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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC.,

Plaintiff,

v.

ZYDUS LIFESCIENCES GLOBAL FZE, ZYDUS PHARMACEUTICALS (USA) INC., and ZYDUS LIFESCIENCES LIMITED,

Defendants.

Civil Action No. 2:25-12188 (MEF)(MAH)

Document Electronically Filed

ZYDUS LIFESCIENCES GLOBAL FZE, ZYDUS PHARMACEUTICALS (USA) INC., AND ZYDUS LIFESCIENCES LIMITED'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT

Defendants Zydus Lifesciences Global FZE ("Zydus Global"), Zydus Pharmaceuticals (USA) Inc. ("Zydus USA"), and Zydus Lifesciences Limited ("Zydus Lifesciences"), (collectively, "Defendants"), for their Answer, Affirmative Defenses, and Counterclaims to the Complaint of Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff"), state as follows:

All averments not expressly admitted are denied.

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"); and 9,662,338 ("the '338 patent"), attached hereto as Exhibits A–C (collectively, "the patents-in-suit").

ANSWER: The allegations in paragraph 1 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiff's Complaint purports to be a civil action alleging infringement of U.S. Patent Nos. 9,358,204 ("the '204 patent"), 9,603,853 ("the '853 patent"), and 9,662,338 ("the '338 patent") (collectively, the "Patents-in-Suit") under Title 35 of the United States Code. Defendants further admit that what purports to be copies of the '204, '853, and '338 patents are attached to Plaintiff's Complaint as Exhibits A, B, and C, respectively. Defendants deny all other allegations in paragraph 1.

THE PARTIES

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

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 2 and therefore deny them.

3. Upon information and belief, Defendant Zydus FZE is a corporation organized and existing under the laws of Dubai, United Arab Emirates, having a principal place of business at Fzjo B2601, Jebel Ali Free Zone Dubai, Dubai, United Arab Emirates.

ANSWER: Defendants admit that Zydus Global is an entity organized and existing under the laws of Dubai, United Arab Emirates and that Zydus Global has a principal place of business at FZJO B2601, Jebel Ali Free Zone Dubai, Dubai, United Arab Emirates. Defendants deny all other allegations in paragraph 3.

4. Upon information and belief, Defendant Zydus USA is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

ANSWER: Admitted.

5. Upon information and belief, Defendant Zydus Limited is a corporation organized and existing under the laws of India, having a principal place of business located at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, India.

ANSWER: Defendants admit that Zydus Lifesciences is an entity organized and existing under the laws of India and that Zydus Lifesciences has a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad 382481, India. Defendants deny all other allegations in paragraph 5.

6. Upon information and belief, Defendants Zydus FZE and Zydus USA are wholly-owned subsidiaries of Zydus Limited.

ANSWER: Admitted.

7. Zydus USA's website states:

> Zydus Pharmaceuticals (USA) Inc. is the US generic drug division of a much larger company known as Zydus Lifesciences. Zydus Lifesciences is a global, fully integrated pharmaceutical company with a presence in 50 countries and is committed to growing its presence around the world and in the United States.

https://zydususa.com/ (last visited on June 25, 2025).

ANSWER: Defendants admit that the website, https://zydususa.com (last accessed September 22, 2025), states, in part:

> Zydus Pharmaceuticals (USA) Inc. is the US generic drug division of a much larger company known as Zydus Lifesciences. Zydus Lifesciences is a global, fully integrated pharmaceutical company with a presence in 50 countries and is committed to growing its presence around the world and in the United States.

Defendants deny all other allegations in paragraph 7.

JURISDICTION AND VENUE

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

ANSWER: The allegations in paragraph 8 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest subject matter jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Defendants in this case and solely as they apply to the viloxazine extended-release capsules, 100 mg, 150 mg, and 200 mg described in ANDA No. 220545 ("Zydus Global's Proposed ANDA Product"). Defendants deny all other allegations in paragraph 8.

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

ANSWER: The allegations in paragraph 9 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Defendants in this case and solely as they apply to Zydus Global's Proposed ANDA Product. Defendants deny all other allegations in paragraph 9.

