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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC., Plaintiff, v. CREEKWOOD PHARMACEUTICALS, LLC, Defendant.	Civil Action No. 2:25-cv-13201 (MEF-MAH) *Document Electronically Filed*

CREEKWOOD PHARMACEUTICALS, LLC'S ANSWER, DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT

Defendant Creekwood Pharmaceuticals, LLC ("Creekwood" or "Defendant"), by and through its undersigned attorneys, hereby answers the Complaint of Plaintiff Supernus

Pharmaceuticals, Inc. ("Supernus" or "Plaintiff") as follows:

GENERAL DENIAL

Pursuant to Federal Rule of Civil Procedure 8(b)(3), Creekwood denies all allegations in Plaintiff's Complaint except those specifically admitted below.

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 9,358,204 ("the '204 patent"); 9,603,853 ("the '853 patent"); 9,662,338 ("the '338 patent"); 11,324,753 ("the '753 patent"); 11,458,143 ("the '143 patent"); and 12,121,523 ("the '523 patent"), attached hereto as Exhibits A–F (collectively, "the patents-in-suit").

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that the Complaint is for alleged patent infringement of U.S. Patent Nos. 9,358,204 ("the '204 patent"); 9,603,853 ("the '853 patent"); 9,662,338 ("the '338 patent"); 11,324,753 ("the '753 patent"); 11,458,143 ("the '143 patent"); and 12,121,523 ("the '523 patent") (collectively, the "Patents-in-Suit"), but denies that Supernus is entitled to any relief. Answering further, Creekwood states that what purports to be a copy of the '204 patent is attached to the Complaint as Exhibit A; what purports to be a copy of the '852 patent is attached to the Complaint as Exhibit B; what purports to be a copy of the '338 patent is attached to the Complaint as Exhibit C; what purports to be a copy of the '753 patent is attached to the Complaint as Exhibit D; what purports to be a copy of the '143 patent is attached to the Complaint as Exhibit E; and what purports to be a copy of the '523 patent is attached to the Complaint as Exhibit F. Creekwood denies any suggestion that the Patents-in-Suit were duly and legally issued, as well as any suggestion or implication that the Patents-in-Suit are valid or enforceable, or that Creekwood infringes any claim of the Patents-in-Suit. Creekwood denies any remaining allegations contained in this paragraph.

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: Paragraph 2 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2 and therefore denies them.

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

ANSWER: Admitted.

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

ANSWER: Paragraph 4 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that Creekwood does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Answering further, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the United States Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the Patents-in-Suit; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the Patents-in-Suit. Creekwood denies any remaining allegations contained in this paragraph, including that Creekwood has committed any alleged patent infringement and that Supernus is entitled to any relief.

5. Upon information and belief, Creekwood, either directly or through one or more of

its affiliates and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic pharmaceutical products, including in the State of New Jersey.

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that Creekwood does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Answering further, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the Patents-in-Suit; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the Patents-in-Suit. Creekwood denies any remaining allegations contained in this paragraph, including that Creekwood has committed any alleged patent infringement and that Supernus is entitled to any relief.

6. Upon information and belief, Creekwood 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 0450862533. Upon information and belief, Creekwood is registered with the State of New Jersey's Department of Health as a drug and medical device "Manufacturer and Wholesale[r]" with Registration Number 5006135.

ANSWER: Admitted.

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

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that it submitted ANDA No. 220277 to the FDA pursuant to 21 U.S.C. § 355(j) seeking approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg. Creekwood denies any remaining allegations contained in this paragraph.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that this Court has subject matter jurisdiction over Plaintiff's infringement claims with respect to the '204, '853, '338, '753, '143, and '523 patents against Creekwood under 35 U.S.C. § 271(e)(2)(A) for purposes of this action only. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that Creekwood does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Creekwood denies any remaining allegations contained in this paragraph.

10. This Court has personal jurisdiction over Creekwood at least because, upon information and belief: (i) Creekwood maintains a principal place of business in New Jersey located at 1130 Route 46 W, Suite 21, Parsippany, New Jersey 07054; (ii) Creekwood, itself and through related entities and agents, regularly transacts and solicits business, performs work, and contracts to supply goods and services in New Jersey and/or derives substantial revenue from goods or services used or consumed in New Jersey and thus maintains continuous and systematic contacts with this Judicial District; (iii) Creekwood, itself and through related entities and agents, is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (iv) Creekwood, itself and through related entities and agents, has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (v) Creekwood 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 0450862533; (vi) Creekwood is registered with the State of New Jersey's Department of Health as a drug and medical device "Manufacturer and Wholesale[r]" with Registration Number 5006135; (vii) Creekwood, itself and through related entities and agents, has purposefully availed itself of the rights, benefits, and privileges of New Jersey's laws by continuously and systematically placing goods in the stream of commerce for importation, use, sale, offer for sale, and/or distribution throughout the United States, including the State of New Jersey; (viii) Creekwood's website states that "[t]he company operates through its own development and manufacturing hub in India and Co-development/in-licensing partnerships across

the globe" (*see* https://creekwoodpharma.com/about-us/ (last visited July 7, 2025)); (ix) Creekwood's contacts with this Judicial District—e.g., the manufacturing, importation, use, sale, offer for sale, and/or distribution of generic pharmaceutical products (including the accused products at issue in this action)—give rise to and/or are related to Plaintiff's claims; and (x) if Defendant's ANDA receives final approval, Defendant's ANDA Products will be marketed and distributed by Creekwood 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 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that Creekwood does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the Patents-in-Suit; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the Patents-in-Suit. Answering further, Creekwood does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that Creekwood does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that Creekwood does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that Creekwood does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that Creekwood does not contest personal

jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states the Creekwood does not contest venue in the District of New Jersey solely for the limited purpose of this action only. Creekwood denies any remaining allegations contained in this paragraph.

