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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC., Plaintiff, v. MSN PHARMACEUTICALS INC., Defendant.	Civil Action No.: 2:25-cv-13204-MEF-MAH

DEFENDANT MSN PHARMACEUTICALS INC.'S
ANSWER, DEFENSES, AND COUNTERCLAIMS TO
PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT

Defendant MSN Pharmaceuticals Inc. ("MSN") by and through its undersigned attorneys, hereby files its Answer, Defenses, and Counterclaims in response to the Complaint for Patent

Infringement ("Complaint") (Dkt. No. 1) filed on July 11, 2025, by Plaintiff Supernus Pharmaceuticals, Inc. ("Plaintiff").

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:

MSN admits that Plaintiff's Complaint purports to state an action for infringement of U.S. 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") and that this action purports to arise under the patent laws of the United States, 35 U.S.C. § 100 *et seq*. MSN denies the remaining allegations of Paragraph 1.

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:

MSN lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 2 and on that basis denies these allegations.

3. Upon information and belief, defendant MSN Pharmaceuticals Inc. is a Delaware corporation with a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

ANSWER:

MSN admits that it is a corporation organized and existing under the laws of Delaware and maintains a place of business at 20 Duke Road, Piscataway, New Jersey 08854. MSN denies the remaining allegations of Paragraph 3.

4. Upon information and belief, MSN 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:

MSN admits that it markets pharmaceutical products in the United States, including New Jersey, which include generic drug products that are the subject of Abbreviated New Drug Applications ("ANDAs") approved by the U.S. Food and Drug Administration ("FDA"). MSN does not contest this Court's personal jurisdiction over MSN solely for the limited purposes of this action only, and reserves the right to contest personal jurisdiction in any other case. MSN denies the remaining allegations of Paragraph 4.

5. Upon information and belief, MSN, 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:

MSN admits that it markets pharmaceutical products in the United States, including New Jersey. MSN does not contest this Court's personal jurisdiction over MSN solely for the limited purposes of this action only, and reserves the right to contest personal jurisdiction in any other case. MSN denies the remaining allegations of Paragraph 5.

6. Upon information and belief, MSN is registered with the State of New Jersey's Treasury Department Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0400627791. Upon information and belief MSN is registered with the State of New Jersey's Department of Health as a "Manufacturer and Wholesale[r]" with Registration Number 5006107.

ANSWER:

MSN admits that it is registered with the State of New Jersey's Treasury Department Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0400627791. MSN also admits that it is registered with the State of New Jersey's Department of Health as a "Manufacturer and Wholesale[r]" with Registration Number 5006107. MSN does not contest this Court's personal jurisdiction over MSN solely for the limited purposes of this action only, and reserves the right to contest personal jurisdiction in any other case. MSN denies the remaining allegations of Paragraph 6.

7. Upon information and belief, MSN filed Abbreviated New Drug Application ("ANDA") No. 220551 ("Defendant's ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of generic viloxazine extended-release capsules, containing 100 mg, 150 mg, and 200 mg of viloxazine ("Defendant's ANDA Products").

ANSWER:

MSN admits that it submitted ANDA No. 220551 ("MSN's ANDA") to FDA seeking approval to market the products described in MSN's ANDA No. 220551 ("MSN's ANDA Products") in the United States. MSN denies the remaining allegations of Paragraph 7.

JURISDICTION AND VENUE

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

ANSWER:

MSN does not contest this Court's subject matter jurisdiction solely for the limited purposes of this action only, and expressly reserves the right to contest subject matter jurisdiction in any other case as to any party, including Plaintiff. MSN denies the remaining allegations of Paragraph 8.

9. This Court has personal jurisdiction over Defendant under Fed. R. Civ. P. 4(k)(1) and N.J. Ct. R. 4:4-4.

ANSWER:

MSN does not contest this Court's personal jurisdiction over MSN solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. MSN denies the remaining allegations of Paragraph 9.

10. This Court has personal jurisdiction over MSN at least because, upon information and belief: (i) MSN maintains a principal place of business in New Jersey located at 20 Duke Road, Piscataway, New Jersey 08854; (ii) MSN, 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; (iii) MSN, itself and through related entities and agents, is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (iv) MSN has consented and submitted to this Court's jurisdiction in prior civil actions and has invoked the benefits and protections of this Court by asserting counterclaims in prior civil actions;[1] (v) MSN is registered with the State of New Jersey's Treasury Department Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0400627791; (vi) MSN is registered with the State of New Jersey's Department of Health as a "Manufacturer and Wholesale[r]" with Registration Number 5006107; (vii) MSN, 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; (viii) MSN's website identifies MSN as a "Specialized Pharmaceutical Generic development and manufacturing facility based out of Piscataway, New Jersey" (*see* https://msnpi.com/ (last visited July 8, 2025)); (ix) MSN's contacts with this Judicial District—e.g., the manufacturing, importation, use, sale, offer for sale, and/or distribution of

[1] Footnote in Complaint: "*See, e.g., Vifor (International) AG v. MSN Laboratories Private Ltd.*, No. 25-cv-03286, ECF No. 14 (D.N.J.) (filing counterclaims and not contesting personal jurisdiction); *Jazz Pharmaceuticals Ireland Ltd. v. Sandoz Inc.*, No. 24-cv-09110, ECF No. 32 (D.N.J.) (same); *Esperion Therapeutics, Inc. v. MSN Pharmaceuticals Inc.*, No. 24-cv-06386, ECF No. 28 (D.N.J.) (same); *American Regent, Inc. v. MSN Laboratories Private Ltd.*, No. 24-cv-10674, ECF No. 26 (D.N.J.) (same); *Bausch Health Ireland Ltd. v. MSN Laboratories Private Ltd.*, No. 24- cv-07182, ECF No. 8 (D.N.J.) (same); *Esperion Therapeutics, Inc. v. Micro Labs USA, Inc.*, No. 24-cv-05921, ECF No. 84 (D.N.J.) (same); *AbbVie Inc. v. MSN Pharmaceuticals Inc.*, No. 24-cv- 04662, ECF No. 31 (D.N.J.) (same); *BeiGene USA, Inc. v. MSN Pharmaceuticals Inc.*, No. 24- cv-01971, ECF No. 20 (D.N.J.) (same); *Catalyst Pharmaceuticals, Inc. v. MSN Pharmaceuticals Inc.*, No. 23-cv-01945, ECF No. 15 (D.N.J.) (not contesting personal jurisdiction)."