10. This Court has personal jurisdiction over Zydus FZE at least because, upon information and belief: (i) Zydus FZE, itself and through related entities and agents, has purposefully availed itself of the privilege of doing business in the State of New Jersey by continuously and systematically placing goods in the stream of commerce for importation, use, sale, offer for sale, and/or distribution throughout the United States, including the State of New Jersey; (ii) Zydus FZE, itself and through related entities and agents, regularly transacts or solicits business, performs work, and contracts to supply goods and services in New Jersey and/or derives substantial revenue from goods or services used or consumed in New Jersey; (iii) Zydus FZE, itself and through related entities and agents, is in the business of developing and manufacturing generic pharmaceutical products for importation, use, sale, offer for sale, and/or distribution throughout the United States, including in the State of New Jersey; (iv) Zydus FZE has consented and submitted to this Court's jurisdiction in prior civil actions and has invoked the benefits and protections of this Court by asserting counterclaims in prior civil actions;[1] (v) Zydus FZE's contacts with this Judicial District—e.g., the manufacturing, importation, use, sale, offer for sale, and/or distribution of generic pharmaceutical products (including the accused products at issue in this action)—give rise to and/or are related to Plaintiff's claims; (vi) Zydus FZE, itself and through related entities and agents, has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (vii) if Defendants' Abbreviated New Drug Application

[1] *See, e.g., Jazz Pharmaceuticals Ireland Ltd. v. Sandoz Inc.*, No. 24-cv-09110 (RK) (RLS), ECF No. 52 (D.N.J.) (not contesting personal jurisdiction and filing counterclaims); *Genentech, Inc. v. Natco Pharma Ltd.*, No. 24-cv-10567 (BRM) (JSA), ECF No. 30 (D.N.J.) (same).

("ANDA") No. 220545 ("Defendants' ANDA") receives final approval, Defendants' viloxazine extended-release capsules (100 mg, 150 mg, and 200 mg) ("Defendants' ANDA Products") will be marketed and distributed by Zydus FZE 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; and (viii) it is reasonable and fair for this Court to exercise personal jurisdiction over Zydus FZE.

ANSWER: The allegations in paragraph 10 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus Global does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Zydus Global in this case and solely as they apply to Zydus Global's Proposed ANDA Product. In response to allegations (i), (ii), (iii), (v), and (vii), Defendants admit only that (a) Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus Global's Proposed ANDA Products in or into the United States, (b) Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 220545, and (c) Zydus Lifesciences develops and manufactures pharmaceutical products, including generic pharmaceutical products, sold in the United States. In response to allegation (iv) and footnote 1, Defendants admit only that (d) in *Jazz Pharmaceuticals Ireland Ltd. v. Sandoz Inc.*, No. 24-cv-09110 (D.N.J.), D.I. 52 at ¶ 73, Zydus Global stated it "does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Global and solely as they apply to Zydus's Proposed ANDA Product" and that Zydus Global asserted counterclaims, and (e) in *Genentech, Inc. v. Natco Pharma Ltd.*, No. 24-cv-10567, D.I. 30 at ¶ 18, Zydus Global stated it "do[es] not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Global . . . and solely as they apply to the Proposed ANDA Product" and that Zydus Global asserted counterclaims. Defendants deny all other allegations in paragraph 10.

11. In the alternative, this Court has jurisdiction over Zydus FZE under Fed. R. Civ. P. 4(k)(2) because: (i) Supernus's claims arise under federal law; (ii) Zydus FZE is a foreign

defendant not subject to jurisdiction in any state's courts of general jurisdiction; and (iii) Zydus FZE has sufficient contacts with the United States as a whole—including, but not limited to, preparing and submitting ANDAs to the U.S. Food and Drug Administration ("FDA") and/or importing, manufacturing, using, selling, offering to sell, and distributing pharmaceutical products throughout the United States—such that this Court's exercise of jurisdiction over Zydus FZE satisfies due process and is otherwise consistent with the United States Constitution and laws.