FACTS COMMON TO ALL COUNTS

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

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the Patents-in-Suit; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the Patents-in-Suit. Creekwood further admits that it sent a letter on June 4, 2025 via Federal Express to Supernus Pharmaceuticals, Inc. pursuant to 21 U.S.C. § 355(j)(2)(B) ("Creekwood's Notice Letter"), which provided written notification of the paragraph IV certification for the Patents-in-Suit. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To

the extent an answer is required, Creekwood admits that Creekwood's Notice Letter included an Offer of Confidential Access ("OCA") to Application, which complied with all relevant and applicable statutory and regulatory provisions. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that the OCA sent with Creekwood's Notice Letter complied with all relevant and applicable statutory and regulatory provisions and included reasonable terms and conditions necessary to protect highly confidential business information found in Creekwood's ANDA No. 220277. Creekwood further states that Plaintiff did not make a good faith request for any information from Creekwood's ANDA No. 220277. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that it submitted Creekwood's ANDA No. 220277 to the FDA pursuant to 21 U.S.C. § 355(j) seeking approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg. Creekwood denies any remaining allegations contained in this paragraph.

21. Upon information and belief, Defendant is in the business of, *inter alia*: (i) the

development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey, and importing generic pharmaceutical products into the United States, including throughout the State of New Jersey; (ii) the preparation, submission, and filing ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states the Creekwood does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that Creekwood does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 23 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that that Creekwood does not contest personal jurisdiction in the District of New Jersey solely for the limited purpose of this action only. Creekwood denies any remaining allegations contained in this paragraph.

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

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

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Plaintiff appears to have accurately quoted from certain sections of 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7). Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) were in effect on the date of Creekwood's Notice Letter and that Creekwood complied with same. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Creekwood's Notice Letter speaks for itself. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 27 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Creekwood's Notice Letter speaks for itself. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Creekwood's Notice Letter speaks for itself. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that the "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") currently lists Supernus Pharmaceuticals, Inc. as the holder of New Drug Application ("NDA") No. 211964 for QELBREE® (viloxazine hydrochloride), extended-release capsules 100 mg, 150 mg and 200 mg. Answering further, Creekwood admits that the Orange Book identifies "Apr 2, 2021" as the "Approval Date" for NDA No. 211964. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that according to the label for "QELBREE® (viloxazine extended-release capsules)" currently available from the online records of FDA:

> **----------INDICATIONS AND USAGE----------**
> Qelbree is a selective norepinephrine reuptake inhibitor indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older (1)

Creekwood denies any remaining allegations contained in this paragraph.

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

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

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

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

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

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

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

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that according to the label for "QELBREE® (viloxazine extended-release capsules)" currently available from the online records of FDA:

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

- *Pediatric patients 6 to 11 years of age*: Recommended starting dosage is 100 mg once daily. May titrate in increments of 100 mg weekly to the maximum recommended dosage of 400 mg once daily (2.2)
- *Pediatric patients 12 to 17 years of age*: Recommended starting dosage is 200 mg once daily. May titrate after 1 week, by an increment of 200mg, to the maximum recommended dosage of 400 mg once daily (2.2)
- *Adult patients*: Recommended starting dosage is 200 mg once daily. May titrate in increments of 200 mg weekly, to maximum recommended dosage of 600 mg once daily (2.2)
- Capsules may be swallowed whole or opened and the entire contents sprinkled onto applesauce or pudding (2.3)
- Severe Renal Impairment*:* Initial dosage is 100 mg once daily. Titrate in weekly increments of 50 mg to 100 mg to a maximum recommended dosage of 200 mg once daily (2.4, 8.6)

Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Plaintiff caused each of the '204, '853, '338, '753, '143, and '523 patents to be currently listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") in conjunction with NDA No. 211964 for QELBREE®. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that, according to the face of the patent, the

'204 patent is titled "Formulations of Viloxazine," and issued on June 7, 2016. Answering further, Creekwood admits that the face of the '204 patent identifies Michael L. Vieira, Austin B. Huang, and Padmanabh P. Bhatt as the purported inventors, and identifies Supernus Pharmaceuticals, Inc. as the purported assignee. Creekwood denies any remaining allegations contained in this paragraph, including that the '204 patent was duly and legally issued, as well as any suggestion or implication that the patent's claims are valid or enforceable or that Creekwood infringes any claims of the patent.

34. The '853 patent, titled, "Formulations of Viloxazine," was duly and legally issued by the United States Patent and Trademark Office on March 28, 2017, to Supernus upon assignment from inventors Michael Vieira, Austin B. Huang, and Padmanabh P. Bhatt. Supernus owns all rights, title, and interest in the '853 patent.

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that, according to the face of the patent, the '853 patent is titled "Formulations of Viloxazine," and issued on March 28, 2017. Answering further, Creekwood admits that the face of the '853 patent identifies Michael L. Vieira, Austin B. Huang, and Padmanabh P. Bhatt as the purported inventors, and identifies Supernus Pharmaceuticals, Inc. as the purported assignee. Creekwood denies any remaining allegations contained in this paragraph, including that the '853 patent was duly and legally issued, as well as any suggestion or implication that the patent's claims are valid or enforceable or that Creekwood infringes any claims of the patent.

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

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that, according to the face of the patent, the

'338 patent is titled "Formulations of Viloxazine," and issued on May 30, 2017. Answering further, Creekwood admits that the face of the '338 patent identifies Michael L. Vieira, Austin B. Huang, and Padmanabh P. Bhatt as the purported inventors, and identifies Supernus Pharmaceuticals, Inc. as the purported assignee. Creekwood denies any remaining allegations contained in this paragraph, including that the '338 patent was duly and legally issued, as well as any suggestion or implication that the patent's claims are valid or enforceable or that Creekwood infringes any claims of the patent.