generic pharmaceutical products (including the accused products at issue in this action)—give rise to and/or are related to Plaintiff's claims; (x) MSN, itself and through related entities and agents, has committed, induced, and/or contributed to acts of patent infringement in New Jersey; and (xi) if Defendant's ANDA receives final approval, Defendant's ANDA Products will be marketed and distributed by MSN 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:

MSN admits that it maintains a place of business in Piscataway, New Jersey; that it markets pharmaceutical products, which include generic drug products that are the subject of ANDAs approved by the FDA; and that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States. MSN further admits that it is registered with the State of New Jersey's Treasury Department Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0400627791, that it is registered with the State of New Jersey's Department of Health as a "Manufacturer and Wholesale[r]" with Registration Number 5006107, and that its website identifies MSN as a "Specialized Pharmaceutical Generic development and manufacturing facility based out of Piscataway, New Jersey." In addition, MSN does not contest this Court's personal jurisdiction over MSN solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. MSN denies the remaining allegations of Paragraph 10 including Footnote 1.

11. MSN's website describes its presence in New Jersey as follows:

> With a 225,000 square feet facility built on 15 acres of developed land, the facility is replete with Corporate Offices, Research and Development area, Laboratories, and Manufacturing Units. Reliable, Avant garde equipment from Glatt, Fette, Korsch, Bosch and market-leading brands have been installed. The facility is also equipped with a Vault and Cage and top-of-the-line security systems to handle DEA Controlled Substances.

> The facility is built with Flame-resistant panels, terminal HEPA filters in the manufacturing units and an HVAC design that prevents cross-contamination. The infrastructure is also capable of warehousing of Pharmaceutical Finished products, raw materials including Active Pharmaceutical Ingredients (APIs), Excipients and various packing materials.
>
> The facility is strategically located close to the Rutgers University Campus between exits 7 and 8 on the interstate 287 East of the Piscataway weigh station. Located within proxime distance to Exit 10 of the New jersey Turnpike, the Garden State Parkway and provides excellent access to New York City and Tri-state region.

See https://msnpi.com/ (last visited July 8, 2025).

ANSWER:

MSN admits that its website includes the excerpt in Paragraph 11.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 12.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. In addition, MSN does not contest this Court's personal jurisdiction over MSN solely for the limited purposes of this

action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. MSN denies the remaining allegations of Paragraph 13.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. In addition, MSN does not contest this Court's personal jurisdiction over MSN solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. MSN denies the remaining allegations of Paragraph 14.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. In addition, MSN does not contest this Court's personal jurisdiction over MSN solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. MSN denies the remaining allegations of Paragraph 15.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. In addition, MSN does not contest this Court's personal jurisdiction over MSN solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. MSN denies the remaining allegations of Paragraph 16.

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

ANSWER:

MSN does not contest venue in this judicial district solely for the limited purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party, including Plaintiff. MSN denies the remaining allegations of Paragraph 17.

FACTS COMMON TO ALL COUNTS

18. Upon information and belief, on or about June 5, 2025, Defendant sent a letter pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95) regarding the paragraph IV certification that Defendant submitted in Defendant's ANDA and the patents-in-suit (the "Notice Letter") to Supernus at 9715 Key West Avenue, Rockville, Maryland 20850.

ANSWER:

MSN admits that, on or about June 5, 2025, it sent a Notice Letter to Plaintiff at its address of record. MSN denies the remaining allegations of Paragraph 18.

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

ANSWER:

MSN admits that its Notice Letter included an Offer of Confidential access to portions of MSN's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). MSN denies the remaining allegations of Paragraph 19.

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

ANSWER:

MSN admits that Plaintiff and MSN did not reach agreement on the terms of an Offer of Confidential Access. MSN further admits that it did not produce a copy of MSN's ANDA to Plaintiff prior to this lawsuit because Plaintiff did not agree to the reasonable terms set forth in the Offer for Confidential Access. MSN denies the remaining allegations of Paragraph 20.

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

ANSWER:

MSN admits that its Notice Letter states that MSN's ANDA was submitted to obtain approval to engage in the commercial manufacture, use or sale of MSN's ANDA Products. MSN denies the remaining allegations of Paragraph 21.

22. Upon information and belief, Defendant is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of 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 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:

MSN admits that it markets generic drug products in the United States, including New Jersey. MSN does not contest this Court's personal jurisdiction over MSN solely for the limited purposes of this action only, and reserves the right to contest personal jurisdiction in any other case. MSN denies the remaining allegations of Paragraph 22.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States. MSN denies the remaining allegations of Paragraph 23.

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

ANSWER:

MSN admits that it markets generic drug products in the United States, including New Jersey. MSN does not contest this Court's personal jurisdiction over MSN solely for the limited purposes of this action only, and reserves the right to contest personal jurisdiction in any other case. MSN denies the remaining allegations of Paragraph 24.

25. 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:

MSN admits that Paragraph 25 contains excerpts from 21 C.F.R. §§ 314.95(c)(7)(i)-(ii) and 21 U.S.C. § 355(j)(2)(B)(iv)(II). MSN denies the remaining allegations of Paragraph 25.

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

ANSWER:

MSN admits that it is aware of the provisions in 21 C.F.R. §§ 314.95(c)(7) and 21 U.S.C. § 355(j)(2)(B)(iv)(II). MSN denies the remaining allegations of Paragraph 26.

