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

SUPERNUS PHARMACEUTICALS, INC., *Plaintiff,* v. APPCO PHARMA LLC and SOMERSET THERAPEUTICS LLC, *Defendants.*	Civil Action No. 2:25-cv-12183-MEF-MAH *Document Filed Electronically*

DEFENDANTS APPCO PHARMA LLC AND SOMERSET THERAPEUTICS, LLC's ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants Appco Pharma LLC ("Appco") and Somerset Pharmaceuticals, LLC ("Somerset," and collectively with Appco, "Defendants"), by and through their undersigned counsel, hereby submit the following Answer ("Answer") in response to the Complaint ("Complaint") filed by Supernus Pharmaceuticals, Inc. ("Supernus").

Pursuant to Federal Rules of Civil Procedure 8(b)(3), Defendants deny all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported

conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts.

RESPONSE TO "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: Defendants admit that, on its face, the Complaint purports to be an action for patent infringement of United States Patent Nos. 9,358,204 (the "'204 patent"); 9,603,853 (the "'853 patent"); 9,662,338 (the "'338 patent"); 11,324,753 (the "'753 patent"); 11,458,143 (the "'143 patent"); and 12,121,523 (the "'523 patent") (collectively, "the Patents-in-Suit") arising under the law of the United States of America relating to the Patents-in-Suit. Defendants also admit that, on its face, Exhibit A to the Complaint purports to be a copy of the '204 patent. Defendants also admit that, on its face, Exhibit B to the Complaint purports to be a copy of the '853 patent. Defendants also admit that, on its face, Exhibit C to the Complaint purports to be a copy of the '338 patent. Defendants also admit that, on its face, Exhibit D to the Complaint purports to be a copy of the '753 patent. Defendants also admit that, on its face, Exhibit E to the Complaint purports to be a copy of the '143 patent. Defendants also admit that, on its face, Exhibit F to the Complaint purports to be a copy of the '523 patent. Defendants deny any patent infringement as alleged by Supernus and specifically deny all legal conclusions in Paragraph 1. Defendants deny any remaining allegations in Paragraph 1.

RESPONSE TO "THE PARTIES"

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

ANSWER: Defendants lack sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 2, and therefore deny the same.

3. Upon information and belief, defendant Appco Pharma LLC is a corporation organized and existing under the laws of the State of New Jersey with principal places of business at 120 Belmont Drive, Somerset NJ 08873 and 262 Old New Brunswick Road, Suite N, Piscataway, New Jersey 08854.

ANSWER: Appco admits, and Somerset admits upon information and belief, the allegations of Paragraph 3.

4. Upon information and belief, defendant Somerset Therapeutics LLC is a limited liability company organized and existing under the laws of Delaware with a principal place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873.

ANSWER: Somerset admits, and Appco admits upon information and belief, the allegations of Paragraph 4.

RESPONSE TO "JURISDICTION AND VENUE"

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

ANSWER: Paragraph 5 calls for a legal conclusion to which no response is required. To the extent a response is required, Defendants state that, on its face, the Complaint appears to be an action arising under 28 U.S.C. §§ 1331 and 1338(a). Further, Defendants state that they are not contesting this Court's subject matter jurisdiction over this action only and reserve the right to contest subject matter jurisdiction in any other case or action.

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

ANSWER: Paragraph 6 calls for a legal conclusion to which no response is required. To the extent a response is required, Defendants state that they are not contesting this Court's personal jurisdiction in this action only. Defendants reserve the right to contest personal jurisdiction in any other case or action.

7. This Court has personal jurisdiction over Appco at least because, upon information and belief: (i) Appco maintains principal places of business in New Jersey located at 120 Belmont Drive, Somerset New Jersey 08873 and 262 Old New Brunswick Road, Suite N, Piscataway, New Jersey 08854; (ii) Appco is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iii) Appco is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (iv) Appco has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (v) Appco has previously admitted that the United States District Court for the District of New Jersey has personal jurisdiction over Appco;[1] (vi) Appco's website states: "Established in 2012, Appco is a **New Jersey based** generic drug development and manufacturing company. It operates through U.S. FDA-approved manufacturing sites in Piscataway NJ" (*see* http://appcopharma.com/about.html) (emphasis added); and (vii) if Abbreviated New Drug Application ("ANDA") No. 220326 ("Defendants' ANDA") receives final approval, Defendants' viloxazine extended-release capsules (100 mg, 150 mg, and 200 mg) ("Defendants' ANDA Products") will be marketed and distributed by Appco in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey.

ANSWER: Paragraph 7 calls for a legal conclusion to which no response is required. To the extent a response is required, Appco admits, and Somerset admits upon information and belief, that Appco engages in, among others, the business of developing and manufacturing pharmaceutical products, including products manufactured and sold according to approved ANDAs. Appco admits, and Somerset admits upon information and belief, that, to the extent the statement quoted in Paragraph 7(vi) accurately reproduces the language of Appco's website, that its website contains the statement recited in Paragraph 7(vi). Defendants further admit that Appco submitted ANDA No. 220326 ("Appco's ANDA") seeking FDA approval of the 100 mg, 150 mg, and 200 mg viloxazine extended-release capsulates that are the subject of ANDA No. 220326 ("Appco's ANDA Product"). Defendants are not contesting this Court's personal jurisdiction in this action only. Defendants reserve the right to contest personal jurisdiction in any other case or action. Defendants otherwise deny any remaining allegations of Paragraph 7.

8. Upon information and belief, Appco is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business

[1] *See, e.g.*, *Pfizer Inc. v. Appco Pharma Ltd.*, No. 3-18-cv-02272 (BRM) (TJB), ECF No. 19 (D.N.J.) (admitting personal jurisdiction and filing counterclaims).

Identification Numbers 0600414990 and 0600477799. Upon information and belief, Appco is registered with the State of New Jersey's Department of Health as a drug and medical device "manufacturer and wholesaler" with Registration Number 5004511.

ANSWER: Appco admits, and Somerset admits upon information and belief, the allegations of Paragraph 8.

9. This Court has personal jurisdiction over Somerset at least because, upon information and belief: (i) Somerset maintains an established and regular place of business in New Jersey located at 300 Franklin Square Drive, Somerset, New Jersey 08873; (ii) Somerset is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iii) Somerset is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (iv) Somerset has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (v) Somerset has previously consented and/or not contested that the United States District Court for the District of New Jersey has personal jurisdiction over Somerset;[2] (vi) Somerset has purposefully directed its activities at residents and corporate entities within the State of New Jersey; (vii) the claims set forth herein as to Somerset arise out of or relate to those activities; (viii) Somerset's contacts with the State of New Jersey (direct and/or indirect) are continuous and systematic; (ix) it is reasonable and fair for this Court to exercise personal jurisdiction over Somerset; (x) if Defendants' ANDA receives final approval, Defendants' ANDA Products will be marketed and distributed by Somerset 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.

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[2] *See, e.g.*, *Esperion Therapeutics, Inc. v. Renata Ltd*., No. 2:24-cv-06017 (JXN) (CLW), ECF No. 35 (D.N.J.) (filing counterclaims and not contesting personal jurisdiction); *Nexus Pharm., Inc. v. Somerset Therapeutics*, LLC, No. 3:23-cv-01248 (ZNQ) (RLS), ECF No. 8 (D.N.J.) (same); *American Regent, Inc. v. Somerset Therapeutics, LLC*, No. 24-cv-17807 (BRM) (CLW) , ECF No. 10 (D.N.J.) (same); *American Regent, Inc. v. Somerset Therapeutics, LLC*, No. 24-cv-01022 (BRM) (CLW), ECF No. 12 (D.N.J.) (same); *American Regent, Inc. v. Somerset Therapeutics, LLC*, No. 24-cv-01030 (BRM) (CLW), ECF No. 12 (D.N.J.) (same); *In re Selenious Acid Litig*., No. 24-cv-07791 (BRM) (CLW), ECF No. 75 (D.N.J.) (same); *Rayner Surgical Inc. v. Somerset*

[2]*See, e.g., Esperion Therapeutics, Inc. v. Renata Ltd.,* No. 2:24-cv-06017 (JXN) (CLW), ECF No. 35 (D.N.J.) (filing counterclaims and not contesting personal jurisdiction); *Nexus Pharm., Inc. v. Somerset Therapeutics, LLC,* No. 3:23-cv-01248 (ZNQ) (RLS), ECF No. 8 (D.N.J.) (same); *American Regent, Inc. v. Somerset Therapeutics, LLC,* No. 24-cv-17807 (BRM) (CLW) , ECF No. 10 (D.N.J.) (same); *American Regent, Inc. v. Somerset Therapeutics, LLC,* No. 24-cv-01022 (BRM) (CLW), ECF No. 12 (D.N.J.) (same); *American Regent, Inc. v. Somerset Therapeutics, LLC*, No. 24-cv-01030 (BRM) (CLW), ECF No. 12 (D.N.J.) (same); *In re Selenious Acid Litig.,* No. 24-cv-07791 (BRM) (CLW), ECF No. 75 (D.N.J.) (same); *Rayner Surgical Inc. v. Therapeutics, LLC*, No. 2:24-cv-09017 (GC) (JBD), ECF No. 9 (D.N.J.) (not contesting personal jurisdiction).