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

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that, according to the face of the patent, the '753 patent is titled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)," and issued on May 10, 2022. Answering further, Creekwood admits that the face of the '753 patent identifies Christopher D. Breder as the purported inventor and identifies Supernus Pharmaceuticals, Inc. as the purported assignee. Creekwood denies any remaining allegations contained in this paragraph, including that the '753 patent was duly and legally issued, as well as any suggestion or implication that the patent's claims are valid or enforceable or that Creekwood infringes any claims of the patent.

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

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that, according to the face of the patent, the

'143 patent is titled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)," and issued on October 4, 2022. Answering further, Creekwood admits that the face of the '143 patent identifies Christopher D. Breder as the purported inventor and identifies Supernus Pharmaceuticals, Inc. as the purported assignee. Creekwood denies any remaining allegations contained in this paragraph, including that the '143 patent was duly and legally issued, as well as any suggestion or implication that the patent's claims are valid or enforceable or that Creekwood infringes any claims of the patent.

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

ANSWER: Paragraph 38 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that, according to the face of the patent, the '523 patent is titled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)," and issued on October 22, 2024. Answering further, Creekwood admits that the face of the '523 patent identifies Christopher D. Breder as the purported inventor and identifies Supernus Pharmaceuticals, Inc. as the purported assignee. Creekwood denies any remaining allegations contained in this paragraph, including that the '523 patent was duly and legally issued, as well as any suggestion or implication that the patent's claims are valid or enforceable or that Creekwood infringes any claims of the patent.

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

ANSWER: Paragraph 39 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that the reference listed drug ("RLD") identified in Creekwood's ANDA No. 220277 is QELBREE® (viloxazine hydrochloride)

extended-release capsules. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 40 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that it submitted Creekwood's ANDA No. 220277 to the FDA pursuant to 21 U.S.C. § 355(j) seeking approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg ("Creekwood's ANDA Products"). Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 41 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 meets all statutory requirements, including the bioavailability and/or bioequivalence data and/or bioequivalence waiver required by 21 U.S.C. § 355(j)(4)(F) and 21 C.F.R. §§ 314.94(a)(7). Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 42 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Plaintiff appears to have accurately quoted from certain sections of 21 U.S.C. § 355 et seq. Creekwood denies any remaining allegations

contained in this paragraph.

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

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that the content of Creekwood's Notice Letter and ANDA No. 220277 speaks for itself. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 44 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that the content of Creekwood's ANDA No. 220277 speaks for itself. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 45 contains legal conclusions to which no answer is required. To

the extent an answer is required, Creekwood states that the content of Creekwood's ANDA No. 220277 speaks for itself. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 46 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that the content of Creekwood's ANDA No. 220277 speaks for itself. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 47 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that the content of Creekwood's ANDA No. 220277 speaks for itself. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 48 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that the content of Creekwood's ANDA No. 220277 speaks for itself. Creekwood denies any remaining allegations contained in this paragraph.

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

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

ANSWER: Creekwood restates and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 50 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the '204 patent; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the '204 patent. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 51 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the '204 patent; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the '204 patent. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 52 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) were in effect on the date of Creekwood's Notice Letter and that Creekwood

complied with same. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 53 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that it sent Creekwood's Notice Letter on June 4, 2025 via Federal Express to Supernus Pharmaceuticals, Inc. pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1). Answering further, Creekwood admits that Creekwood's Notice Letter complied with all relevant and applicable statutory and regulatory provisions. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 54 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the Patents-in-Suit; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the Patents-in-Suit. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 55 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph

IV certifications to the Patents-in-Suit; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the Patents-in-Suit. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 58 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that Creekwood's ANDA No. 220277 meets all statutory requirements, including those of 21 U.S.C. §§ 355(j)(2)(A)(i), 355(j)(2)(A)(v), and 21 C.F.R. § 314.94(a)(8)(iv). Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

60. Upon information and belief, the use of Defendant's ANDA Products by third

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

intends infringement of the '204 patent.

ANSWER: Denied.

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

ANSWER: Paragraph 65 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood submitted ANDA No. 220277 to the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Creekwood's ANDA Products. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Creekwood restates and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 69 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was

submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the '853 patent; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the '853 patent. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 70 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the '853 patent; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the '853 patent. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 71 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) were in effect on the date of Creekwood's Notice Letter and that Creekwood complied with same. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 72 contains legal conclusions to which no answer is required. To

the extent an answer is required, Creekwood admits that it sent Creekwood's Notice Letter on June 4, 2025 via Federal Express to Supernus Pharmaceuticals, Inc. pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1). Answering further, Creekwood admits that Creekwood's Notice Letter complied with all relevant and applicable statutory and regulatory provisions. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 73 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the Patents-in-Suit; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the Patents-in-Suit. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 74 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the Patents-in-Suit; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the Patents-in-Suit. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 77 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that Creekwood's ANDA No. 220277 meets all statutory requirements, including those of 21 U.S.C. §§ 355(j)(2)(A)(i), 355(j)(2)(A)(v), and 21 C.F.R. § 314.94(a)(8)(iv). Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

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

ANSWER: Denied.