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

ANSWER:

MSN admits that MSN did not disclose invalidity contentions for the ’204 patent, the ’853 patent, and the ’338 patent in the Notice Letter because MSN disclosed detailed bases for why MSN does not infringe the claims of those patents. MSN denies the remaining allegations of Paragraph 27, including the allegation that it “acknowledges and admits that the ’204 patent, the ’853 patent, and the ’338 patent are not invalid.” MSN’s Notice letter expressly reserved the right to “raise any additional defenses relating to invalidity . . .”

28. The Notice Letter does not disclose any noninfringement contentions or opinions specifically directed any claims of the ’143 patent. Accordingly, upon information and belief, Defendant acknowledges and admits infringement of the ’143 patent.

ANSWER:

MSN admits that MSN did not disclose noninfringement contentions explicitly directed to claims of the ’143 patent in the Notice Letter because MSN disclosed detailed bases for why the claims of that patent are invalid and invalid claims cannot be infringed. MSN denies the remaining allegations of Paragraph 28, including the allegation that it “acknowledges and admits infringement of the ’143 patent.” MSN’s Notice letter expressly reserved the right to “raise any additional defenses relating to . . . non-infringement.”

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

ANSWER:

MSN admits that MSN’s Notice Letter does not explicitly disclose unenforceability contentions for the patents-in-suit because the Notice Letter discloses multiple other grounds of non-infringement and invalidity for the patents-in-suit. MSN’s Notice letter expressly reserved

the right to "raise any additional defenses relating to . . . unenforceability . . ." MSN denies the remaining allegations of Paragraph 29.

30. 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:

MSN admits that the FDA's website indicates NDA No. 211964 is owned by Supernus and was approved for viloxazine extended-release capsules of 100 mg, 150 mg, and 200 mg, marketed under the name Qelbree®. MSN lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 30 and on that basis denies these allegations.

31. 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:

MSN admits that the package insert for Qelbree® dated April 2022, available www.accessdata.fda.gov/drugsatfda_docs/label/2022/211964s003lbl.pdf (last visited September 6, 2025), states the following:

----------INDICATIONS AND USAGE----------
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 (1)

MSN denies the remaining allegations of Paragraph 31.

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

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

- Pediatric patients 12 to 17 years of age: Recommended starting dosage is 200 mg once daily. May titrate after 1

week, by an increment of 200mg, to the maximum recommended dosage of 400 mg once daily

- Adult patients: Recommended starting dosage is 200 mg once daily. May titrate in increments of 200 mg weekly, to maximum recommended dosage of 600 mg once daily
- Capsules may be swallowed whole or opened and the entire contents sprinkled onto applesauce or pudding
- Severe Renal Impairment: Initial dosage is 100 mg once daily. Titrate in weekly increments of 50 mg to 100 mg to a maximum recommended dosage of 200 mg once daily

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

ANSWER:

MSN admits that the package insert for Qelbree® dated April 2022, available at www.accessdata.fda.gov/drugsatfda_docs/label/2022/211964s003lbl.pdf (last visited September 6, 2025), states the following:

----------DOSAGE AND ADMINISTRATION----------

- *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 (2.2)
- *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 (2.2)
- *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 (2.2)
- Capsules may be swallowed whole or opened and the entire contents sprinkled onto applesauce or pudding (2.3)
- 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 (2.4, 8.6)

MSN denies the remaining allegations of Paragraph 32.

33. 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:

MSN admits that the Orange Book listing for NDA 21164 includes the patents-in-suit and the dates that the patents-in-suit were allegedly submitted to FDA. MSN denies remaining allegations in Paragraph 33.

34. 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:

MSN admits that, on its face, the '204 patent is titled "Formulations of Viloxazine." MSN further admits that the face of the '204 patent states that the '204 patent purports to have been issued on June 7, 2016. MSN further admits that the face of the '204 patent lists Michael Vieira, Austin B. Huang, and Padmanabh P. Bhatt as named inventors. MSN denies the remaining allegations of Paragraph 34.

35. 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:

MSN admits that, on its face, the '853 patent is titled "Formulations of Viloxazine." MSN further admits that the face of the '853 patent states that the '853 patent purports to have been issued on March 28, 2017. MSN further admits that the face of the '853 patent lists Michael Vieira, Austin B. Huang, and Padmanabh P. Bhatt as named inventors. MSN denies the remaining allegations of Paragraph 35.

36. 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:

MSN admits that, on its face, the ’338 patent is titled “Formulations of Viloxazine.” MSN further admits that the face of the ’338 patent states that the ’338 patent purports to have been issued on May 30, 2017. MSN further admits that the face of the ’338 patent lists Michael Vieira, Austin B. Huang, and Padmanabh P. Bhatt as named inventors. MSN denies the remaining allegations of Paragraph 36.

37. 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:

MSN admits that, on its face, the ’753 patent is titled “Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD).” MSN further admits that the face of the ’753 patent states that the ’753 patent purports to have been issued on May 10, 2022. MSN further admits that the face of the ’753 patent lists Christopher D. Breder as the named inventor. MSN denies the remaining allegations of Paragraph 37.

38. 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:

MSN admits that, on its face, the ’143 patent is titled “Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD).” MSN further admits that the face of the ’143 patent states that the ’143 patent purports to have been issued on October 4, 2022. MSN further admits that the face of the ’143 patent lists Christopher D. Breder as the named inventor. MSN denies the remaining allegations of Paragraph 38.

39. 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:

MSN admits that, on its face, the ’523 patent is titled “Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD).” MSN further admits that the face of the ’523 patent states that the ’523 patent purports to have been issued on October 22, 2024. MSN further admits that the face of the ’523 patent lists Christopher D. Breder as the named inventor. MSN denies the remaining allegations of Paragraph 39.