ANSWER: The allegations in paragraph 11 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus Global does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Zydus Global in this case and solely as they apply to Zydus Global's Proposed ANDA Product. In response to allegation (i), Defendants admit only that Plaintiff's Complaint purports to be a civil action alleging infringement of the Patents-in-Suit. In response to allegation (ii), Defendants admit only that Zydus Global is an entity organized and existing under the laws of Dubai, United Arab Emirates. In response to allegation (iii), Defendants admit only that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus Global's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 11.

12. This Court has personal jurisdiction over Zydus Limited at least because, upon information and belief: (i) Zydus Limited, itself and through related entities and agents, has purposefully availed itself of the privilege of doing business in the State of New Jersey by continuously and systematically placing goods in the stream of commerce for importation, use, sale, offer for sale, and/or distribution throughout the United States, including the State of New Jersey; (ii) Zydus Limited, itself and through related entities and agents, regularly transacts or solicits business, performs work, and contracts to supply goods and services in New Jersey and/or derives substantial revenue from goods or services used or consumed in New Jersey; (iii) Zydus Limited, itself and through related entities and agents, is in the business of developing and manufacturing generic pharmaceutical products for importation, use, sale, offer for sale, and/or distribution throughout the United States, including in the State of New Jersey; (iv) Zydus Limited has consented and submitted to this Court's jurisdiction in prior civil actions and has invoked the benefits and protections of this Court by asserting counterclaims in prior civil

actions;[2] (v) Zydus Limited's contacts with this Judicial District—e.g., the manufacturing, importation, use, sale, offer for sale, and/or distribution of generic pharmaceutical products (including the accused products at issue in this action)—give rise to and/or are related to Plaintiff's claims; (vi) Zydus Limited, itself and through related entities and agents, has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (vii) if Defendants' ANDA receives final approval, Defendants' ANDA Products will be marketed and distributed by Zydus Limited 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; and (viii) it is reasonable and fair for this Court to exercise personal jurisdiction over Zydus Limited.

ANSWER: The allegations in paragraph 12 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus Lifesciences does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Zydus Lifesciences in this case and solely as they apply to Zydus Global's Proposed ANDA Product. In response to allegations (i), (ii), (iii), (v), and (vii), Defendants admit only that (a) Zydus Lifesciences manufactures pharmaceutical products, including generic pharmaceuticals products, sold in the United States, and (b) Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. In response to allegation (iv) and footnote 2, Defendants admit only that (c) in *AstraZeneca Pharms. LP v. Zydus Pharms. (USA) Inc.*, No. 24-cv-10629 (D.N.J.), D.I. 11 at ¶ 17, Zydus Lifesciences stated that "Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA Products" and that Zydus Lifesciences asserted counterclaims, (d) in *Jazz Pharmaceuticals Ireland Ltd. v. Sandoz Inc.*, No. 24-cv-09110 (D.N.J.), D.I. 52 at ¶ 77,

[2] *See, e.g.*, *AstraZeneca Pharms. LP v. Zydus Pharms. (USA) Inc.*, No. 24-cv-10629 (RK) (TJB), ECF No. 11 (D.N.J.) (consenting to personal jurisdiction and filing counterclaims); *Jazz Pharms. Ireland Ltd. v. Sandoz Inc.*, No. 24-cv-09110 (RK) (RLS), ECF No. 52 (D.N.J.) (same); *Genentech, Inc. v. Natco Pharma Ltd.*, No. 24-cv-10567 (BRM) (JSA), ECF No. 30 (D.N.J.) (same).

Zydus Lifesciences stated it "does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Lifesciences and solely as they apply to Zydus's Proposed ANDA Product" and that Zydus Lifesciences asserted counterclaims, and (e) in *Genentech, Inc. v. Natco Pharma Ltd.*, No. 24-cv-10567, D.I. 30 at ¶ 23, Zydus Lifesciences stated it "does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Lifesciences and solely as they apply to the Proposed ANDA Product" and that Zydus Lifesciences asserted counterclaims. Defendants deny all other allegations in paragraph 12.

