware, with its principal place of business at 9715 Key West Avenue, Rockville, Maryland 20850.

2. Counterclaim-Plaintiff Macleods Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at Atlanta Arcade, Marol Church Rd., Andheri (East), Mumbai, 400059, India

3. Counterclaim-Plaintiff Macleods Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 500 College Road East, Suite 250, Princeton, NJ 08540.

NATURE OF THE ACTION

4. Macleods seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, that 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"), (collectively, the "Patents-In-Suit") are invalid and/or not infringed.

JURISDICTION AND VENUE

5. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Plaintiff because, among other reasons, Plaintiff subjected itself to the jurisdiction of this Court by filing its complaint here.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b), and by Plaintiffs' choice of forum.

8. There is an actual and justiciable controversy between the parties as to the infringement and invalidity of the Patents-in-Suit.

BACKGROUND

A. FDA Approval of New Brand Name Drugs

9. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

10. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

11. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b)(1), (c)(2).

12. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 C.F.R. § 314.53(e).

13. FDA's duties with respect to the Orange Book are purely ministerial. If the NDA holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

B. FDA Approval of New Generic Drugs

14. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

15. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

16. Among other things, an ANDA must also contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

17. A "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

18. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of each of its paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

19. Upon receiving notice of the paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

20. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the paragraph IV certifications because doing so, regardless of merit, prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions requiring court actions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

21. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the proposed product in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

C. Macleods' ANDA and Plaintiffs' Complaint

22. Macleods submitted Abbreviated New Drug Application ("ANDA") No. 220570 ("Macleods' ANDA") to obtain FDA approval to engage in the commercial manufacture, use, and sale of generic viloxazine tablets, 150 mg and 200 mg ("Macleods' ANDA Product").

23. On information and belief, Plaintiff holds approved New Drug Application ("NDA") No. 211964 for Qelbree® under Section 505(b) of the Federal Food Drug and Cosmetic Act ("FFDCA").

24. Macleods' ANDA shows that Macleods' ANDA Product are bioequivalent to the products that are the subject of NDA No. 211964.

25. On information and belief, Plaintiff caused the Patents-in-Suit to be listed in the publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly called the "Orange Book," as patents that purportedly claim the drug listed in, and/or purportedly claim a method of using the drug for which Plaintiff submitted, NDA No. 211964.

26. The '204 patent is entitled "Formulations of Viloxazine"; the issue date identified on the cover of the '204 patent is June 7, 2016; and Plaintiff is identified as the assignee of the '204 patent.

27. The '853 patent is entitled "Formulations of Viloxazine"; the issue date identified on the cover of the '853 patent is March 28, 2017; and Plaintiff is identified as the assignees of the '853 patent.

28. The '338 patent is entitled "Formulations of Viloxazine"; the issue date identified on the cover of the '338 patent May 30, 2017; and Plaintiff is identified as the assignees of the '338 patent.

29. The '753 patent is entitled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)"; the issue date identified on the cover of the '753 patent

is May 10, 2022; and Plaintiff is identified as the assignee of the '753 patent.

30. The '143 patent is entitled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)"; the issue date identified on the cover of the '143 patent is October 4, 2022; and Plaintiff is identified as the assignee of the '143 patent.

31. The '523 patent is entitled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)"; the issue date identified on the cover of the '523 patent is October 22, 2024; and Plaintiff is identified as the assignee of the '523 patent.

32. Macleods' ANDA contains "Paragraph IV" certifications under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Macleods' ANDA Product.

33. On August 1, 2025 Macleods sent Plaintiff written notice of Macleods' Paragraph IV Certifications ("Macleods' Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Macleods' Notice Letter asserted that the claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by Macleods' ANDA or the products or activities described therein.

COUNT I: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '204 PATENT

34. Macleods incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

35. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Macleods regarding whether the filing of Macleods' ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Macleods' ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '204 patent.

36. Macleods incorporates by reference Macleods' Notice Letter, which contains exemplary and nonlimiting explanations that the '204 patent is not infringed by Macleods' ANDA

or the products or activities described therein.

37. Macleods is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '204 patent and is not liable for such infringement.

COUNT II: DECLARATORY JUDGMENT OF INVALIDITY OF THE '204 PATENT

38. Macleods incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

39. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Macleods regarding whether the claims of the '204 patent are invalid.

40. Macleods incorporates by reference Macleods' Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '204 patent are invalid.

41. Macleods is entitled to a declaration that all claims of the '204 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT III: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '853 PATENT

42. Macleods incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

43. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Macleods regarding whether the filing of Macleods' ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Macleods' ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '853 patent.

44. Macleods incorporates by reference Macleods' Notice Letter, which contains exemplary and nonlimiting explanations that the '853 patent is not infringed by Macleods' ANDA

or the products or activities described therein.

45. Macleods is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '853 patent and is not liable for such infringement.

COUNT IV: DECLARATORY JUDGMENT OF INVALIDITY OF THE '853 PATENT

46. Macleods incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

47. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Macleods regarding whether the claims of the '853 patent are invalid.

48. Macleods incorporates by reference Macleods' Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '853 patent are invalid.

49. Macleods is entitled to a declaration that all claims of the '853 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT V: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '338 PATENT

50. Macleods incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

51. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Macleods regarding whether the filing of Macleods' ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Macleods' ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '338 patent.

52. Macleods incorporates by reference Macleods' Notice Letter, which contains exemplary and nonlimiting explanations that the '338 patent is not infringed by Macleods' ANDA

or the products or activities described therein.

53. Macleods is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '338 patent and is not liable for such infringement.

COUNT VI: DECLARATORY JUDGMENT OF INVALIDITY OF THE '338 PATENT

54. Macleods incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

55. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Macleods regarding whether the claims of the '338 patent are invalid.