40. Upon information and belief, Defendant’s ANDA is based upon Qelbree® (viloxazine extended-release capsules), 100 mg, 150 mg, and 200 mg, as its reference listed drug.

ANSWER:

MSN admits that the reference listed drug for MSN’s ANDA is Qelbree®. MSN denies the remaining allegations of Paragraph 40.

41. Upon information and belief, Defendant’s ANDA Products are viloxazine extended-release capsules, 100 mg, 150 mg, and 200 mg.

ANSWER:

MSN admits that of the MSN ANDA Products are viloxazine extended-release capsules, 100 mg, 150 mg and 200 mg. MSN denies the remaining allegations of Paragraph 41.

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

ANSWER:

MSN admits that MSN’s ANDA contains the required bioavailability data and/or bioequivalence waiver. MSN denies the remaining allegations of Paragraph 42.

43. 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:

MSN admits that Paragraph 43 contains excerpts from 21 U.S.C. § 355(j)(2)(A)(i) and 21 U.S.C. § 355(j)(2)(A)(v). MSN denies the remaining allegations of Paragraph 43.

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

ANSWER:

MSN admits that its Notice Letter states that MSN filed an ANDA to obtain approval to engage in the commercial manufacture, use or sale of viloxazine extended-release capsules, 100 mg, 150 mg and 200 mg and that the Notice Letter speaks for itself. MSN denies the remaining allegations of Paragraph 44.

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

ANSWER:

MSN admits that it submitted proposed prescribing information with its ANDA and that the proposed prescribing information, at this time, is highly confidential. MSN denies the remaining allegations of Paragraph 45.

46. Upon information and belief, the proposed prescribing information for Defendant's ANDA Products includes a section titled, "Dosage and Administration," containing information about the recommended dosage for adult and pediatric patients. Upon information and belief, the proposed prescribing information for Defendant's ANDA Products recommends: (i) administering

100 mg orally once daily as the recommended starting dosage for pediatric patients 6 to 11 years of age, which may be titrated in increments of 100 mg at weekly intervals to a maximum recommended dose of 400 mg once daily, depending on response and tolerability, (ii) administering 200 mg orally once daily as the recommended starting dosage for pediatric patients 12 to 17 years of age, which may be titrated in increments of 200 mg after one week to the maximum recommended dosage of 400 mg once daily, depending on response and tolerability; and (iii) administering 200 mg orally once daily as the recommended starting dosage for adults, which may be titrated in increments of 200 mg weekly to the maximum recommended dosage of 600 mg once daily, depending on response and tolerability.

ANSWER:

MSN admits that it submitted proposed prescribing information with its ANDA and that the proposed prescribing information, at this time, is highly confidential. MSN denies the remaining allegations of Paragraph 46.

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

ANSWER:

MSN admits that it submitted proposed prescribing information with its ANDA and that the proposed prescribing information, at this time, is highly confidential. MSN denies the remaining allegations of Paragraph 47.

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

ANSWER:

MSN admits that it submitted proposed prescribing information with its ANDA and that the proposed prescribing information, at this time, is highly confidential. MSN denies the remaining allegations of Paragraph 48.

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

ANSWER:

MSN admits that it submitted proposed labeling with its ANDA and that the proposed labeling, at this time, is highly confidential and that it is not yet known what labeling will be approved in connection with MSN's ANDA Products. MSN denies the remaining allegations of Paragraph 49.

FIRST COUNT: ALLEGED INFRINGEMENT OF THE '204 PATENT

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

ANSWER:

MSN repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 51.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN further admits that MSN's ANDA contains a paragraph IV certification to the '204 patent. MSN denies the remaining allegations of Paragraph 52.

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

ANSWER:

MSN admits that it was aware of the provisions in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) as of the date of the Notice letter. MSN denies the remaining allegations of Paragraph 53.

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

ANSWER:

MSN admits that it sent the Notice Letter to Supernus pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

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

ANSWER:

Denied.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 56.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

MSN admits that it submitted proposed labeling with its ANDA and that the proposed labeling, at this time, is highly confidential. MSN denies the remaining allegations of Paragraph 59.

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

ANSWER:

Denied.

61. Upon information and belief, the use of Defendant's ANDA Products by third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) according to the instructions on the label of Defendant's ANDA Products will constitute an act of direct infringement of one or more of the claims of the '204 patent.

ANSWER:

Denied.

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

encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the ’204 patent.

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

MSN admits that it submitted MSN’s ANDA to FDA seeking approval to market MSN’s ANDA Products in the United States before the expiration of the patents-in-suit. MSN further

admits that MSN's ANDA contains a paragraph IV certification to the '204 patent. MSN denies the remaining allegations of Paragraph 65.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 66.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

SECOND COUNT: ALLEGED INFRINGEMENT OF THE '853 PATENT

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

ANSWER:

MSN repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 70.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN further admits that MSN's ANDA contains paragraph IV certifications. MSN denies the remaining allegations of Paragraph 71.

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

ANSWER:

MSN admits that it was aware of the provisions in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) as of the date of the Notice Letter. MSN denies the remaining allegations of Paragraph 72.

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

ANSWER:

MSN admits that MSN sent the Notice Letter to Supernus pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1). MSN denies the remaining allegations of paragraph 73.

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

ANSWER:

Denied.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 75.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

MSN admits that it submitted proposed labeling with its ANDA and that the proposed labeling, at this time, is highly confidential. MSN denies the remaining allegations of Paragraph 78.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

82. Upon information and belief, Defendant intends such infringement by third parties, as Defendant is in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendant knows that its actions will induce acts that constitute direct infringement of claims of the '853 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN further admits that MSN's ANDA contains a paragraph IV certification to the '853 patent. MSN denies the remaining allegations of Paragraph 84.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 85.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

THIRD COUNT: ALLEGED INFRINGEMENT OF THE '338 PATENT

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

ANSWER:

MSN repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 89.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN further

admits that MSN's ANDA contains a paragraph IV certification to the '338 patent. MSN denies the remaining allegations of Paragraph 90.