ANSWER: Paragraph 9 calls for a legal conclusion to which no response is required. To the extent a response is required, Somerset admits, and Appco admits upon information and belief, that Somerset engages in, among others, the business of developing and manufacturing pharmaceutical products, including products manufactured and sold according to approved ANDAs. Defendants further admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the Patents-in-Suit. Defendants are not contesting this Court's personal jurisdiction in this action only. Somerset reserves the right to contest personal jurisdiction in any other case or action. Defendants otherwise deny any remaining allegations of Paragraph 9.

10. Upon information and belief, Somerset is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0451084958. Upon information and belief, Somerset is registered with the State of New Jersey's Department of Health as a drug and medical device "manufacturer" with Registration Number 5004837.

ANSWER: Somerset admits, and Appco admits upon information and belief, the allegations of Paragraph 10.

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

ANSWER: Paragraph 11 calls for a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the Patents-in-Suit. Defendants otherwise deny any remaining allegations of Paragraph 11.

12. Upon information and belief, Defendants acted collaboratively in the preparation and submission of ANDA No. 220326 to the FDA.

ANSWER: Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above. Defendants deny any remaining allegations of Paragraph 12.

13. This Court has personal jurisdiction over Defendants at least because, upon information and belief, if ANDA No. 220326 receives final approval, Defendants' ANDA Products will be manufactured, sold, distributed, and/or used by Defendants in New Jersey, prescribed by physicians practicing in New Jersey, and/or administered to patients in New Jersey.

ANSWER: Paragraph 13 calls for a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the Patents-in-Suit. Defendants further state that they are not contesting this Court's personal jurisdiction in this action only. Defendants reserve the right to contest personal jurisdiction in any other case or action. Defendants otherwise deny any remaining allegations of Paragraph 13.

14. Upon information and belief, Defendants' acts of preparing and filing ANDA No. 220326 and directing notice of their ANDA submission to Plaintiff are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, and/or sale of Defendants' ANDA Products before the expiration of the patents-in-suit throughout the United States, including in this Judicial District. Because defending against an infringement lawsuit such as this one is an essential and expected part of an ANDA filer's business, Defendants reasonably anticipate being sued in New Jersey.

ANSWER: Paragraph 14 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco prepared and filed Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the Patents-in-Suit. Defendants further state that they are not contesting this Court's personal jurisdiction in this action only. Defendants reserve the right to contest personal jurisdiction in any other case or action. Defendants otherwise deny any remaining allegations of Paragraph 14.

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

ANSWER: Paragraph 15 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants state they are not contesting this Court's personal jurisdiction in this action only. Defendants reserve the right to contest personal jurisdiction in any other case or action. Defendants otherwise deny any remaining allegations of Paragraph 15.

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

ANSWER: Paragraph 16 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants state they are not contesting this Court's personal jurisdiction in this action only. Defendants reserve the right to contest personal jurisdiction in any other case or action. Defendants otherwise deny any remaining allegations of Paragraph 16.

17. Upon information and belief, Defendants will market Defendants' ANDA Products in New Jersey upon receiving final FDA approval of ANDA No. 220326.

ANSWER: Defendants state they are not contesting this Court's personal jurisdiction in this action only. Defendants reserve the right to contest personal jurisdiction in any other case or action. Defendants otherwise deny any remaining allegations of Paragraph 17.

18. Upon information and belief, Defendants have thus been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of ANDA No. 220326 and intend to benefit from ANDA No. 220326 upon receiving final FDA approval.

ANSWER: Defendants admit that Appco drafted and submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above and is seeking final FDA approval of ANDA No. 220326. Defendants deny any remaining allegations of Paragraph 18.

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

ANSWER: Paragraph 19 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants state that they are not contesting venue solely for the purpose of this action and reserve the right to contest venue in any other case or action. Defendants otherwise deny any remaining allegations of Paragraph 19.

RESPONSE TO "FACTS COMMON TO ALL COUNTS"

20. Upon information and belief, on or about May 21, 2025, Defendants sent a letter pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95) regarding the paragraph IV certification that Defendants submitted in ANDA No. 220326 and the patents-in-suit (the "May 21, 2025, Notice Letter") to Supernus at 9715 Key West Avenue, Rockville, Maryland 20850.

ANSWER: Defendants admit that, by letter dated May 21, 2025, and received by Supernus via FedEx no later than on May 22, 2025 ("Defendants' First Notice Letter"), Defendants informed Supernus that Appco had submitted Appco's ANDA to the FDA for approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the Patents-in-Suit. Defendants otherwise deny the allegations of Paragraph 20.

21. The May 21, 2025, Notice Letter included an Offer of Confidential Access ("OCA") to unspecified portions of ANDA No. 220326, purportedly pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). The OCA accompanying the May 21, 2025, Notice Letter did not identify Supernus as the "Receiving Party."

ANSWER: Defendants state that the Offer of Confidential Access in Defendants' First Notice Letter speaks for itself. Defendants otherwise deny the allegations of Paragraph 21.

22. Upon information and belief, on or about June 9, 2025, Defendants sent a second letter pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95) regarding the paragraph IV certification that Defendants submitted in ANDA No. 220326 and the patents-in-suit (the "June 9, 2025, Notice Letter," and together with the May 21, 2025, Notice Letter, "the Notice Letters") to Supernus at 9715 Key West Avenue, Rockville, Maryland 20850.

ANSWER: Defendants admit that, by letter dated June 9, 2025, and received by Supernus via FedEx no later than on June 10, 2025 ("Defendants' Second Notice Letter"), Defendants informed Supernus that Appco had submitted Appco's ANDA to the FDA for approval

of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the Patents-in-Suit. Defendants otherwise deny the allegations of Paragraph 22.

23. The June 9, 2025, Notice Letter included an OCA to unspecified portions of ANDA No. 220326, purportedly pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). The OCA accompanying the June 9, 2025, Notice Letter, for the first time, identified Supernus as the "Receiving Party."

ANSWER: Defendants state that the Offer of Confidential Access in Defendants' Second Notice Letter speaks for itself. Defendants otherwise deny the allegations of Paragraph 23.

24. Defendants' OCA accompanying the June 9, 2025, Notice Letter contained numerous unreasonable and overly restrictive provisions. Plaintiff proposed revisions that comport with restrictions that "would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." *See* 21 U.S.C. § 355. Plaintiff and Defendants did not reach agreement on the terms of an Offer of Confidential Access and, to date, Defendants have not produced a copy of ANDA No. 220326 to Plaintiff.

ANSWER: Defendants deny the allegations of Paragraph 24.

25. According to the Notice Letters, Defendants filed Defendants' ANDA with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Defendants' ANDA Products.

ANSWER: Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the Patents-in-Suit. Defendants otherwise deny any remaining allegations of Paragraph 25.

26. The Notice Letters both state that "[t]his is a notice of certification letter on behalf of Appco Pharma LLC ('Appco'), for itself, **and its partner** Somerset Therapeutics LLC ('Somerset')." (emphasis added).

ANSWER: Defendants state that Defendant's First and Second Notice Letters speak for themselves. Defendants otherwise deny any remaining allegations of Paragraph 26.

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

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

ANSWER: Defendants admit that both Somerset and Appco each engage in, among others, the business of developing and manufacturing pharmaceutical products, including products manufactured and sold according to approved ANDAs. Defendants otherwise deny any remaining allegations of Paragraph 27.

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

ANSWER: Paragraph 28 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 28.

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

ANSWER: Defendants admit that both Somerset and Appco each engage in, among others, the business of developing and manufacturing pharmaceutical products, including products manufactured and sold according to approved ANDAs. Defendants otherwise deny any remaining allegations of Paragraph 29.

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

ANSWER: Defendants admit that both Somerset and Appco derive revenue from directly or indirectly selling pharmaceutical products, including products manufactured and sold according to approved ANDAs. Defendants otherwise deny any remaining allegations of Paragraph 30.

31. Appco's website states: "Established in 2012, Appco is a New Jersey based generic drug development and manufacturing company. It operates through U.S. FDA-approved manufacturing sites in Piscataway NJ." (http://appcopharma.com/about.html.)

ANSWER: Defendants state that Appco's website speaks for itself. Defendants otherwise deny any remaining allegations of Paragraph 31.

32. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 C.F.R. § 314.95(c)(7) requires that such a letter include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)-(ii).

ANSWER: Paragraph 32 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 32.

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

ANSWER: Defendants admit the allegations of Paragraph 33.

34. Upon information and belief, the Notice Letters do not disclose any invalidity contentions or opinions specifically directed to any claims of the '204 patent, the '853 patent, or the '338 patent. Accordingly, upon information and belief, Defendants acknowledge and admit that the '204 patent, the '853 patent, and the '338 patent are not invalid.

ANSWER: Defendants deny the allegations of Paragraph 34.