80. Upon information and belief, by making, using, selling, offering for sale, and/or

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 84 contains legal conclusions to which no answer is required. To

the extent an answer is required, Creekwood admits that Creekwood submitted ANDA No. 220277 to the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Creekwood's ANDA Products. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Creekwood restates and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 88 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the '338 patent; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the '338 patent. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 89 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the '338 patent; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the '338 patent. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 90 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) were in effect on the date of Creekwood's Notice Letter and that Creekwood complied with same. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 91 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that it sent Creekwood's Notice Letter on June 4, 2025 via Federal Express to Supernus Pharmaceuticals, Inc. pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1). Answering further, Creekwood admits that Creekwood's Notice Letter complied with all relevant and applicable statutory and regulatory provisions. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 92 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the Patents-in-Suit; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the Patents-in-Suit. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 93 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the Patents-in-Suit; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the Patents-in-Suit. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

95. Upon information and belief, the commercial manufacture, use, offer to sell, or sale of the Defendant's ANDA Products prior to the expiration of the '338 patent will directly infringe

the ’338 patent under 35 U.S.C. § 271(a), will actively induce another’s infringement of the ’338 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the ’338 patent under 35 U.S.C. § 271(c).

ANSWER: Denied.

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

ANSWER: Paragraph 96 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that Creekwood’s ANDA No. 220277 meets all statutory requirements, including those of 21 U.S.C. §§ 355(j)(2)(A)(i), 355(j)(2)(A)(v), and 21 C.F.R. § 314.94(a)(8)(iv). Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 103 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood submitted ANDA No. 220277 to the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Creekwood's ANDA Products. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Creekwood restates and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 107 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the '753 patent; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the '753 patent. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 108 contains legal conclusions to which no answer is required.

To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the '753 patent; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the '753 patent. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 109 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) were in effect on the date of Creekwood's Notice Letter and that Creekwood complied with same. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 110 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that it sent Creekwood's Notice Letter on June 4, 2025 via Federal Express to Supernus Pharmaceuticals, Inc. pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1). Answering further, Creekwood admits that Creekwood's Notice Letter complied with all relevant and applicable statutory and regulatory provisions. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 111 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the Patents-in-Suit; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the Patents-in-Suit. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 112 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the Patents-in-Suit; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the Patents-in-Suit. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 115 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that Creekwood's ANDA No. 220277 meets all statutory requirements, including those of 21 U.S.C. §§ 355(j)(2)(A)(i), 355(j)(2)(A)(v), and 21 C.F.R. § 314.94(a)(8)(iv). Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 122 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood submitted ANDA No. 220277 to the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Creekwood's ANDA Products. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

124. Unless Defendant is permanently enjoined by this Court, the acts of infringement

set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law.

ANSWER: Denied.

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

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

ANSWER: Creekwood restates and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 126 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the '143 patent; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the '143 patent. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 127 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the '143 patent; and that Creekwood seeks approval from FDA to engage in

the commercial manufacture, use, sale, or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the '143 patent. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 128 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) were in effect on the date of Creekwood's Notice Letter and that Creekwood complied with same. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 129 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that it sent Creekwood's Notice Letter on June 4, 2025 via Federal Express to Supernus Pharmaceuticals, Inc. pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1). Answering further, Creekwood admits that Creekwood's Notice Letter complied with all relevant and applicable statutory and regulatory provisions. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 130 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph

IV certifications to the Patents-in-Suit; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the Patents-in-Suit. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 131 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the Patents-in-Suit; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the Patents-in-Suit. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 134 contains legal conclusions to which no answer is required.

To the extent an answer is required, Creekwood states that Creekwood's ANDA No. 220277 meets all statutory requirements, including those of 21 U.S.C. §§ 355(j)(2)(A)(i), 355(j)(2)(A)(v), and 21 C.F.R. § 314.94(a)(8)(iv). Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 141 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood submitted ANDA No. 220277 to the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Creekwood's ANDA Products. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Creekwood restates and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 145 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the '523 patent; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the '523 patent. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 146 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the '523 patent; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the '523 patent. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 147 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) were in effect on the date of Creekwood's Notice Letter and that Creekwood complied with same. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 148 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that it sent Creekwood's Notice Letter on June 4, 2025 via Federal Express to Supernus Pharmaceuticals, Inc. pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1). Answering further, Creekwood admits that Creekwood's Notice Letter complied with all relevant and applicable statutory and regulatory provisions. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 149 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the Patents-in-Suit; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the Patents-in-Suit. Creekwood

denies any remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 150 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood's ANDA No. 220277 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Creekwood's ANDA contains paragraph IV certifications to the Patents-in-Suit; and that Creekwood seeks approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of viloxazine extended-release capsules, 100 mg and 200 mg, before the expiration of the Patents-in-Suit. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 153 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood states that Creekwood's ANDA No. 220277 meets all statutory requirements, including those of 21 U.S.C. §§ 355(j)(2)(A)(i), 355(j)(2)(A)(v), and 21 C.F.R. § 314.94(a)(8)(iv). Creekwood denies any remaining allegations contained in this

paragraph.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 160 contains legal conclusions to which no answer is required. To the extent an answer is required, Creekwood admits that Creekwood submitted ANDA No. 220277 to the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Creekwood's ANDA Products. Creekwood denies any remaining allegations contained in this paragraph.

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

ANSWER: Denied.

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

ANSWER: Denied.

* * *

RESPONSE TO PRAYER FOR RELIEF

Creekwood denies that Plaintiff is entitled to any relief whatsoever, and further requests that: (a) Plaintiff's Complaint be dismissed with prejudice; (b) judgment be entered in favor of

Creekwood; (c) Creekwood be awarded its attorneys' fees and costs incurred in defending this suit under 35 U.S.C. § 285; and (d) Creekwood be awarded such further relief as the Court deems just and appropriate.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted (and, for purposes of clarity, those allegations not specifically admitted are denied), and without undertaking any of the burdens imposed by law on Plaintiff, Creekwood asserts the following defenses to the Complaint:

First Defense

The Complaint fails to state a claim upon which relief can be granted.