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

ANSWER:

MSN admits that it was aware of the provisions in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) as of the date of the Notice letter. MSN denies the remaining allegations of Paragraph 91.

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

ANSWER:

MSN admits that it sent the Notice Letter to Supernus pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1). MSN denies the remaining allegations of Paragraph 92.

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

ANSWER:

Denied.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 94.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

MSN admits that it submitted proposed labeling with its ANDA and that the proposed labeling, at this time, is highly confidential. MSN denies the remaining allegations of Paragraph 97.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

102. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendant's ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant will contribute to the infringement of the '338 patent by third parties because: (i) Defendant's ANDA Products constitute a material part of the formulations claimed in the '338 patent; (ii) Defendant knows or should know that Defendant's ANDA Products will be made for uses that directly infringe the formulations claimed in the '338 patent; and (iii) Defendant's ANDA Products are not staple articles or commodities of commerce suitable for substantial noninfringing uses.

ANSWER:

Denied.

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

Upon information and belief, through such activities, Defendant specifically intends infringement of the ’338 patent.

ANSWER:

MSN admits that it submitted MSN’s ANDA to FDA seeking approval to market MSN’s ANDA Products in the United States before the expiration of the patents-in-suit. MSN further admits that MSN’s ANDA contains a paragraph IV certifications to the ’338 patent. MSN denies the remaining allegations of Paragraph 103.

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

ANSWER:

MSN admits that it submitted MSN’s ANDA to FDA seeking approval to market MSN’s ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 104.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

FOURTH COUNT: ALLEGED INFRINGEMENT OF THE ’753 PATENT

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

ANSWER:

MSN repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 108.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN further admits that MSN's ANDA contains a paragraph IV certification to the '753 patent. MSN denies the remaining allegations of Paragraph 109.

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

ANSWER:

MSN admits that it was aware of the provisions in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) as of the date of the notice letter. MSN denies the remaining allegations of Paragraph 110.

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

ANSWER:

MSN admits that it sent the Notice Letter to Supernus pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1).

MSN denies the remaining allegations of paragraph 111.

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

ANSWER:

Denied.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 113.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

MSN admits that it submitted proposed labeling with its ANDA and that the proposed labeling, at this time, is highly confidential. MSN denies the remaining allegations of Paragraph 116.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

119. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Defendant's ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the making or use of which infringes the claims, of the '753 patent.

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN further admits that MSN's ANDA contains a paragraph IV certification to the '753 patent. MSN denies the remaining allegations of Paragraph 122.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 123.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

FIFTH COUNT: ALLEGED INFRINGEMENT OF THE '143 PATENT

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

ANSWER:

MSN repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 127.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN further

admits that MSN's ANDA contains a paragraph IV certification to the '143 patent. MSN denies the remaining allegations of Paragraph 128.

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

ANSWER:

MSN admits that it was aware of the provisions in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) as of the date of the Notice letter. MSN denies the remaining allegations of Paragraph 129.

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

ANSWER:

MSN admits that it sent the Notice Letter to Supernus pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1). MSN denies the remaining allegations of paragraph 130.

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

ANSWER:

Denied.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 132.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

MSN admits that it submitted proposed labeling with its ANDA and that the proposed labeling, at this time, is highly confidential. MSN denies the remaining allegations of Paragraph 135.

136. Upon information and belief, the label for Defendant's ANDA Products that will be made available to third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists) upon FDA approval of Defendant's ANDA will encourage such third parties to infringe one or more of the methods claimed in the '143 patent.

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

140. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendant's ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendant will contribute to the infringement of the '143 patent by third parties because: (i) Defendant's ANDA Products constitute a material part of the methods of treatment claimed in the '143 patent; (ii) Defendant knows or should know that Defendant's ANDA Products will be made for uses that directly infringe the methods of treatment claimed in the '143 patent; and (iii) Defendant's ANDA Products are not staple articles or commodities of commerce suitable for substantial noninfringing uses.

ANSWER:

Denied.

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

Upon information and belief, through such activities, Defendant specifically intends infringement of the ’143 patent.

ANSWER:

MSN admits that it submitted MSN’s ANDA to FDA seeking approval to market MSN’s ANDA Products in the United States before the expiration of the patents-in-suit. MSN further admits that MSN’s ANDA contains a paragraph IV certification to the ’143 patent. MSN denies the remaining allegations of Paragraph 141.

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

ANSWER:

MSN admits that it submitted MSN’s ANDA to FDA seeking approval to market MSN’s ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 142.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

SIXTH COUNT: ALLEGED INFRINGEMENT OF THE ’523 PATENT

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

ANSWER:

MSN repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 146.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN further admits that MSN's ANDA contains a paragraph IV certification to the '523 patent. MSN denies the remaining allegations of Paragraph 147.

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

ANSWER:

MSN admits that it was aware of the provisions in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) as of the date of the Notice letter. MSN denies the remaining allegations of Paragraph 148.

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

ANSWER:

MSN admits that it sent the Notice Letter to Supernus pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1). MSN denies the remaining allegations of Paragraph 149.

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

ANSWER:

Denied.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 151.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

MSN admits that it submitted proposed labeling with its ANDA and that the proposed labeling, at this time, is highly confidential. MSN denies the remaining allegations of Paragraph 154.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

158. Upon information and belief, Defendant intends such infringement by third parties, as Defendant is in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendant knows that its actions will induce acts that constitute direct infringement of claims of

the ’523 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

MSN admits that it submitted MSN’s ANDA to FDA seeking approval to market MSN’s ANDA Products in the United States before the expiration of the patents-in-suit. MSN further admits that MSN’s ANDA contains a paragraph IV certification to the ’523 patent. MSN denies the remaining allegations of Paragraph 160.