35. Upon information and belief, the Notice Letters do not disclose any unenforceability contentions for the patents-in-suit.

ANSWER: Defendants admit that Defendants' First and Second Notice Letters did not contain unenforceability contentions.

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

ANSWER: Upon information and belief, admitted.

37. 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: Defendants admit that, on its face, the prescribing information for Qelbree® states it 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.

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

- Pediatric patients 6 to 11 years of age: Recommended starting dosage is 100 mg once daily. May titrate in increments of 100 mg weekly to the maximum recommended dosage of 400 mg once daily
- Pediatric patients 12 to 17 years of age: Recommended starting dosage is 200 mg once daily. May titrate after 1 week, by an increment of 200mg, to the maximum recommended dosage of 400 mg once daily
- Adult patients: Recommended starting dosage is 200 mg once daily. May titrate in increments of 200 mg weekly, to maximum recommended dosage of 600 mg once daily
- Capsules may be swallowed whole or opened and the entire contents sprinkled onto applesauce or pudding
- Severe Renal Impairment: Initial dosage is 100 mg once daily. Titrate in weekly increments of 50 mg to 100 mg to a maximum recommended dosage of 200 mg once daily

ANSWER: To the extent that Paragraph 38 accurately reproduces the "Dosage and Administration" section of the Qelbree® label, admitted.

39. 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 the FDA with or after the approval of NDA No. 211964. The patents-in-suit are listed in the Orange Book as covering Qelbree®.

ANSWER: Upon information and belief, Defendants admit that the Orange Book lists the Patents-in-Suit for NDA No. 211964. Defendants deny the remaining allegations of Paragraph 39.

40. 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: Defendants admit, that on its face, the '204 patent is entitled "Formulations of Viloxazine" and purports to have been issued on June 7, 2016. Defendants further admit that, on its face, the '204 patent lists Michael L. Viera, Austin B. Huang, and Padmanabh P. Bhatt as inventors and Supernus Pharmaceuticals Inc. as the Assignee. Defendants deny that the '204 patent was duly and legally issued. Defendants lack sufficient knowledge or information to form an opinion or belief as to the remaining allegations of Paragraph 40, and therefore deny the same.

41. 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: Defendants admit, that on its face, the '853 patent is entitled "Formulations of Viloxazine" and purports to have been issued on March 28, 2017. Defendants further admit that, on its face, the '853 patent lists Michael L. Viera, Austin B. Huang, and Padmanabh P. Bhatt as inventors and Supernus Pharmaceuticals Inc. as the Assignee. Defendants deny that the '853 patent was duly and legally issued. Defendants lack sufficient knowledge or information to form an opinion or belief as to the remaining allegations of Paragraph 41, and therefore deny the same.

42. 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: Defendants admit, that on its face, the '338 patent is entitled "Formulations of Viloxazine" and purports to have been issued on May 30, 2017. Defendants further admit that, on its face, the '338 patent lists Michael L. Viera, Austin B. Huang, and Padmanabh P. Bhatt as inventors and Supernus Pharmaceuticals Inc. as the Assignee. Defendants deny that the '338 patent was duly and legally issued. Defendants lack sufficient knowledge or information to form an opinion or belief as to the remaining allegations of Paragraph 42, and therefore deny the same.

43. 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: Defendants admit, that on its face, the ’753 patent is entitled “Methods of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)” and purports to have been issued on May 10, 2022. Defendants further admit that, on its face, the ’753 patent lists Christopher D. Breder as inventor and Supernus Pharmaceuticals Inc. as the Assignee. Defendants deny that the ’753 patent was duly and legally issued. Defendants lack sufficient knowledge or information to form an opinion or belief as to the remaining allegations of Paragraph 43, and therefore deny the same.

44. 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: Defendants admit, that on its face, the ’143 patent is entitled “Methods of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)” and purports to have been issued on October 4, 2022. Defendants further admit that, on its face, the ’143 patent lists Christopher D. Breder as inventor and Supernus Pharmaceuticals Inc. as the Assignee. Defendants deny that the ’143 patent was duly and legally issued. Defendants lack sufficient knowledge or information to form an opinion or belief as to the remaining allegations of Paragraph 44, and therefore deny the same.

45. 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: Defendants admit, that on its face, the ’523 patent is entitled “Methods of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)” and purports to have been issued

on October 22, 2024. Defendants further admit that, on its face, the '523 patent lists Christopher D. Breder as inventor and Supernus Pharmaceuticals Inc. as the Assignee. Defendants deny that the '523 patent was duly and legally issued. Defendants lack sufficient knowledge or information to form an opinion or belief as to the remaining allegations of Paragraph 45, and therefore deny the same.

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

ANSWER: Defendants admit that Appco has identified Qelbree® (viloxazine extended-release capsules), 100 mg, 150 mg and 200 mg as the reference-listed drug for Appco's ANDA. Defendants otherwise deny any remaining allegations of Paragraph 46.

47. Upon information and belief, Defendants' ANDA Products are viloxazine extended-release capsules, 100 mg, 150 mg and 200 mg.

ANSWER: Defendants admit that Appco's ANDA seeks approval of Appco's ANDA Product, as defined by Defendants above, which includes viloxazine extended-release capsules in the 100 mg, 150 mg, and 200 mg strengths. Defendants otherwise deny any remaining allegations of Paragraph 47.

48. Upon information and belief, Defendants have represented to FDA in ANDA No. 220326 that Defendants' ANDA Products are bioequivalent to Qelbree®.

ANSWER: Defendants admit that Appco has represented to the FDA that Appco's ANDA product is bioequivalent to Qelbree®. Defendants otherwise deny any remaining allegations of Paragraph 48.

49. 21 U.S.C. § 355(j)(2)(A)(i) requires that an ANDA contain "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7)." In addition, 21 U.S.C. § 355(j)(2)(A)(v) provides that an ANDA must contain "information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers."

ANSWER: Paragraph 49 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 49.

50. The Notice Letters do not indicate that Defendants intend to market Defendants' ANDA Products with labeling that materially differs from the Qelbree® label, including, for example, in terms of indications and usage, dosage and administration, dosage forms and strengths, contraindications, warnings and precautions, adverse reactions, drug interactions, use in specific populations, overdosage, description, clinical pharmacology, nonclinical toxicology, clinical studies, how supplied/storage and handling, patient counseling information, or composition of Defendants' ANDA Products. *See, e.g.,* https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/211964s013lbl.pdf#page=21 (last visited June 17, 2025).

ANSWER: Paragraph 50 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 50.

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

ANSWER: Defendants admit that the proposed prescribing information for Appco's ANDA Product, as defined by Defendants above, will include information pertaining to the indication and usage of Appco's ANDA Product. Defendants otherwise deny any remaining allegations of Paragraph 51.

52. Upon information and belief, the proposed prescribing information for Defendants' ANDA Products includes a section titled, "Dosage and Administration," containing information about the recommended dosage for adult and pediatric patients. Upon information and belief, the proposed prescribing information for Defendants' ANDA Products recommends: (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: Defendants admit that the proposed prescribing information for Appco's ANDA Product, as defined by Defendants above, will include information pertaining to the dosage and administration of Appco's ANDA Product. Defendants otherwise deny any remaining allegations of Paragraph 52.

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

ANSWER: Defendants admit that the proposed prescribing information for Appco's ANDA Product, as defined by Defendants above, will include information pertaining to the mechanism of action of Appco's ANDA Product. Defendants otherwise deny any remaining allegations of Paragraph 53.

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

ANSWER: Defendants admit that the proposed prescribing information for Appco's ANDA Product, as defined by Defendants above, will include information pertaining to the pharmacodynamics of Appco's ANDA Product. Defendants otherwise deny any remaining allegations of Paragraph 54.

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

ANSWER: Defendants admit that the proposed prescribing information for Appco's ANDA Product, as defined by Defendants above, will include information pertaining to side effects of Appco's ANDA Product. Defendants otherwise deny any remaining allegations of Paragraph 55.

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

ANSWER: Defendants deny the allegations of Paragraph 56.

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

ANSWER: Defendants deny the allegations of Paragraph 57.

RESPONSE TO "FIRST COUNT
(Defendants' Infringement of the '204 Patent)"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, Defendants incorporate by reference their response to each preceding paragraph as if fully set forth herein.

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

ANSWER: Paragraph 59 contains a legal conclusion to which no response it required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '204 patent. Defendants deny the remaining allegations of Paragraph 59.

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

ANSWER: Defendants deny the allegations of Paragraph 60.

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

ANSWER: Defendants deny the allegations of Paragraph 61.

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

ANSWER: Paragraph 62 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 62.

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

ANSWER: Paragraph 63 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '204 patent. Defendants deny the remaining allegations of Paragraph 63.

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

ANSWER: Defendants admit the allegations of Paragraph 64.

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

ANSWER: Paragraph 65 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit to sending Defendants' First and Second Notice Letters to Supernus. Defendants further admit Defendants' First and Second Notice Letters were sent pursuant to 21 U.S.C. § 355(j)(2)(B)(iv). Defendants deny the remaining allegations of Paragraph 65.