56. Macleods incorporates by reference Macleods' Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '338 patent are invalid.

57. Macleods is entitled to a declaration that all claims of the '338 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT VII: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '753 PATENT

58. Macleods incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

59. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Macleods regarding whether the filing of Macleods' ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Macleods' ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '753 patent.

60. Macleods incorporates by reference Macleods' Notice Letter, which contains exemplary and nonlimiting explanations that the '753 patent is not infringed by Macleods' ANDA

or the products or activities described therein.

61. Macleods is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '753 patent and is not liable for such infringement.

COUNT VIII: DECLARATORY JUDGMENT OF INVALIDITY OF THE '753 PATENT

62. Macleods incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

63. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Macleods regarding whether the claims of the '753 patent are invalid.

64. Macleods incorporates by reference Macleods' Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '753 patent are invalid.

65. Macleods is entitled to a declaration that all claims of the '753 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT IX: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '143 PATENT

66. Macleods incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

67. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Macleods regarding whether the filing of Macleods' ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Macleods' ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '143 patent.

68. Macleods incorporates by reference Macleods' Notice Letter, which contains exemplary and nonlimiting explanations that the '143 patent is not infringed by Macleods' ANDA

or the products or activities described therein.

69. Macleods is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '143 patent and is not liable for such infringement.

COUNT X: DECLARATORY JUDGMENT OF INVALIDITY OF THE '143 PATENT

70. Macleods incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

71. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Macleods regarding whether the claims of the '143 patent are invalid.

72. Macleods incorporates by reference Macleods' Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '143 patent are invalid.

73. Macleods is entitled to a declaration that all claims of the '143 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT XI: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '523 PATENT

74. Macleods incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

75. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Macleods regarding whether the filing of Macleods' ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Macleods' ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '523 patent.

76. Macleods incorporates by reference Macleods' Notice Letter, which contains exemplary and nonlimiting explanations that the '523 patent is not infringed by Macleods' ANDA

or the products or activities described therein.

77. Macleods is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '523 patent and is not liable for such infringement.

COUNT XII: DECLARATORY JUDGMENT OF INVALIDITY OF THE '523 PATENT

78. Macleods incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

79. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Macleods regarding whether the claims of the '523 patent are invalid.

80. Macleods incorporates by reference Macleods' Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '523 patent are invalid.

81. Macleods is entitled to a declaration that all claims of the '523 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

PRAYER FOR RELIEF

WHEREFORE, Macleods respectfully requests that this Court enter a judgment in its favor and against Plaintiff as follows:

(a) Dismissing the Complaint with prejudice and entering judgment for Macloeds;

(b) Declaring that no valid claim of the Patents-in-Suit would be infringed by the manufacture, use, sale, offer for sale, and/or importation of Macleods' ANDA Products pursuant to ANDA No. 220570;

(c) Declaring that the claims of the Patents-in-Suit are invalid;

(d) Entering judgment for Macleods on its affirmative defenses and any and all additional defenses and counterclaims that discovery may reveal;

(e) Enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with Counterclaim-Defendant from threatening to assert or otherwise attempting to enforce the Patents-in-Suit against Macleods, its customers, suppliers, or anyone in privity with Macleods;

(f) Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Macleods its reasonable attorneys' fees and costs incurred in this action;

(g) Awarding Macleods its costs and expenses incurred in this action; and

(h) Awarding Macleods such other and further relief as this Court may deem proper.

MIDLIGE RICHTER LLC
Attorneys for Defendants
Macleods Pharmaceuticals Ltd. and
Macleods Pharma USA, Inc.

By: s/ James S. Richter
James S. Richter
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Dated: September 29, 2025

OF COUNSEL:

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify, to the best of my knowledge, the same drugs and patents are at issue in the following actions currently pending in this District:

- SUPERNUS PHARMACEUTICALS, INC. v. APPCO PHARMA LLC et al Civil Action No. 2:25-cv-12183-MEF-MAH
- SUPERNUS PHARMACEUTICALS, INC. v. APOTEX INC. Civil Action No. 2:25-cv-12184-MEF-MAH
- SUPERNUS PHARMACEUTICALS, INC. v. AUROBINDO PHARMA LIMITED et al Civil Action No. 2:25-cv-12186-MEF-MAH
- SUPERNUS PHARMACEUTICALS, INC. v. ZYDUS LIFESCIENCES GLOBAL FZE et al Civil Action No. 2:25-cv-12188-MEF-MAH
- SUPERNUS PHARMACEUTICALS, INC. v. CREEKWOOD PHARMACEUTICALS, LLC Civil Action No. 2:25-cv-13201-MEF-MAH
- SUPERNUS PHARMACEUTICALS, INC. v. MSN PHARMACEUTICALS INC. Civil Action No. 2:25-cv-13204-MEF-MAH
- SUPERNUS PHARMACEUTICALS, INC. v. ZENARA PHARMA PRIVATE LIMITED et al Civil Action No. 2:25-cv-13207-MEF-MAH
- SUPERNUS PHARMACEUTICALS, INC. v. MACLEODS PHARMACEUTICALS LTD. et al Civil Action No. 2:25-cv-15399-MEF-MAH

Macleods is not aware of any other action in any court or any pending arbitration or administrative proceeding related to this matter.

s/ James S. Richter
James S. Richter

Dated: September 29, 2025

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc., by and through their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

s/ James S. Richter
James S. Richter

Dated: September 29, 2025

CERTIFICATION OF SERVICE

I certify that on September 29, 2025, a true and correct copy of the foregoing Answer, Affirmative Defenses, and Counterclaims to Plaintiff's Complaint for Patent Infringement was served upon all counsel of record by notice of electronic filing.

s/ James S. Richter
James S. Richter

Dated: September 29, 2025