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

ANSWER:

MSN admits that it submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Products in the United States before the expiration of the patents-in-suit. MSN denies the remaining allegations of Paragraph 161.

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

ANSWER:

Denied.

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

ANSWER:

Denied.

RESPONSES TO PRAYER FOR RELIEF

All remaining allegations not specifically admitted herein are denied. MSN further denies that Plaintiff is entitled to any of the relief set forth in its "Prayer for Relief" or to any relief whatsoever.

DEFENSES

Without any admission or implication as to burden of proof and expressly reserving its right to assert any additional defenses or counterclaims that discovery may reveal, MSN asserts the following defenses:

FIRST DEFENSE
(NON-INFRINGEMENT OF THE '204, '853, '338, '753, '143, AND '523 PATENTS BY MSN'S ANDA PRODUCTS)

The manufacture, use, sale, offer for sale, and/or importation of MSN's ANDA Products does not and will not infringe, induce infringement of, and/or contribute to the infringement of any

valid and/or enforceable claims of the ’204, ’853, ’338, ’753, ’143, and ’523 patents, either literally or by the doctrine of equivalents. For example, without limitation, the manufacture, use, sale, offer for sale, or importation of MSN’s ANDA Products has not infringed, does not infringe, and would not infringe any valid claim of the ’204, ’853, ’338, ’753, ’143, and ’523 patents for at least the reasons set forth in MSN’s Notice Letter.

SECOND DEFENSE
(INVALIDITY OF THE ’204, ’853, ’338, ’753, ’143, AND ’523 PATENTS)

One or more claims of the ’204, ’853, ’338, ’753, ’143, and ’523 patents are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including without limitation, one or more of Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents. For example, without limitation, the ’753, ’143, and ’523 patents are invalid for at least the reasons set forth in MSN’s Notice Letter.

THIRD DEFENSE
(FAILURE TO STATE A CLAIM FOR DIRECT INFRINGEMENT)

Plaintiff has failed to state a claim upon which relief can be granted with respect to purported direct infringement of the ’204, ’853, ’338, ’753, ’143, and ’523 patents. The Complaint contains only conclusory allegations including that “the commercial manufacture, use, offer to sell, or sale of the Defendant’s ANDA Products prior to the expiration of the [patents-in-suit] will directly infringe the ’204 patent under 35 U.S.C. § 271(a)” or that “the label for Defendant’s ANDA Products that will be made available to third parties . . . upon FDA approval of Defendant’s ANDA will encourage such third parties to infringe one or more of the claims of the [patents-in-suit].” As such, Plaintiff’s Complaint fails to state a claim for direct infringement.

FOURTH DEFENSE
(FAILURE TO STATE A CLAIM FOR INDIRECT INFRINGEMENT)

Plaintiff has failed to state a claim upon which relief can be granted with respect to purported indirect infringement of the '204, '853, '338, '753, '143, and '523 patents. The Complaint contains only conclusory allegations including that "the commercial manufacture, use, offer to sell, or sale of the Defendant's ANDA Products prior to the expiration of the [patents-in-suit] . . . will actively induce another's infringement of the [patents-in-suit] under 35 U.S.C. § 271(b), and will constitute contributory infringement of the [patents-in-suit] under 35 U.S.C. § 271(c)." As such, Plaintiff's Complaint fails to state a claim for either induced infringement or contributory infringement.

FIFTH DEFENSE
(NOT AN EXCEPTIONAL CASE)

MSN's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

SIXTH DEFENSE
(SAFE HARBOR UNDER 35 U.S.C. § 271(e)(1))

Pursuant to 35 U.S.C. § 271(e)(1), MSN's actions do not constitute infringement.

RESERVATION OF DEFENSES

MSN hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure, Local Patent Rules, and U.S. Patent Law and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation, including unenforceability.

COUNTERCLAIMS OF MSN PHARMACEUTICALS INC.

Defendant/Counterclaim-Plaintiff MSN Pharmaceuticals Inc. ("MSN") brings the following Counterclaims against Plaintiff/Counterclaim-Defendant Supernus Pharmaceuticals, Inc. ("Supernus"), and states as follows:

NATURE OF THE ACTION

1. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C), based on an actual controversy between the parties to declare that MSN is free to continue to seek approval of its Abbreviated New Drug Application ("ANDA") No. 220551 ("MSN's ANDA"), and upon approval by the U.S. Food and Drug Administration ("FDA"), to engage in commercial manufacture, importation, sale, and/or offer for sale of the products described in MSN's ANDA No. 220551 ("MSN's ANDA Products").

THE PARTIES

2. MSN is a corporation organized and existing under the laws of Delaware, with a place of business at 20 Duke Road, Piscataway, New Jersey 08854.

3. Supernus purports to be a corporation organized and existing under the laws of Delaware, having a place of business at 9715 Key West Avenue, Rockville, Maryland 20850.

4. Supernus purports to be the assignee of U.S. 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").

5. Supernus purports to be the holder of New Drug Application ("NDA") No. 211964 for the marketing and sale of Qelbree® (viloxazine extended-release capsules).

JURISDICTION AND VENUE

6. These Counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C).

7. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331, 1337(a) and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under 21 U.S.C. § 355(j)(5)(C).

8. This Court has personal jurisdiction over Supernus because Supernus has availed itself of the rights and privileges and subjected itself to the jurisdiction of this forum by suing MSN in this District, and/or because Supernus conducts substantial business in, and has regular systemic contact with, this District.

9. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400 and 21 U.S.C. § 355(j)(5)(C).

BACKGROUND

10. On July 11, 2025, Supernus filed a Complaint for Patent Infringement ("Complaint") in this Court alleging that the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Products before the expiration of the patents-in-suit would constitute infringement of those patents, either literally or under the doctrine of equivalents. Supernus further alleged that MSN will actively induce infringement of, and/or contribute to infringement by others of the patents-in-suit.