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

ANSWER: Paragraph 66 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 66.

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

ANSWER: Paragraph 67 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants lack sufficient information to admit or deny the allegations of Paragraph 67, and therefore deny the same.

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

ANSWER: Paragraph 68 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 68.

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

ANSWER: Paragraph 69 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '204 patent. Defendants deny the remaining allegations of Paragraph 69.

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

ANSWER: Defendants deny the allegations of Paragraph 70.

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

ANSWER: Paragraph 71 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 71.

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

ANSWER: Paragraph 72 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 72.

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

ANSWER: Paragraph 73 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 73.

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

ANSWER: Paragraph 74 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 74.

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

ANSWER: Paragraph 75 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 75.

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

ANSWER: Paragraph 76 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 76.

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

ANSWER: Paragraph 77 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 77.

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

ANSWER: Paragraph 78 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 78.

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

ANSWER: Paragraph 79 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 79.

RESPONSE TO "SECOND COUNT
(Defendants' Infringement of the '853 Patent)"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, Defendants incorporate by reference their response to each preceding paragraph as if fully set forth herein.

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

ANSWER: Paragraph 81 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '853 patent. Defendants deny the remaining allegations of Paragraph 81.

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

ANSWER: Defendants deny the allegations of Paragraph 82.

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

ANSWER: Defendants deny the allegations of Paragraph 83.

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

ANSWER: Paragraph 84 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 84.

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

ANSWER: Paragraph 85 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '853 patent. Defendants deny the remaining allegations of Paragraph 85.

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

ANSWER: Defendants admit the allegations of Paragraph 86.

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

ANSWER: Paragraph 87 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit to sending Defendants' First and Second Notice Letters to Supernus. Defendants further admit that Defendants' First and Second Notice Letters were sent pursuant to 21 U.S.C. § 355(j)(2)(B)(iv). Defendants deny the remaining allegations of Paragraph 87.

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

ANSWER: Paragraph 88 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 88.

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

ANSWER: Paragraph 89 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the Patents-in-Suit. Defendants deny the remaining allegations of Paragraph 89.

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

ANSWER: Paragraph 90 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 90.

91. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Defendants' ANDA Products prior to the expiration of the '853 patent will directly infringe

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

ANSWER: Paragraph 91 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco’s ANDA seeking FDA approval of Appco’s ANDA Product, as defined by Defendants above, prior to the expiration of the ’853 patent. Defendants deny the remaining allegations of Paragraph 91.

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

ANSWER: Defendants deny the allegations of Paragraph 92.

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

ANSWER: Paragraph 93 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 93.

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

ANSWER: Paragraph 94 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 94.

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

ANSWER: Paragraph 95 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 95.

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

ANSWER: Paragraph 96 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 96.

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

ANSWER: Paragraph 97 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 97.

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

ANSWER: Paragraph 98 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 98.

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

ANSWER: Paragraph 99 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 99.

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

ANSWER: Paragraph 100 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 100.

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

ANSWER: Paragraph 101 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 101.

RESPONSE TO "THIRD COUNT
(Defendants' Infringement of the '338 Patent)"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, Defendants incorporate by reference their response to each preceding paragraph as if fully set forth herein.

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

ANSWER: Paragraph 103 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '338 patent. Defendants deny the remaining allegations of Paragraph 103.

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

ANSWER: Defendants deny the allegations of Paragraph 104.

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

ANSWER: Defendants deny the allegations of Paragraph 105.

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

ANSWER: Paragraph 106 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 106.

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

ANSWER: Paragraph 107 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '338 patent. Defendants deny the remaining allegations of Paragraph 107.

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

ANSWER: Defendants admit the allegations of Paragraph 108.

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

ANSWER: Paragraph 109 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit to sending Defendants' First and Second Notice Letters to Supernus. Defendants further admit that Defendants' First and Second Notice Letters were sent pursuant to 21 U.S.C. § 355(j)(2)(B)(iv). Defendants deny the remaining allegations of Paragraph 109.

110. Under 35 U.S.C. § 271(e)(2)(A), the submission of Defendants' ANDA with a paragraph IV certification to the '338 patent for the purpose of obtaining approval to engage in the

commercial manufacture, use, or sale of Defendants' ANDA Products before the expiration of the '338 patent is itself an act of infringement of the '338 patent.

ANSWER: Paragraph 110 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 110.

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

ANSWER: Paragraph 111 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the Patents-in-Suit. Defendants deny the remaining allegations of Paragraph 111.

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

ANSWER: Paragraph 112 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 112.

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

ANSWER: Paragraph 113 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '338 patent. Defendants deny the remaining allegations of Paragraph 113.

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

ANSWER: Defendants deny the allegations of Paragraph 114.

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

ANSWER: Paragraph 115 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 115.

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

ANSWER: Paragraph 116 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 116.

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

ANSWER: Paragraph 117 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 117.

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

ANSWER: Paragraph 118 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 118.

119. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendants' ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to the infringement of the '338 patent by third parties because: (i) Defendants' ANDA Products

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

ANSWER: Paragraph 119 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 119.

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

ANSWER: Paragraph 120 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 120.

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

ANSWER: Paragraph 121 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 121.

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

ANSWER: Paragraph 122 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 122.

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

ANSWER: Paragraph 123 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 123.

RESPONSE TO "FOURTH COUNT
(Defendants' Infringement of the '753 Patent)"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, Defendants incorporate by reference their response to each preceding paragraph as if fully set forth herein.

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

ANSWER: Paragraph 125 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '753 patent. Defendants deny the remaining allegations of Paragraph 125.

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

ANSWER: Defendants deny the allegations of Paragraph 126.

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

ANSWER: Defendants deny the allegations of Paragraph 127.

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

ANSWER: Paragraph 128 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 128.

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

ANSWER: Paragraph 129 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '753 patent. Defendants deny the remaining allegations of Paragraph 129.

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

ANSWER: Defendants admit the allegations of Paragraph 130.

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

ANSWER: Paragraph 131 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit to sending Defendants' First and Second Notice Letters to Supernus. Defendants further admit that Defendants' First and Second Notice Letters were sent pursuant to 21 U.S.C. § 355(j)(2)(B)(iv). Defendants deny the remaining allegations of Paragraph 131.

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

ANSWER: Paragraph 132 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 132.

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

ANSWER: Paragraph 133 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the Patents-in-Suit. Defendants deny the remaining allegations of Paragraph 133.

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

ANSWER: Paragraph 134 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 134.

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

ANSWER: Paragraph 135 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '753 patent. Defendants deny the remaining allegations of Paragraph 135.

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

ANSWER: Defendants deny the allegations of Paragraph 136.

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

ANSWER: Paragraph 137 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 137.

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

ANSWER: Paragraph 138 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 138.

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

ANSWER: Paragraph 139 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 139.

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

ANSWER: Paragraph 140 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 140.

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

ANSWER: Paragraph 141 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 141.

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

ANSWER: Paragraph 142 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 142.

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

ANSWER: Paragraph 143 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 143.

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

ANSWER: Paragraph 144 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 144.

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

ANSWER: Paragraph 145 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 145.

RESPONSE TO "FIFTH COUNT
(Defendants' Infringement of the '143 Patent)"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, Defendants incorporate by reference their response to each preceding paragraph as if fully set forth herein.

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

ANSWER: Paragraph 147 contains a legal conclusion to which no response it required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA

seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '143 patent. Defendants deny the remaining allegations of Paragraph 147.

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

ANSWER: Defendants deny the allegations of Paragraph 148.

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

ANSWER: Defendants deny the allegations of Paragraph 149.

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

ANSWER: Paragraph 150 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 150.

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

ANSWER: Paragraph 151 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '143 patent. Defendants deny the remaining allegations of Paragraph 151.

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

ANSWER: Defendants admit the allegations of Paragraph 152.

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

ANSWER: Paragraph 153 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit to sending Defendants' First and Second Notice Letters to Supernus. Defendants further admit Defendants' First and Second Notice Letters were sent pursuant to 21 U.S.C. § 355(j)(2)(B)(iv). Defendants deny the remaining allegations of Paragraph 153.

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

ANSWER: Paragraph 154 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 154.

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

ANSWER: Paragraph 155 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the Patents-in-Suit. Defendants deny the remaining allegations of Paragraph 155.

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

ANSWER: Paragraph 156 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 156.

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

ANSWER: Paragraph 157 contains a legal conclusion to which no response is required. To the extent a response is required, Appco admits, and Somerset admits upon information and belief, that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '143 patent. Defendants deny the remaining allegations of Paragraph 157.

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

ANSWER: Defendants deny the allegations of Paragraph 158.

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

ANSWER: Paragraph 159 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 159.

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

ANSWER: Paragraph 160 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 160.

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

ANSWER: Paragraph 161 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 161.

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

ANSWER: Paragraph 162 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 162.

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

ANSWER: Paragraph 163 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 163.

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

ANSWER: Paragraph 164 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 164.

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

ANSWER: Paragraph 165 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 165.

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

ANSWER: Paragraph 166 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 166.