Second Defense

The manufacture, use, or sale of the viloxazine extended-release capsules, 100 mg and 200 mg, products described in Creekwood's ANDA No. 220277 has not infringed, does not infringe, and will not—if made, used, sold, offered for sale, imported, or marketed—infringe either directly or indirectly, any valid and/or enforceable claim of the '204, '853, '338, '753, '143 and/or '523 patents.

Third Defense

Creekwood has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '204, '853, '338, '753, '143 and/or '523 patents.

Fourth Defense

Creekwood has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '204, '853, '338, '753, '143 and/or '523 patents.

Fifth Defense

The claims of the '204, '853, '338, '753, '143 and/or '523 patents are invalid for failure to comply with one or more of the requirements in 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

Sixth Defense

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

Seventh Defense

The Complaint fails to state a claim for exceptional case or willful infringement.

Eighth Defense

Any additional defenses or counterclaims that discovery may reveal.

* * *

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff Creekwood Pharmaceuticals, LLC ("Creekwood") for its Counterclaims against Plaintiff/Counterclaim-Defendant Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff"), alleges as follows:

THE PARTIES

1. Creekwood is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 1130 Route 46, Suite 21, Parsippany, New Jersey 07054-2148.

2. On information and belief, and according to Plaintiff's Complaint, 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. (Complaint at ¶ 2).

JURISDICTION

3. These Counterclaims arise under the Patent Law of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

4. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

5. This Court has personal jurisdiction over Plaintiff because: (i) Plaintiff has availed itself of the rights and privileges—and subjected itself to the jurisdiction—of this forum by suing Creekwood in this District; (ii) Supernus Pharmaceuticals, Inc. is organized and existing under the laws of the State of Delaware; and/or (iii) Plaintiff conducts substantial business in, and has regular and systematic contact with, this District.

6. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

A. FDA Approval of New Brand-Name Drugs

7. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and as further amended by Title XI of the MMA, sets forth a statutory framework that the U.S. Food and Drug Administration ("FDA") follows for the approval of both brand-name and generic drugs.

8. Under the FFDCA, as amended by Hatch-Waxman and the MMA, an applicant seeking to market a new brand-name drug that has not been previously approved must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

9. An NDA includes, among other things, the number of any patent that the NDA holder asserts claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. §§ 355(b)(1), 355(c)(2); 21 C.F.R. §§ 314.53(b), 314.53(c)(2). The decision to submit patent information to the FDA rests solely with the NDA holder.

10. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

B. Generic Competition – Abbreviated New Drug Applications

11. In 1984, Congress enacted the Hatch-Waxman Amendments to the FFDCA. Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under Hatch-Waxman, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j).

12. To receive approval of its ANDA, an applicant generally must, *inter alia*, show that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

13. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant generally must also "certif[y]" that any patent information listed in the Orange Book does not preclude FDA approval of a generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

14. When seeking FDA approval to market prior to patent expiration, an ANDA applicant generally submits a so-called "paragraph IV" certification asserting that the listed patent is invalid, unenforceable, and/or will not be infringed. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

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

16. If the patent holder brings suit within 45 days of receiving the notice required by 21 U.S.C. § 355(j)(2)(B), the FDA typically cannot approve the ANDA for 30 months, unless the District Court enters an order that shortens that period. *See* 21 U.S.C. § 355(j)(5)(B)(iii). For this reason alone, patentees and NDA holders have a significant financial incentive to bring an infringement suit against an ANDA applicant without regard to the merit of that infringement suit.

C. QELBREE® and the Patents-in-Suit

17. Supernus Pharmaceuticals, Inc. purports to be the holder of approved New Drug Application ("NDA") No. 211964, under which the United States Food and Drug Administration ("FDA") granted approval for viloxazine extended-release capsules, 100 mg, 150 mg, and 200 mg, marketed in the United States under the trade name QELBREE®.

18. At the time the Complaint was filed, the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"), which is published by the FDA, listed U.S. Patent Nos. 9,358,204 ("the '204 patent"); 9,603,853 ("the '853 patent"); 9,662,338 ("the '338 patent"); 11,324,753 ("the '753 patent"); 11,458,143 ("the '143 patent"); and 12,121,523 ("the '523 patent"), *inter alia*, in connection with NDA No. 211964.

19. On or about June 7, 2026, according to the electronic records of the USPTO, the '204 patent, titled "Formulations of Viloxazine," issued. The face of the '204 patent identifies

Michael L. Vieira, Austin B. Huang, and Padmanabh P. Bhatt as the purported inventors of the '204 patent. What purports to be a true and correct copy of the '204 patent is attached to Plaintiff's Complaint as Exhibit A.

20. According to the online records of the USPTO and the face of the '204 patent, Supernus Pharmaceuticals, Inc. is purportedly the current assignee of the '204 patent. Plaintiff asserts that "Supernus owns all rights, title, and interest in the '204 patent." (Complaint at ¶ 33).

21. On information and belief, and according to Plaintiff's Complaint, Plaintiff submitted information regarding the '204 patent in the Orange Book with respect to QELBREE®. (Complaint at ¶ 32).

22. By listing the '204 patent in the Orange Book, Plaintiff maintains that an infringement suit can reasonably be asserted against any ANDA applicant—including Creekwood—that attempts to seek approval for, and market, a generic version of QELBREE® before the expiration of the '204 patent.

23. On or about March 28, 2017, according to the electronic records of the USPTO, the '853 patent, titled "Formulations of Viloxazine," issued. The face of the '853 patent identifies Michael L. Vieira, Austin B. Huang, and Padmanabh P. Bhatt as the purported inventors of the '853 patent. What purports to be a true and correct copy of the '853 patent is attached to Plaintiff's Complaint as Exhibit B.