11. By virtue of Supernus's Complaint, an immediate and justiciable controversy exists between MSN, on the one hand, and Supernus, on the other, regarding whether MSN's ANDA

Products infringes any valid and enforceable claim of the patents-in-suit and whether MSN's ANDA Products infringes any valid and enforceable claim of the patents-in-suit.

PATENTS-IN-SUIT

12. The face of the '204 patent indicates it was issued by the U.S. Patent and Trademark Office ("USPTO") on or about June 7, 2016.

13. The face of the '853 patent indicates it was issued by the USPTO on or about March 28, 2017.

14. The face of the '338 patent indicates it was issued by the USPTO on or about May 30, 2017.

15. The face of the '753 patent indicates it was issued by the USPTO on or about May 10, 2022.

16. The face of the '143 patent indicates that it was issued by the USPTO on or about October 4, 2022.

17. The face of the '523 patent indicates that it was issued by the USPTO on or about October 22, 2024.

18. Supernus purports and claims to have the right to enforce the '204, '853, '338, '753, '143, and '523 patents.

19. On information and belief, Supernus caused the FDA to list the '204, '853, '338, '753, '143, and '523 patents in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") in connection with NDA No. 211964 for Qelbree®.

20. By maintaining the listing of the '204, '853, '338, '753, '143, and '523 patents in the Orange Book for NDA No. 211964 for Qelbree®, Supernus has represented that the '204, '853, '338, '753, '143, and '523 patents cover viloxazine extended-release capsules, and that a claim of

patent infringement may reasonably be asserted against any ANDA applicant, including MSN, that is not licensed by Supernus and files an ANDA seeking approval to market viloxazine extended-release capsules before the expiration of the ’204, ’853, ’338, ’753, ’143, and ’523 patents.

MSN’S ANDA NO. 220551

21. MSN submitted MSN’s ANDA with FDA seeking approval to engage in the commercial marketing of MSN’s ANDA Products before the expiration of the patents-in-suit.

22. In accordance with the requirements of 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.52(c), MSN sent Supernus a notice letter dated June 5, 2025 (“MSN’s Notice Letter”), stating that MSN’s ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification(s)”), alleging that the ’204, ’853, ’338, ’753, ’143, and ’523 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of MSN’s ANDA Products.

23. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), MSN’s Notice Letter included an Offer of Confidential Access (“OCA”) to MSN’s ANDA for the holder of NDA No. 211964 and owner of the ’204, ’853, ’338, ’753, ’143, and ’523 patents.

24. MSN’s OCA to MSN’s ANDA complied with the requirements of 21 U.S.C. § 355(j)(5)(C)(i)(III), which states in relevant part that the offer shall be for “confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information.”

25. Supernus did not agree to the terms of MSN's OCA.

26. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) of the Federal Drug and Cosmetic Act, MSN's Notice Letter included a detailed statement of the factual and legal bases for MSN's Paragraph IV Certifications ("MSN's Detailed Statement").

27. Supernus's receipt of MSN's Notice Letter initiated a 45-day statutory period during which Supernus had the opportunity to file an action for patent infringement with respect to MSN's ANDA.

28. On July 11, 2025, Supernus filed this infringement action asserting the '204, '853, '338, '753, '143, and '523 patents against MSN.

FIRST COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '204 PATENT BY MSN'S ANDA PRODUCTS)

29. MSN realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

30. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C). By virtue of Supernus's allegations of infringement against MSN, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Supernus and MSN concerning MSN's non-infringement of the '204 patent.

31. MSN seeks a declaration that no valid or enforceable claim of the '204 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of MSN's ANDA Products.

32. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), MSN's Detailed Statement provides factual and legal bases for why MSN has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '204 patent.

33. In MSN's Detailed Statement, MSN expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in MSN's Detailed Statement.

34. Because Supernus maintains that the commercial manufacture, use, offer for sale, or sale of MSN's ANDA Products would infringe the '204 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of MSN's ANDA Products within the United States has not infringed and will not infringe, directly and/or indirectly, the '204 patent.

35. MSN is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of MSN's ANDA Products has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '204 patent.

SECOND COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '204 PATENT)

36. MSN realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

37. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C) and seeks a declaration that the claims of the '204 patent are invalid. By virtue of Supernus's allegations of infringement against MSN, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to

warrant the issuance of a declaration of rights by this Court exists between Supernus and MSN concerning the invalidity of the claims of the ’204 patent.

38. Because Supernus maintains and MSN denies that the ’204 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the ’204 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

39. MSN is entitled to a declaration that the claims of the ’204 patent are invalid.

THIRD COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE ’853 PATENT BY MSN’S ANDA PRODUCTS)

40. MSN realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

41. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C). By virtue of Supernus’s allegations of infringement against MSN, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Supernus and MSN concerning MSN’s non-infringement of the ’853 patent.

42. MSN seeks a declaration that no valid or enforceable claim of the ’853 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of MSN’s ANDA Products.

43. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), MSN's Detailed Statement provides factual and legal bases for why MSN has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '853 patent.

44. In MSN's Detailed Statement, MSN expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in MSN's Detailed Statement.

45. Because Supernus maintains that the commercial manufacture, use, offer for sale, or sale of MSN's ANDA Products would infringe the '853 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of MSN's ANDA Products within the United States has not infringed and will not infringe, directly and/or indirectly, the '853 patent.

46. MSN is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale MSN's ANDA Products has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '853 patent.

FOURTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '853 PATENT)

47. MSN realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

48. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C) and seeks a declaration that the claims of the '853 patent are invalid. By virtue of Supernus's allegations of infringement against MSN, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to

warrant the issuance of a declaration of rights by this Court exists between Supernus and MSN concerning the invalidity of the claims of the ’853 patent.