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

ANSWER: Paragraph 167 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 167.

RESPONSE TO "SIXTH COUNT
(Defendants' Infringement of the '523 Patent)"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, Defendants incorporate by reference their response to each preceding paragraph as if fully set forth herein.

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

ANSWER: Paragraph 169 contains a legal conclusion to which no response it required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '523 patent. Defendants deny the remaining allegations of Paragraph 169.

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

ANSWER: Defendants deny the allegations of Paragraph 170.

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

ANSWER: Defendants deny the allegations of Paragraph 171.

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

ANSWER: Paragraph 172 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 172.

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

ANSWER: Paragraph 173 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '523 patent. Defendants deny the remaining allegations of Paragraph 173.

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

ANSWER: Defendants admit the allegations of Paragraph 174.

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

ANSWER: Paragraph 175 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit to sending Defendants' First and Second Notice Letters to Supernus. Defendants further admit that Defendants' First and Second Notice Letters were sent pursuant to 21 U.S.C. § 355(j)(2)(B)(iv). Defendants deny the remaining allegations of Paragraph 175.

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

ANSWER: Paragraph 176 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 176.

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

ANSWER: Paragraph 177 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the Patents-in-Suit. Defendants deny the remaining allegations of Paragraph 177.

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

ANSWER: Paragraph 178 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 178.

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

ANSWER: Paragraph 179 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that Appco submitted Appco's ANDA seeking FDA approval of Appco's ANDA Product, as defined by Defendants above, prior to the expiration of the '523 patent. Defendants deny the remaining allegations of Paragraph 179.

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

ANSWER: Defendants deny the allegations of Paragraph 180.

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

ANSWER: Paragraph 181 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 181.

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

ANSWER: Paragraph 182 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 182.

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

ANSWER: Paragraph 183 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 183.

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

ANSWER: Paragraph 184 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 184.

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

ANSWER: Paragraph 185 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 185.

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

ANSWER: Paragraph 186 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 186.

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

ANSWER: Paragraph 187 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 187.

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

ANSWER: Paragraph 188 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 188.

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

ANSWER: Paragraph 189 contains a legal conclusion to which no response is required.

To the extent a response is required, Defendants deny the allegations of Paragraph 189.

RESPONSE TO "REQUEST FOR RELIEF"

Defendants deny that Plaintiff is entitled to any relief requested by the Complaint, or any other relief whatsoever.

SEPARATE DEFENSES

Defendants assert the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. Defendants do not assume any of the burden of proof on any asserted defenses, except those that are required by the applicable law governing the defense. Defendants reserve the right to assert other defenses and/or otherwise supplement or amend its Answer and Separate Defenses to the Complaint upon discovery of fact or evidence rendering such action appropriate.

FIRST SEPARATE DEFENSE
(Non-Infringement of the '204 Patent)

The manufacture, use, sale, offer for sale, or importation of Appco's ANDA Product have not, do not, and will not infringe any valid and enforceable claim of the '204 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

SECOND SEPARATE DEFENSE
(Invalidity of the '204 Patent)

For at least the reasons stated in the Confidential and Detailed Legal Bases for their Paragraph IV Certification as to the '204 patent accompanying Defendants' First and Second Notice Letters, the claims of the '204 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 et seq., including but not limited to § 102, § 103, and § 112, statutory and obviousness-type double patenting, and the defenses recognized in 35 U.S.C. § 282(b).

THIRD SEPARATE DEFENSE
(Non-Infringement of the '853 Patent)

The manufacture, use, sale, offer for sale, or importation of Appco's ANDA Product have not, do not, and will not infringe any valid and enforceable claim of the '853 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

FOURTH SEPARATE DEFENSE
(Invalidity of the '853 Patent)

For at least the reasons stated in the Confidential and Detailed Legal Bases for their Paragraph IV Certification as to the '853 patent accompanying Defendants' First and Second Notice Letters, the claims of the '853 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 et seq., including but not limited to § 102, § 103, and § 112, statutory and obviousness-type double patenting, and the defenses recognized in 35 U.S.C. § 282(b).

FIFTH SEPARATE DEFENSE
(Non-Infringement of the '338 Patent)

The manufacture, use, sale, offer for sale, or importation of Appco's ANDA Product have not, do not, and will not infringe any valid and enforceable claim of the '338 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

SIXTH SEPARATE DEFENSE
(Invalidity of the '338 Patent)

For at least the reasons stated in the Confidential and Detailed Legal Bases for their Paragraph IV Certification as to the '338 patent accompanying Defendants' First and Second Notice Letters, the claims of the '338 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 et seq., including but not limited to § 102, § 103, and § 112, statutory and obviousness-type double patenting, and the defenses recognized in 35 U.S.C. § 282(b).

SEVENTH SEPARATE DEFENSE
(Non-Infringement of the '753 Patent)

The manufacture, use, sale, offer for sale, or importation of Appco's ANDA Product have not, do not, and will not infringe any valid and enforceable claim of the '753 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

EIGHT SEPARATE DEFENSE
(Invalidity of the '753 Patent)

For at least the reasons stated in the Confidential and Detailed Legal Bases for their Paragraph IV Certification as to the '753 patent accompanying Defendants' First and Second Notice Letters, the claims of the '753 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 et seq., including but not limited to § 102, § 103, and § 112, statutory and obviousness-type double patenting, and the defenses recognized in 35 U.S.C. § 282(b).

NINTH SEPARATE DEFENSE
(Non-Infringement of the '143 Patent)

The manufacture, use, sale, offer for sale, or importation of Appco's ANDA Product have not, do not, and will not infringe any valid and enforceable claim of the '143 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

TENTH SEPARATE DEFENSE
(Invalidity of the '143 Patent)

For at least the reasons stated in the Confidential and Detailed Legal Bases for their Paragraph IV Certification as to the '143 patent accompanying Defendants' First and Second Notice Letters, the claims of the '143 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 et seq., including but not limited to § 102, § 103, and § 112, statutory and obviousness-type double patenting, and the defenses recognized in 35 U.S.C. § 282(b).

ELEVENTH SEPARATE DEFENSE
(Non-Infringement of the ' 523 Patent)

The manufacture, use, sale, offer for sale, or importation of Appco's ANDA Product have not, do not, and will not infringe any valid and enforceable claim of the '523 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

TWELFTH SEPARATE DEFENSE
(Invalidity of the '523 Patent)

For at least the reasons stated in the Confidential and Detailed Legal Bases for their Paragraph IV Certification as to the '523 patent accompanying Defendants' First and Second Notice Letters, the claims of the '523 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 et seq., including but not limited to § 102, § 103, and § 112, statutory and obviousness-type double patenting, and the defenses recognized in 35 U.S.C. § 282(b).

THIRTEENTH SEPARATE DEFENSE
(Failure to State a Claim)

The Complaint is subject to dismissal for failure to state a claim upon which relief may be granted.

FOURTEENTH SEPARATE DEFENSE
(Additional Defenses or Counterclaims)

Defendants reserve all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent laws and any additional defenses or counterclaims, such as claims of inequitable conduct during the prosecution of one or more of the Patents-in-Suit, that discovery may reveal, including that Plaintiff has failed to aver any facts supporting that this is an exceptional case and an award of attorneys' fees under 35 U.S.C. § 285.

COUNTERCLAIMS

For its counterclaims against Counterclaim-Defendant Supernus Pharmaceuticals, Inc. (collectively, "Counterclaim-Defendant"), Counterclaim-Plaintiffs Appco Pharma LLC ("Appco") and Somerset Pharmaceuticals, LLC ("Somerset," and collectively with Appco, "Counterclaim-Plaintiffs"), state as follows:

Parties

1. Appco Pharma LLC is a corporation organized and existing under the laws of the State of New Jersey with principal places of business at 120 Belmont Drive, Somerset NJ 08873 and 262 Old New Brunswick Road, Suite N, Piscataway, New Jersey 08854.

2. Somerset Therapeutics, LLC is a limited liability company organized and existing under the laws of Delaware with a principal place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873.

3. Upon information and belief, 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.

Jurisdiction and Venue

4. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. §§ 1, 271(e)(5), 1331, 1338(a), *et seq.*, the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA"), 21 Y.S.C. § 355(j)()(C)(i), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202; 35 U.S.C. § 271(e)(5); and 21 U.S.C. § 355 (j)(5)(C)(i).

6. This Court has personal jurisdiction over Supernus because it availed itself to the rights and privileges of this forum by bringing this civil action in this Judicial District, and because, upon information and belief, Counterclaim-Defendant conducts substantial business in, and has regular and systemic contact with, this Judicial District.

7. Venue for these counterclaims is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b) based on the fact that Supernus has asserted the patents-in-suit against Appco and Somerset in this Judicial District.

Factual Background

8. Supernus holds the New Drug Application ("NDA") No. 211964 for which the United States Food and Drug Administration ("FDA") granted approval for the manufacture and sale of the active ingredient viloxazine extended-release capsules 100 mg, 150 mg, and 200 mg, which is prescribed and sold in the United States under the brand name Qelbree®.