24. According to the online records of the USPTO and the face of the '853 patent, Supernus Pharmaceuticals, Inc. is purportedly the current assignee of the '853 patent. Plaintiff asserts that "Supernus owns all rights, title, and interest in the '853 patent." (Complaint at ¶ 34).

25. On information and belief, and according to Plaintiff's Complaint, Plaintiff submitted information regarding the '853 patent in the Orange Book with respect to QELBREE®.

(Complaint at ¶ 32).

26. By listing the ’853 patent in the Orange Book, Plaintiff maintains that an infringement suit can reasonably be asserted against any ANDA applicant—including Creekwood—that attempts to seek approval for, and market, a generic version of QELBREE® before the expiration of the ’853 patent.

27. On or about May 30, 2017, according to the electronic records of the USPTO, the ’338 patent, titled “Formulations of Viloxazine,” issued. The face of the ’338 patent identifies Michael L. Vieira, Austin B. Huang, and Padmanabh P. Bhatt as the purported inventors of the ’338 patent. What purports to be a true and correct copy of the ’338 patent is attached to Plaintiff’s Complaint as Exhibit C.

28. According to the online records of the USPTO and the face of the ’338 patent, Supernus Pharmaceuticals, Inc. is purportedly the current assignee of the ’338 patent. Plaintiff asserts that “Supernus owns all rights, title, and interest in the ’338 patent.” (Complaint at ¶ 35).

29. On information and belief, and according to Plaintiff’s Complaint, Plaintiff submitted information regarding the ’338 patent in the Orange Book with respect to QELBREE®. (Complaint at ¶ 32).

30. By listing the ’338 patent in the Orange Book, Plaintiff maintains that an infringement suit can reasonably be asserted against any ANDA applicant—including Creekwood—that attempts to seek approval for, and market, a generic version of QELBREE® before the expiration of the ’338 patent.

31. On or about May 10, 2022, according to the electronic records of the USPTO, the ’753 patent, titled “Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD),” issued. The face of the ’753 patent identifies Christopher D. Breder as the purported inventor of

the ’753 patent. What purports to be a true and correct copy of the ’753 patent is attached to Plaintiff’s Complaint as Exhibit D.

32. According to the online records of the USPTO and the face of the ’753 patent, Supernus Pharmaceuticals, Inc. is purportedly the current assignee of the ’753 patent. Plaintiff asserts that “Supernus owns all rights, title, and interest in the ’753 patent.” (Complaint at ¶ 36).

33. On information and belief, and according to Plaintiff’s Complaint, Plaintiff submitted information regarding the ’753 patent in the Orange Book with respect to QELBREE®. (Complaint at ¶ 32).

34. By listing the ’753 patent in the Orange Book, Plaintiff maintains that an infringement suit can reasonably be asserted against any ANDA applicant—including Creekwood—that attempts to seek approval for, and market, a generic version of QELBREE® before the expiration of the ’753 patent.

35. On or about October 4, 2022, according to the electronic records of the USPTO, the ’143 patent, titled “Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD),” issued. The face of the ’143 patent identifies Christopher D. Breder as the purported inventor of the ’143 patent. What purports to be a true and correct copy of the ’143 patent is attached to Plaintiff’s Complaint as Exhibit E.

36. According to the online records of the USPTO and the face of the ’143 patent, Supernus Pharmaceuticals, Inc. is purportedly the current assignee of the ’143 patent. Plaintiff asserts that “Supernus owns all rights, title, and interest in the ’143 patent.” (Complaint at ¶ 37).

37. On information and belief, and according to Plaintiff’s Complaint, Plaintiff submitted information regarding the ’143 patent in the Orange Book with respect to QELBREE®. (Complaint at ¶ 32).

38. By listing the '143 patent in the Orange Book, Plaintiff maintains that an infringement suit can reasonably be asserted against any ANDA applicant—including Creekwood—that attempts to seek approval for, and market, a generic version of QELBREE® before the expiration of the '143 patent.

39. On or about October 22, 2024, according to the electronic records of the USPTO, the '523 patent, titled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)," issued. The face of the '523 patent identifies Christopher D. Breder as the purported inventor of the '523 patent. What purports to be a true and correct copy of the '523 patent is attached to Plaintiff's Complaint as Exhibit F.

40. According to the online records of the USPTO and the face of the '523 patent, Supernus Pharmaceuticals, Inc. is purportedly the current assignee of the '523 patent. Plaintiff asserts that "Supernus owns all rights, title, and interest in the '523 patent." (Complaint at ¶ 38).

41. On information and belief, and according to Plaintiff's Complaint, Plaintiff submitted information regarding the '523 patent in the Orange Book with respect to QELBREE®. (Complaint at ¶ 32).

42. By listing the '523 patent in the Orange Book, Plaintiff maintains that an infringement suit can reasonably be asserted against any ANDA applicant—including Creekwood—that attempts to seek approval for, and market, a generic version of QELBREE® before the expiration of the '523 patent.

D. Creekwood's ANDA Products

43. Creekwood filed ANDA No. 220277 ("Creekwood's ANDA") with the FDA seeking approval to engage in the commercial manufacture, use, or sale of viloxazine extended-release capsules, 100 mg and 200 mg ("Creekwood's ANDA Products").

44. Creekwood's ANDA identifies QELBREE® (viloxazine) extended-release capsules as the reference listed drug ("RLD").

45. Because Creekwood's ANDA seeks FDA approval to market its generic viloxazine extended-release capsules, 100 mg and 200 mg, before expiration of the Orange Book-listed '204, '853, '338, '753, '143, and '523 patents, Creekwood's ANDA includes paragraph IV certifications to the '204, '853, '338, '753, '143, and '523 patents.

46. By letter dated June 4, 2025, in accordance with 21 U.S.C. § 355(j)(2)(B) and applicable regulations, Creekwood provided, *inter alia*, Supernus with notice that Creekwood submitted an ANDA containing a paragraph IV certification to the '204, '853, '338, '753, '143, and '523 patents ("Creekwood's Notice Letter").