49. Because Supernus maintains and MSN denies that the ’853 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the ’853 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

50. MSN is entitled to a declaration that the claims of the ’853 patent are invalid.

FIFTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE ’338 PATENT BY MSN’S ANDA PRODUCTS)

51. MSN realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

52. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C). By virtue of Supernus’s allegations of infringement against MSN, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Supernus and MSN concerning MSN’s non-infringement of the ’338 patent.

53. MSN seeks a declaration that no valid or enforceable claim of the ’338 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of MSN’s ANDA Products.

54. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), MSN's Detailed Statement provides factual and legal bases for why MSN has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '338 patent.

55. In MSN's Detailed Statement, MSN expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in MSN's Detailed Statement.

56. Because Supernus maintains that the commercial manufacture, use, offer for sale, or sale of MSN's ANDA Products would infringe the '338 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of MSN's ANDA Products within the United States has not infringed and will not infringe, directly and/or indirectly, the '338 patent.

57. MSN is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of MSN's ANDA Products has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '338 patent.

SIXTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '338 PATENT)

58. MSN realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

59. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C) and seeks a declaration that the claims of the '338 patent are invalid. By virtue of Supernus's allegations of infringement against MSN, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to

warrant the issuance of a declaration of rights by this Court exists between Supernus and MSN concerning the invalidity of the claims of the ’338 patent.

60. Because Supernus maintains and MSN denies that the ’338 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the ’338 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

61. MSN is entitled to a declaration that the claims of the ’338 patent are invalid.

SEVENTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE ’753 PATENT BY MSN’S ANDA PRODUCTS)

62. MSN realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

63. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C). By virtue of Supernus’s allegations of infringement against MSN, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Supernus and MSN concerning MSN’s non-infringement of the ’753 patent.

64. MSN seeks a declaration that no valid or enforceable claim of the ’753 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of MSN’s ANDA Products.

65. Because Supernus maintains that the commercial manufacture, use, offer for sale, or sale of MSN's ANDA Products would infringe the '753 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of MSN's ANDA Products within the United States has not infringed and will not infringe, directly and/or indirectly, the '753 patent.

66. MSN is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of MSN's ANDA Products has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '753 patent.

EIGHTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '753 PATENT)

67. MSN realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

68. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C) and seeks a declaration that the claims of the '753 patent are invalid. By virtue of Supernus's allegations of infringement against MSN, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Supernus and MSN concerning the invalidity of the claims of the '753 patent.

69. Because Supernus maintains and MSN denies that the '753 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '753 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including

Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

70. MSN is entitled to a declaration that the claims of the ’753 patent are invalid.

NINTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE ’143 PATENT BY MSN’S ANDA PRODUCTS)

71. MSN realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

72. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C). By virtue of Supernus’s allegations of infringement against MSN, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Supernus and MSN concerning MSN’s non-infringement of the ’143 patent.

73. MSN seeks a declaration that no valid or enforceable claim of the ’143 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of MSN’s ANDA Products.

74. Because Supernus maintains that the commercial manufacture, use, offer for sale, or sale of MSN’s ANDA Products would infringe the ’143 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of MSN’s ANDA Products within the United States has not infringed and will not infringe, directly and/or indirectly, the ’143 patent.

75. MSN is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of MSN's ANDA Products has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '143 patent.

TENTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '143 PATENT)

76. MSN realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

77. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C) and seeks a declaration that the claims of the '143 patent are invalid. By virtue of Supernus's allegations of infringement against MSN, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Supernus and MSN concerning the invalidity of the claims of the '143 patent.

78. Because Supernus maintains and MSN denies that the '143 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '143 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents. MSN is entitled to a declaration that the claims of the '143 patent are invalid.

ELEVENTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE ’523 PATENT BY MSN’S ANDA PRODUCTS)

79. MSN realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

80. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C). By virtue of Supernus’s allegations of infringement against MSN, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Supernus and MSN concerning MSN’s non-infringement of the ’523 patent.

81. MSN seeks a declaration that no valid or enforceable claim of the ’523 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of MSN’s ANDA Products.

82. Because Supernus maintains that the commercial manufacture, use, offer for sale, or sale of MSN’s ANDA Products would infringe the ’523 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of MSN’s ANDA Products within the United States has not infringed and will not infringe, directly and/or indirectly, the ’523 patent.

83. MSN is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of MSN’s ANDA Products has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the ’523 patent.

TWELFTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '523 PATENT)

84. MSN realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

85. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C) and seeks a declaration that the claims of the '523 patent are invalid. By virtue of Supernus's allegations of infringement against MSN, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Supernus and MSN concerning the invalidity of the claims of the '523 patent.

86. Because Supernus maintains and MSN denies that the '523 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '523 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

MSN is entitled to a declaration that the claims of the '523 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Defendant/Counterclaim-Plaintiff MSN respectfully requests that this Court enter a Judgment and Order:

A. dismissing the Complaint, and the claims for relief contained therein, with prejudice;

B. declaring that MSN and MSN's ANDA Products have not infringed, are not infringing, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '204, '853, '338, '753, '143, and '523 patents;

C. declaring that the claims of the '204, '853, '338, '753, '143, and '523 patents are invalid;

D. declaring this an exceptional case under 35 U.S.C. § 285 and awarding MSN attorney fees, costs, and expenses; and

E. granting MSN such other and further relief as this Court deems just and proper.

Dated: September 22, 2025

Respectfully submitted,

s/Gregory D. Miller

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Attorneys for Defendant MSN Pharmaceuticals Inc.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: September 22, 2025

s/Gregory D. Miller
Gregory D. Miller

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, injunctive and declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: September 22, 2025

s/ Gregory D. Miller
Gregory D. Miller

CERTIFICATE OF SERVICE

I hereby certify that on September 22, 2025, the foregoing document described as **DEFENDANT MSN PHARMACEUTICALS INC.'S ANSWER, DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT** was served via electronic mail on counsel of record in this matter.

Dated: September 22, 2025

Respectfully submitted,

By: *s/ Gregory D. Miller*
Gregory D. Miller