9. Counterclaim-Plaintiff Appco filed Abbreviated New Drug Application ("ANDA") No. 220326 seeking approval from the FDA of generic viloxazine extended-release capsules 100 mg, 150 mg, and 200 mg, as described therein.

10. Upon information and belief, and upon its representations in the Complaint, Counterclaim-Defendant purports to own and to have the right to enforce 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") (the "Counterclaim Patents").

11. The Counterclaim Patents are listed in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") in association with the Qelbree® drug product. As a result of such a listing, Counterclaim-Defendant maintains, and has affirmatively asserted, that a claim for patent infringement could be asserted against any generic ANDA applicant attempting of a generic product before patent expiration, including Counterclaim-Plaintiffs.

12. Counterclaim-Plaintiffs have certified to the FDA that its ANDA product will not infringe the Counterclaim Patents, or that such patents are invalid and/or unenforceable, and have

further notified Supernus of the legal and factual bases for that certification. This created the necessary case or controversy for Counterclaim-Plaintiffs to file and maintain a counterclaim for declaratory judgment of patent non-infringement and/or invalidity of Counterclaim Patents.

13. Supernus has already created a substantial controversy through its suit of Counterclaim-Plaintiffs for alleged infringement of the Counterclaim Patents. There is an actual, substantial, and continuing justiciable case and controversy between Counterclaim-Plaintiffs (on one side) and Supernus (on the other) regarding whether Counterclaim-Plaintiffs will infringe at least one valid claim of the Counterclaim Patents, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

14. Counterclaim-Plaintiffs are entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of Counterclaim-Plaintiffs' ANDA Product do not and will not infringe the Counterclaim Patents, and/or that such patents are invalid. Absent the exercise of jurisdiction by this Court and such declaratory relief, Counterclaim-Plaintiffs will be harmed by the delay of market entry of its 100 mg, 150 mg, and 200 mg viloxazine extended-release capsules described in ANDA No. 220326.

U.S. Patent No. 9,358,204

15. The '204 patent is listed in the Orange Book in association with NDA No. 211964 for Qelbree® viloxazine extended-release capsules 100 mg, 150 mg, and 200 mg.

16. On June 7, 2016, the United States Patent and Trademark Office ("USPTO") issued the '204 patent, entitled "Formulations of Viloxazine."

17. Upon information and belief, Supernus holds all substantial rights to the '204 patent.

18. Counterclaim-Plaintiffs submitted ANDA No. 220326 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval of the 100 mg, 150 mg, and 200 mg viloxazine extended-release capsules described therein in the United States, prior to the expiration of the '204 patent. That ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '204 patent is invalid, unenforceable, and/or will not be infringed.

19. By letter dated May 21, 2025, Counterclaim-Plaintiffs provided Supernus with notice of the filing of ANDA No. 220326 and that said ANDA contained a Paragraph IV Certification with respect to the '204 patent, as required under 21 U.S.C. § 355(j)(2)(B) ("Counterclaim-Plaintiffs' First Notice Letter").

20. Counterclaim-Plaintiffs' First Notice Letter contained an Offer of Confidential Access to its ANDA No. 220326 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

21. By letter dated June 9, 2025, Counterclaim-Plaintiffs provided Supernus with notice of the filing of ANDA No. 220326 and that said ANDA contained a Paragraph IV Certification with respect to the '204 patent, as required under 21 U.S.C. § 355(j)(2)(B) ("Counterclaim-Plaintiffs' Second Notice Letter").

22. Counterclaim-Plaintiffs' Second Notice Letter contained an Offer of Confidential Access to its ANDA No. 220326 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

23. On June 26, 2025, Supernus initiated this civil action, 2:25-cv-12183, against Counterclaim-Plaintiffs in this Judicial District alleging infringement of the '204 patent.

24. For at least the reasons stated in their First and Second Notice Letters, Counterclaim-Plaintiffs seek a declaratory judgment that the '204 patent is not valid and/or is not infringed.

U.S. Patent No. 9,603,853

25. The ’853 patent is listed in the Orange Book in association with NDA No. 211964 for Qelbree® viloxazine extended-release capsules 100 mg, 150 mg, and 200 mg.

26. On March 28, 2017, the United States Patent and Trademark Office (“USPTO”) issued the ’853 patent, entitled “Formulations of Viloxazine.”

27. Upon information and belief, Supernus holds all substantial rights to the ’853 patent.

28. Counterclaim-Plaintiffs submitted ANDA No. 220326 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval of the 100 mg, 150 mg, and 200 mg viloxazine extended-release capsules described therein in the United States, prior to the expiration of the ’853 patent. That ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) that the ’853 patent is invalid, unenforceable, and/or will not be infringed.

29. By letter dated May 21, 2025, Counterclaim-Plaintiffs provided Supernus with notice of the filing of ANDA No. 220326 and that said ANDA contained a Paragraph IV Certification with respect to the ’853 patent, as required under 21 U.S.C. § 355(j)(2)(B) (“Counterclaim-Plaintiffs’ First Notice Letter”).

30. Counterclaim-Plaintiffs’ First Notice Letter contained an Offer of Confidential Access to its ANDA No. 220326 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

31. By letter dated June 9, 2025, Counterclaim-Plaintiffs provided Supernus with notice of the filing of ANDA No. 220326 and that said ANDA contained a Paragraph IV Certification with respect to the ’853 patent, as required under 21 U.S.C. § 355(j)(2)(B) (“Counterclaim Plaintiffs’ Second Notice Letter”).

32. Counterclaim-Plaintiffs' Second Notice Letter contained an Offer of Confidential Access to its ANDA No. 220326 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

33. On June 26, 2025, Supernus initiated this civil action, 2:25-cv-12183, against Counterclaim-Plaintiffs in this Judicial District alleging infringement of the '853 patent.

34. For at least the reasons stated in their First and Second Notice Letters, Counterclaim-Plaintiffs seek a declaratory judgment that the '853 patent is not valid and/or is not infringed.

U.S. Patent No. 9,662,338

35. The '338 patent is listed in the Orange Book in association with NDA No. 211964 for Qelbree® viloxazine extended-release capsules 100 mg, 150 mg, and 200 mg.

36. On May 30, 2017, the United States Patent and Trademark Office ("USPTO") issued the '338 patent, entitled "Formulations of Viloxazine."

37. Upon information and belief, Supernus holds all substantial rights to the '338 patent.

38. Counterclaim-Plaintiffs submitted ANDA No. 220326 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval of the 100 mg, 150 mg, and 200 mg viloxazine extended-release capsules described therein in the United States, prior to the expiration of the '338 patent. That ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '338 patent is invalid, unenforceable, and/or will not be infringed.

39. By letter dated May 21, 2025, Counterclaim-Plaintiffs provided Supernus with notice of the filing of ANDA No. 220326 and that said ANDA contained a Paragraph IV

Certification with respect to the '338 patent, as required under 21 U.S.C. § 355(j)(2)(B) ("Counterclaim-Plaintiffs' First Notice Letter").

40. Counterclaim-Plaintiffs' First Notice Letter contained an Offer of Confidential Access to its ANDA No. 220326 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

41. By letter dated June 9, 2025, Counterclaim-Plaintiffs provided Supernus with notice of the filing of ANDA No. 220326 and that said ANDA contained a Paragraph IV Certification with respect to the '338 patent, as required under 21 U.S.C. § 355(j)(2)(B) ("Counterclaim-Plaintiffs' Second Notice Letter").

42. Counterclaim-Plaintiffs' Second Notice Letter contained an Offer of Confidential Access to its ANDA No. 220326 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

43. On June 26, 2025, Supernus initiated this civil action, 2:25-cv-12183, against Counterclaim-Plaintiffs in this Judicial District alleging infringement of the '338 patent.

44. For at least the reasons stated in their First and Second Notice Letters, Counterclaim-Plaintiffs seek a declaratory judgment that the '338 patent is not valid and/or is not infringed.

U.S. Patent No. 11,324,753

45. The '753 patent is listed in the Orange Book in association with NDA No. 211964 for Qelbree® viloxazine extended-release capsules 100 mg, 150 mg, and 200 mg.

46. On May 10, 2022, the United States Patent and Trademark Office ("USPTO") issued the '753 patent, entitled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)."

47. Upon information and belief, Supernus holds all substantial rights to the '753 patent.

48. Counterclaim-Plaintiffs submitted ANDA No. 220326 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval of the 100 mg, 150 mg, and 200 mg viloxazine extended-release capsules described therein in the United States, prior to the expiration of the '753 patent. That ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '753 patent is invalid, unenforceable, and/or will not be infringed.

49. By letter dated May 21, 2025, Counterclaim-Plaintiffs provided Supernus with notice of the filing of ANDA No. 220326 and that said ANDA contained a Paragraph IV Certification with respect to the '753 patent, as required under 21 U.S.C. § 355(j)(2)(B) ("Counterclaim-Plaintiffs' First Notice Letter").