47. Creekwood's Notice Letter included a detailed statement setting forth factual and legal bases as to why each claim of the '204, '853, '338, '753, '143, and '523 patents is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the products described in Creekwood's ANDA No. 220277, and, *inter alia*, expressly reserved the right to raise additional defenses in the event that suit was filed on the '204, '853, '338, '753, '143, and/or '523 patents.

48. Supernus received a copy of Creekwood's Notice Letter.

49. On July 11, 2025, Plaintiff filed the above-captioned action against Creekwood asserting infringement of the '204, '853, '338, '753, '143, and '523 patents.

COUNT I
Declaration of Non-Infringement of the '204 Patent

50. Creekwood realleges and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

51. A present, genuine, and justiciable controversy exists between Plaintiff and Creekwood regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, or importation of Creekwood's ANDA Products would infringe any valid and enforceable claim of the '204 patent.

52. The manufacture, use, offer for sale, sale, or importation of Creekwood's ANDA Products would not directly or indirectly infringe any valid and enforceable claim of the '204 patent, either literally or under the doctrine of equivalents.

53. Creekwood is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of Creekwood's ANDA Products would not infringe any valid and enforceable claim of the '204 patent.

COUNT II
Declaration of Non-Infringement of the '853 Patent

54. Creekwood realleges and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

55. A present, genuine, and justiciable controversy exists between Plaintiff and Creekwood regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, or importation of Creekwood's ANDA Products would infringe any valid and enforceable claim of the '853 patent.

56. The manufacture, use, offer for sale, sale, or importation of Creekwood's ANDA Products would not directly or indirectly infringe any valid and enforceable claim of the '853 patent, either literally or under the doctrine of equivalents.

57. Creekwood is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of Creekwood's ANDA Products would not infringe any valid and enforceable claim of the '853 patent.

COUNT III
Declaration of Non-Infringement of the ’338 Patent

58. Creekwood realleges and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

59. A present, genuine, and justiciable controversy exists between Plaintiff and Creekwood regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, or importation of Creekwood’s ANDA Products would infringe any valid and enforceable claim of the ’338 patent.

60. The manufacture, use, offer for sale, sale, or importation of Creekwood’s ANDA Products would not directly or indirectly infringe any valid and enforceable claim of the ’338 patent, either literally or under the doctrine of equivalents.

61. Creekwood is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of Creekwood’s ANDA Products would not infringe any valid and enforceable claim of the ’338 patent.

COUNT IV
Declaration of Non-Infringement of the ’753 Patent

62. Creekwood realleges and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

63. A present, genuine, and justiciable controversy exists between Plaintiff and Creekwood regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, or importation of Creekwood’s ANDA Products would infringe any valid and enforceable claim of the ’753 patent.

64. The manufacture, use, offer for sale, sale, or importation of Creekwood’s ANDA Products would not directly or indirectly infringe any valid and enforceable claim of the ’753 patent, either literally or under the doctrine of equivalents.

65. Creekwood is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of Creekwood's ANDA Products would not infringe any valid and enforceable claim of the '753 patent.

COUNT V
Declaration of Non-Infringement of the '143 Patent

66. Creekwood realleges and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

67. A present, genuine, and justiciable controversy exists between Plaintiff and Creekwood regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, or importation of Creekwood's ANDA Products would infringe any valid and enforceable claim of the '143 patent.

68. The manufacture, use, offer for sale, sale, or importation of Creekwood's ANDA Products would not directly or indirectly infringe any valid and enforceable claim of the '143 patent, either literally or under the doctrine of equivalents.

69. Creekwood is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of Creekwood's ANDA Products would not infringe any valid and enforceable claim of the '143 patent.

COUNT VI
Declaration of Non-Infringement of the '523 Patent

70. Creekwood realleges and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

71. A present, genuine, and justiciable controversy exists between Plaintiff and Creekwood regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, or importation of Creekwood's ANDA Products would infringe any valid and enforceable claim of the '523 patent.

72. The manufacture, use, offer for sale, sale, or importation of Creekwood's ANDA Products would not directly or indirectly infringe any valid and enforceable claim of the '523 patent, either literally or under the doctrine of equivalents.

73. Creekwood is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of Creekwood's ANDA Products would not infringe any valid and enforceable claim of the '523 patent.

COUNT VII
Declaration of Invalidity of the '753 Patent

74. Creekwood realleges and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

75. A present, genuine, and justiciable controversy exists between Plaintiff and Creekwood regarding, *inter alia*, the invalidity of the '753 patent.

76. The claims of the '753 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or for obviousness-type double patenting, the bases for which include, at the very least, one or more of the following:

a. The alleged invention of the '753 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '753 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '753 patent and would have had a reasonable expectation of success in doing so.

b. The subject matter claimed in the ’753 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the claimed invention as a whole would have been obvious at the time the alleged invention was made, and/or before the effective filing date of the claimed invention, would have been obvious before the effective filing date of the claimed invention to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed invention pertains. Non-limiting examples of prior art rendering each of the claims of the ’753 patent invalid under, at least, 35 U.S.C. §§ 102 and/or 103, include, but are expressly not limited to, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Creekwood’s Notice Letter.

c. The claims of the ’753 patent are invalid because they do not inform those skilled in the art about the scope of the alleged invention with reasonable certainty, and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

77. Creekwood is entitled to a declaration that the claims of the ’753 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, and/or for obviousness-type double patenting.

COUNT VIII
Declaration of Invalidity of the ’143 Patent

78. Creekwood realleges and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

79. A present, genuine, and justiciable controversy exists between Plaintiff and Creekwood regarding, *inter alia*, the invalidity of the '143 patent.