50. Counterclaim-Plaintiffs' First Notice Letter contained an Offer of Confidential Access to its ANDA No. 220326 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

51. By letter dated June 9, 2025, Counterclaim-Plaintiffs provided Supernus with notice of the filing of ANDA No. 220326 and that said ANDA contained a Paragraph IV Certification with respect to the '753 patent, as required under 21 U.S.C. § 355(j)(2)(B) ("Counterclaim-Plaintiffs' Second Notice Letter").

52. Counterclaim-Plaintiffs' Second Notice Letter contained an Offer of Confidential Access to its ANDA No. 220326 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

53. On June 26, 2025, Supernus initiated this civil action, 2:25-cv-12183, against Counterclaim-Plaintiffs in this Judicial District alleging infringement of the '753 patent.

54. For at least the reasons stated in their First and Second Notice Letters, Counterclaim-Plaintiffs seek a declaratory judgment that the '753 patent is not valid and/or is not infringed.

U.S. Patent No. 11,458,143

55. The '143 patent is listed in the Orange Book in association with NDA No. 211964 for Qelbree® viloxazine extended-release capsules 100 mg, 150 mg, and 200 mg.

56. On October 4, 2022, the United States Patent and Trademark Office ("USPTO") issued the '143 patent, entitled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)."

57. Upon information and belief, Supernus holds all substantial rights to the '143 patent.

58. Counterclaim-Plaintiffs submitted ANDA No. 220326 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval of the 100 mg, 150 mg, and 200 mg viloxazine extended-release capsules described therein in the United States, prior to the expiration of the '143 patent. That ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '143 patent is invalid, unenforceable, and/or will not be infringed.

59. By letter dated May 21, 2025, Counterclaim-Plaintiffs provided Supernus with notice of the filing of ANDA No. 220326 and that said ANDA contained a Paragraph IV Certification with respect to the '143 patent, as required under 21 U.S.C. § 355(j)(2)(B) ("Counterclaim-Plaintiffs' First Notice Letter").

60. Counterclaim-Plaintiffs' First Notice Letter contained an Offer of Confidential Access to its ANDA No. 220326 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

61. By letter dated June 9, 2025, Counterclaim-Plaintiffs provided Supernus with notice of the filing of ANDA No. 220326 and that said ANDA contained a Paragraph IV

Certification with respect to the '143 patent, as required under 21 U.S.C. § 355(j)(2)(B) ("Counterclaim Plaintiffs' Second Notice Letter").

62. Counterclaim-Plaintiffs' Second Notice Letter contained an Offer of Confidential Access to its ANDA No. 220326 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

63. On June 26, 2025, Supernus initiated this civil action, 2:25-cv-12183, against Counterclaim-Plaintiffs in this Judicial District alleging infringement of the '143 patent.

64. For at least the reasons stated in their First and Second Notice Letters, Counterclaim-Plaintiffs seek a declaratory judgment that the '143 patent is not valid and/or is not infringed.

U.S. Patent No. 12,121,523

65. The '523 patent is listed in the Orange Book in association with NDA No. 211964 for Qelbree® viloxazine extended-release capsules 100 mg, 150 mg, and 200 mg.

66. On October 22, 2024, the United States Patent and Trademark Office ("USPTO") issued the '523 patent, entitled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)."

67. Upon information and belief, Supernus holds all substantial rights to the '523 patent.

68. Counterclaim-Plaintiffs submitted ANDA No. 220326 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval of the 100 mg, 150 mg, and 200 mg viloxazine extended-release capsules described therein in the United States, prior to the expiration of the '523 patent. That ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '523 patent is invalid, unenforceable, and/or will not be infringed.

69. By letter dated May 21, 2025, Counterclaim-Plaintiffs provided Supernus with notice of the filing of ANDA No. 220326 and that said ANDA contained a Paragraph IV Certification with respect to the '523 patent, as required under 21 U.S.C. § 355(j)(2)(B) ("Counterclaim-Plaintiffs' First Notice Letter").

70. Counterclaim-Plaintiffs' First Notice Letter contained an Offer of Confidential Access to its ANDA No. 220326 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

71. By letter dated June 9, 2025, Counterclaim-Plaintiffs provided Supernus with notice of the filing of ANDA No. 220326 and that said ANDA contained a Paragraph IV Certification with respect to the '523 patent, as required under 21 U.S.C. § 355(j)(2)(B) ("Counterclaim Plaintiffs' Second Notice Letter").

72. Counterclaim-Plaintiffs' Second Notice Letter contained an Offer of Confidential Access to its ANDA No. 220326 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

73. On June 26, 2025, Supernus initiated this civil action, 2:25-cv-12183, against Counterclaim-Plaintiffs in this Judicial District alleging infringement of the '523 patent.

74. For at least the reasons stated in their First and Second Notice Letters, Counterclaim-Plaintiffs seek a declaratory judgment that the '523 patent is not valid and/or is not infringed.

COUNT I
(Declaratory Judgment of Invalidity of the '204 Patent)

75. Counterclaim-Plaintiffs restate and re-allege each of the foregoing Paragraphs 1-74 of the counterclaims as if fully set forth herein.

76. As evidenced by Counterclaim-Defendant's Complaint and Counterclaim-Plaintiffs' Answers in this action, there is an actual substantial and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendant having adverse-legal

interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '204 patent.

77. Upon information and belief, the claims of the '204 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 et seq., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

78. The Court should declare that the claims of the '204 patent are invalid and/or unenforceable.

COUNT II
(Declaratory Judgment of Non-Infringement of the '204 Patent)

79. Counterclaim-Plaintiffs restate and re-allege each of the foregoing Paragraphs 1-78 of the counterclaims as if fully set forth herein.

80. Supernus has alleged that Counterclaim-Plaintiffs' filing of ANDA 220326 infringes the '204 patent.

81. As evidenced by Supernus' Complaint and Counterclaim-Plaintiffs' Answers in this action, there is an actual substantial and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendant having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the '204 patent.

82. The manufacture, use, sale, offer for sale, and/or importation by Counterclaim-Plaintiffs of Counterclaim-Plaintiffs' ANDA Product will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '204.

83. Counterclaim-Plaintiffs are entitled to a judicial determination that Counterclaim-Plaintiffs' ANDA Product which is the subject of ANDA No. 220326 have not infringed, do not infringe, and would not infringe, if marketed, any valid claim of the '204 patent.

COUNT III
(Declaratory Judgment of Invalidity of the '853 Patent)

84. Counterclaim-Plaintiffs restate and re-allege each of the foregoing Paragraphs 1-83 of the counterclaims as if fully set forth herein.

85. As evidenced by Counterclaim-Defendant's Complaint and Counterclaim-Plaintiffs' Answers in this action, there is an actual substantial, and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendant having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '853 patent.

86. Upon information and belief, the claims of the '853 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 et seq., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

87. The Court should declare that the claims of the '853 patent are invalid and/or unenforceable.

COUNT IV
(Declaratory Judgment of Non-Infringement of the '853 Patent)

88. Counterclaim-Plaintiffs restate and re-allege each of the foregoing Paragraphs 1-87 of the counterclaims as if fully set forth herein.

89. Supernus has alleged that Counterclaim-Plaintiffs' filing of ANDA 220326 infringes the '853 patent.

90. As evidenced by Supernus' Complaint and Counterclaim-Plaintiffs' Answers in this action, there is an actual substantial, and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendant having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the '853 patent.

91. The manufacture, use, sale, offer for sale, and/or importation by Counterclaim-Plaintiffs of Counterclaim-Plaintiffs' ANDA Product will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '853.

92. Counterclaim-Plaintiffs are entitled to a judicial determination that Counterclaim-Plaintiffs' ANDA Product which is the subject of ANDA No. 220326 have not infringed, do not infringe, and would not infringe, if marketed, any valid claim of the '853 patent.

COUNT V
(Declaratory Judgment of Invalidity of the '338 Patent)

93. Counterclaim-Plaintiffs restate and re-allege each of the foregoing Paragraphs 1-92 of the counterclaims as if fully set forth herein.

94. As evidenced by Counterclaim-Defendant's Complaint and Counterclaim-Plaintiffs' Answers in this action, there is an actual substantial, and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendant having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '338 patent.

95. Upon information and belief, the claims of the '338 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 et seq., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

96. The Court should declare that the claims of the ’338 patent are invalid and/or unenforceable.

COUNT VI
(Declaratory Judgment of Non-Infringement of the ’338 Patent)

97. Counterclaim-Plaintiffs restates and re-alleges each of the foregoing Paragraphs 1-96 of the counterclaims as if fully set forth herein.

98. Supernus has alleged that Counterclaim-Plaintiffs’ filing of ANDA 220326 infringes the ’338 patent.

99. As evidenced by Supernus’ Complaint and Counterclaim-Plaintiffs’ Answers in this action, there is an actual substantial, and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendant having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the ’338 patent.

100. The manufacture, use, sale, offer for sale, and/or importation by Counterclaim-Plaintiffs of Counterclaim-Plaintiffs’ ANDA Product will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’338.

101. Counterclaim-Plaintiffs is entitled to a judicial determination that Counterclaim-Plaintiffs’ ANDA Product which is the subject of ANDA No. 220326 have not infringed, do not infringe, and would not infringe, if marketed, any valid claim of the ’338 patent.

COUNT VII
(Declaratory Judgment of Invalidity of the ’753 Patent)

102. Counterclaim-Plaintiffs restate and re-allege each of the foregoing Paragraphs 1-101 of the counterclaims as if fully set forth herein.

103. As evidenced by Counterclaim-Defendant’s Complaint and Counterclaim-Plaintiffs’ Answers in this action, there is an actual substantial and continuing justiciable case or

controversy between Counterclaim-Plaintiffs and Counterclaim-Defendant having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '753 patent.

104. Upon information and belief, the claims of the '753 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 et seq., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

105. The Court should declare that the claims of the '753 patent are invalid and/or unenforceable.

COUNT VIII
(Declaratory Judgment of Non-Infringement of the '753 Patent)

106. Counterclaim-Plaintiffs restates and re-alleges each of the foregoing Paragraphs 1-105 of the counterclaims as if fully set forth herein.

107. Supernus has alleged that Counterclaim-Plaintiffs' filing of ANDA 220326 infringes the '753 patent.

108. As evidenced by Supernus' Complaint and Counterclaim-Plaintiffs' Answers in this action, there is an actual substantial and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendant having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the '753 patent.

109. The manufacture, use, sale, offer for sale, and/or importation by Counterclaim-Plaintiffs of Counterclaim-Plaintiffs' ANDA Product will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '753 patent.

110. Counterclaim-Plaintiffs is entitled to a judicial determination that Counterclaim-Plaintiffs' ANDA Product which is the subject of ANDA No. 220326 have not infringed, do not infringe, and would not infringe, if marketed, any valid claim of the '753 patent.

COUNT IX
(Declaratory Judgment of Invalidity of the '143 Patent)

111. Counterclaim-Plaintiffs restate and re-allege each of the foregoing Paragraphs 1-110 of the counterclaims as if fully set forth herein.

112. As evidenced by Counterclaim-Defendant's Complaint and Counterclaim-Plaintiffs' Answers in this action, there is an actual substantial and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendant having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '143 patent.

113. Upon information and belief, the claims of the '143 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 et seq., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

114. The Court should declare that the claims of the '143 patent are invalid and/or unenforceable.

COUNT X
(Declaratory Judgment of Non-Infringement of the '143 Patent)

115. Counterclaim-Plaintiffs restate and re-allege each of the foregoing Paragraphs 1-114 of the counterclaims as if fully set forth herein.

116. Supernus has alleged that Counterclaim-Plaintiffs' filing of ANDA 220326 infringes the '143 patent.

117. As evidenced by Supernus' Complaint and Counterclaim-Plaintiffs' Answers in this action, there is an actual substantial and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendant having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the '143 patent.

118. The manufacture, use, sale, offer for sale, and/or importation by Counterclaim-Plaintiffs of Counterclaim-Plaintiffs' ANDA Product will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '143 patent.

119. Counterclaim-Plaintiffs is entitled to a judicial determination that Counterclaim-Plaintiffs' ANDA Product which is the subject of ANDA No. 220326 have not infringed, do not infringe, and would not infringe, if marketed, any valid claim of the '143patent.

COUNT XI
(Declaratory Judgment of Invalidity of the '523 Patent)

120. Counterclaim-Plaintiffs restate and re-allege each of the foregoing Paragraphs 1-119 of the counterclaims as if fully set forth herein.

121. As evidenced by Counterclaim-Defendant's Complaint and Counterclaim-Plaintiffs' Answers in this action, there is an actual substantial, and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendant having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '523 patent.

122. Upon information and belief, the claims of the '523 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 et seq., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

123. The Court should declare that the claims of the ’523 patent are invalid and/or unenforceable.

COUNT XII
(Declaratory Judgment of Non-Infringement of the ’523 Patent)

124. Counterclaim-Plaintiffs restate and re-allege each of the foregoing Paragraphs 1-123 of the counterclaims as if fully set forth herein.

125. Supernus has alleged that Counterclaim-Plaintiffs’ filing of ANDA 220326 infringes the ’523 patent.

126. As evidenced by Supernus’ Complaint and Counterclaim-Plaintiffs’ Answers in this action, there is an actual substantial and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendant having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the ’523 patent.

127. The manufacture, use, sale, offer for sale, and/or importation by Counterclaim-Plaintiffs of Counterclaim-Plaintiffs’ ANDA Product will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’523 patent.

128. Counterclaim-Plaintiffs are entitled to a judicial determination that Counterclaim-Plaintiffs’ ANDA Product which is the subject of ANDA No. 220326 have not infringed, do not infringe, and would not infringe, if marketed, any valid claim of the ’523 patent.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiffs respectfully request the following relief:

(a) Dismissing the Complaint with prejudice and entering a judgment of non-infringement and invalidity in favor of Counterclaim-Plaintiffs;

(b) Declaring that no valid claim of the ’204, ’853, ’338, ’753, ’143, and ’523 patents would be infringed, either directly or indirectly, literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of Counterclaim-Plaintiffs’ ANDA Product;

(c) Declaring that all the asserted claims of the ’204, ’853, ’338, ’753, ’143, and ’523 patents are invalid;

(d) Enjoining Plaintiff/Counter-Defendant, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Plaintiff/Counter-Defendant from threatening to assert or otherwise attempting to enforce the ’204, ’853, ’338, ’753, ’143, and ’523 patents against Defendants/Counterclaim-Plaintiffs, their customers, suppliers, or anyone in privity with Defendants/Counterclaim-Plaintiffs;

(e) Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Defendants/Counterclaim-Plaintiffs their reasonable attorneys’ fees and costs incurred in this action;

(f) Awarding Defendants/Counterclaim-Plaintiffs their costs and expenses incurred in this action; and

(g) Awarding Defendants/Counterclaim-Plaintiffs such other and further relief as this Court may deem proper.

DATED: September 22, 2025

Respectfully Submitted,

/s/ Katherine A. Escanlar

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Attorneys for Defendants APPCO PHARMA LLC and SOMERSET THERAPEUTICS, LLC

LOCAL CIVIL RULES 11.2 & 40.1 CERTIFICATION

I, counsel of record for Defendants in the above-referenced matter, hereby certify that to the best of my knowledge, there are no matters in controversy related to the following actions, except *Supernus Pharmaceuticals, Inc. v. Apotex Inc.*, District of New Jersey, Case No. 2:25-cv-12184, Complaint filed June 26, 2025; *Supernus Pharmaceuticals, Inc. v. Aurobindo Pharma Limited et al*, District of New Jersey, Case No. 2:25-cv-12186, Complaint filed June 26, 2025; *Supernus Pharmaceuticals, Inc. v. Appco Pharma LLC et al*, District of New Jersey, Case No. 2:25-cv-12183, Complaint filed June 26, 2025; *Supernus Pharmaceuticals, Inc. v. Zydus Lifesciences Global FZE et al*, District of New Jersey, Case No. 2:25-cv-12188, Complaint filed June 26, 2025; *Supernus Pharmaceuticals, Inc. v. Aurobindo Pharma Limited*, District of Delaware, Case No. 1:25-cv-00808, Complaint filed July 1, 2025; *Supernus Pharmaceuticals, Inc. v. Appco Pharma LLC*, District of Delaware, Case No. 1:25-cv-00807, Complaint filed July 1, 2025; *Supernus Pharmaceuticals, Inc. v. Zenara Pharma Private Limited et al*, District of New Jersey, Case No. 2:25-cv-13207, Complaint filed July 11, 2025; *Supernus Pharmaceuticals, Inc. v. MSN Pharmaceuticals Inc.*, District of New Jersey, Case No. 2:25-cv-13204, Complaint filed July 11, 2025; *Supernus Pharmaceuticals, Inc. v. Creekwood Pharmaceuticals LLC*, District of New Jersey, Case No. 2:25-cv-13201, Complaint filed July 11, 2025; *Supernus Pharmaceuticals, Inc. v. MSN Pharmaceuticals Inc.*, District of Delaware, Case No. 1:25-cv-00879, Complaint filed July 15, 2025; *Supernus Pharmaceuticals, Inc. v. Creekwood Pharmaceuticals LLC*, District of Delaware, Case No. 1:25-cv-00880, Complaint filed July 15, 2025; *Supernus Pharmaceuticals, Inc. v. Macleods Pharmaceuticals Ltd. et al*, District of New Jersey, Case No. 2:25-cv-15399, Complaint filed September 9, 2025; *Supernus Pharmaceuticals, Inc. v. Macleods Pharmaceuticals Ltd. et al*, District of Delaware, Case No. 1:25-cv-01146, Complaint filed September 15, 2025.

Dated: September 22, 2025

Respectfully submitted,

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APPCO PHARMA LLC and SOMERSET THERAPEUTICS, LLC

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Defendants hereby certifies that Plaintiff seeks declaratory relief and therefore, this action is not appropriate for compulsory arbitration.

Dated: September 22, 2025

Respectfully submitted,

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