80. The claims of the '143 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or for obviousness-type double patenting, the bases for which include, at the very least, one or more of the following:

a. The alleged invention of the '143 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '143 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '143 patent and would have had a reasonable expectation of success in doing so.

b. The subject matter claimed in the '143 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the claimed invention as a whole would have been obvious at the time the alleged invention was made, and/or before the effective filing date of the claimed invention, would have been obvious before the effective filing date of the claimed invention to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed invention pertains. Non-limiting examples of prior art rendering each of the claims of the '143 patent invalid under, at least, 35 U.S.C. §§ 102 and/or 103, include, but are

expressly not limited to, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Creekwood's Notice Letter.

c. The claims of the '143 patent are invalid because they do not inform those skilled in the art about the scope of the alleged invention with reasonable certainty, and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

81. Creekwood is entitled to a declaration that the claims of the '143 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, and/or for obviousness-type double patenting.

COUNT IX
Declaration of Invalidity of the '523 Patent

82. Creekwood realleges and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

83. A present, genuine, and justiciable controversy exists between Plaintiff and Creekwood regarding, *inter alia*, the invalidity of the '523 patent.

84. The claims of the '523 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or for obviousness-type double patenting, the bases for which include, at the very least, one or more of the following:

a. The alleged invention of the '523 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '523 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the

teachings of the prior art to achieve the alleged invention of the '523 patent and would have had a reasonable expectation of success in doing so.

b. The subject matter claimed in the '523 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the claimed invention as a whole would have been obvious at the time the alleged invention was made, and/or before the effective filing date of the claimed invention, would have been obvious before the effective filing date of the claimed invention to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed invention pertains. Non-limiting examples of prior art rendering each of the claims of the '523 patent invalid under, at least, 35 U.S.C. §§ 102 and/or 103, include, but are expressly not limited to, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Creekwood's Notice Letter.

c. The claims of the '523 patent are invalid because they do not inform those skilled in the art about the scope of the alleged invention with reasonable certainty, and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

85. Creekwood is entitled to a declaration that the claims of the '523 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, and/or for obviousness-type double patenting.

PRAYER FOR RELIEF

WHEREFORE, Creekwood respectfully requests that this Court enter a Judgment and

Order in its favor and against Plaintiff/Counterclaim-Defendant Supernus as follows:

(a) Declaring that the manufacture, sale, offer for sale, use, or importation of the viloxazine extended-release capsules, 100 mg and 200 mg, products described in Creekwood's ANDA No. 220277 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '204 patent;

(b) Declaring that the manufacture, sale, offer for sale, use, or importation of the viloxazine extended-release capsules, 100 mg and 200 mg, products described in Creekwood's ANDA No. 220277 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '853 patent;

(c) Declaring that the manufacture, sale, offer for sale, use, or importation of the viloxazine extended-release capsules, 100 mg and 200 mg, products described in Creekwood's ANDA No. 220277 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '338 patent;

(d) Declaring that the manufacture, sale, offer for sale, use, or importation of the viloxazine extended-release capsules, 100 mg and 200 mg, products described in Creekwood's ANDA No. 220277 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '753 patent;

(e) Declaring that the manufacture, sale, offer for sale, use, or importation of viloxazine extended-release capsules, 100 mg and 200 mg, products described in Creekwood's ANDA No.

220277 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '143 patent;

(f) Declaring that the manufacture, sale, offer for sale, use, or importation of viloxazine extended-release capsules, 100 mg and 200 mg, products described in Creekwood's ANDA No. 220277 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '523 patent;

(g) Declaring that the claims of the '753 patent are invalid;

(h) Declaring that the claims of the '143 patent are invalid;

(i) Declaring that the claims of the '523 patent are invalid;

(j) Ordering that Plaintiff's Complaint be dismissed with prejudice and judgment be entered in favor of Creekwood;

(k) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Creekwood attorneys' fees, costs, and expenses in this action; and

(l) Awarding Creekwood any further and additional relief as the Court deems just and proper.

Dated: September 19, 2025

Respectfully submitted,

s/ *Eric I. Abraham*
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Attorneys for Defendant Creekwood Pharmaceuticals, LLC

LOCAL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in this action is related to the following actions in the District Court for the District of New Jersey:

- *Supernus Pharmaceuticals, Inc. v. Appco Pharma LLC et al*, 2:25-12183 (MEF-MAH);
- *Supernus Pharmaceuticals, Inc. v. Apotex Inc.*, 2:25-12184 (MEF-MAH);
- *Supernus Pharmaceuticals, Inc. v. Aurobindo Pharma Limited, et al*, 2:25-12186 (MEF-MAH);
- *Supernus Pharmaceuticals, Inc. v. Zydus Lifesciences Global FZE et al*, 2:25-12188 (MEF-MAH);
- *Supernus Pharmaceuticals, Inc. v. MSN Pharmaceuticals Inc.*, 2:25-13204 (MEF-MAH);
- *Supernus Pharmaceuticals, Inc. v. Zenara Pharma Private Limited et al*, 2:25-13207 (MEF-MAH); and
- *Supernus Pharmaceuticals, Inc. v. Macleods Pharmaceuticals Ltd. et al*, 2:25-15399 (MEF-MAH).

LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

Dated: September 19, 2025

Respectfully submitted,

s/ *Eric I. Abraham*
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Attorneys for Defendant Creekwood Pharmaceuticals, LLC

CERTIFICATE OF SERVICE

I hereby certify that on September 19, 2025, I caused a true and correct copy of the foregoing document to be served by notice of electronic filing and via electronic mail on counsel of record in this matter.

By: *s/ Eric I. Abraham*
Eric I. Abraham