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

ANSWER: The allegations in paragraph 13 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus Lifesciences does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Zydus Lifesciences in this case and solely as they apply to Zydus Global's Proposed ANDA Product. In response to allegation (i), Defendants admit only that Plaintiff's Complaint purports to be a civil action alleging infringement of the Patents-in-Suit. In response to allegation (ii), Defendants admit only that Zydus Lifesciences is an entity organized and existing under the laws of India. In response to allegation (iii), Defendants admit only that Zydus Lifesciences manufactures pharmaceutical products, including generic pharmaceuticals products, sold in the United States. Defendants deny all other allegations in paragraph 13.

14. This Court has personal jurisdiction over Zydus USA at least because, upon information and belief: (i) Zydus USA is incorporated in New Jersey; (ii) Zydus USA maintains

principal places of business in New Jersey located at 73 Route 31 North, Pennington, New Jersey 08534; (iii) Zydus USA is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iv) Zydus USA is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (v) Zydus USA has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (vi) Zydus USA has consented and submitted to this Court's jurisdiction in prior civil actions and has invoked the benefits and protections of this Court by asserting counterclaims in prior civil actions;[3] (vii) Zydus USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0100915422; (viii) Zydus USA is registered with the State of New Jersey's Department of Health as a drug and medical device "wholesale" with Registration Number 5003171; (ix) if Defendants' ANDA receives final approval, Defendants' ANDA Products will be marketed and distributed by Zydus USA in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey; and (x) it is reasonable and fair for this Court to exercise personal jurisdiction over Zydus USA.

ANSWER: The allegations in paragraph 14 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus USA does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Zydus USA in this case and solely as they apply to Zydus Global's Proposed ANDA Product. In response to allegations (i) and (ii), Defendants admit only that Zydus USA is a New Jersey corporation with a principal place of business in Pennington, New Jersey. In response to allegations (iii) and (iv), Defendants admit only that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. In response to allegation (vi) and footnote 3, Defendants admit only that (a) in *AstraZeneca Pharms. LP v. Zydus Pharms. (USA) Inc.*, No. 24-cv-10629 (D.N.J.), D.I. 11 at ¶ 17, Zydus USA stated that "Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA

[3] *See, e.g.*, *AstraZeneca Pharms. LP v. Zydus Pharms. (USA) Inc.*, No. 24-cv-10629 (RK) (TJB), ECF No. 11 (D.N.J.) (not contesting personal jurisdiction and filing counterclaims); *Jazz Pharms. Ireland Ltd. v. Sandoz Inc.*, No. 24-cv-09110 (RK) (RLS), ECF No. 52 (D.N.J.) (same); *Genentech, Inc. v. Natco Pharma Ltd.*, No. 24-cv-10567 (BRM) (JSA), ECF No. 30 (D.N.J.) (same).

Products" and that Zydus USA asserted counterclaims, (b) in *Jazz Pharmaceuticals Ireland Ltd. v. Sandoz Inc.*, No. 24-cv-09110 (D.N.J.), D.I. 52 at ¶ 75, Zydus USA stated it "does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA and solely as they apply to Zydus's Proposed ANDA Product" and that Zydus USA asserted counterclaims, and (c) in *Genentech, Inc. v. Natco Pharma Ltd.*, No. 24-cv-10567, D.I. 30 at ¶ 29, Zydus USA stated it "does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA and solely as they apply to the Proposed ANDA Product" and that Zydus USA asserted counterclaims. In response to allegation (vii), Defendants admit only that Zydus USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0100915422. In response to allegation (viii), Defendants admit only that Zydus USA is registered with the State of New Jersey's Department of Health as a drug and medical device wholesaler with Registration Number 5003171. In response to allegation (ix), Defendants admit only that (d) Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States and (e) Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 220545. Defendants deny all other allegations in paragraph 14.

15. Upon information and belief, pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), Defendants have prepared, submitted, and filed with FDA, and FDA has received, Defendants' ANDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Defendants' ANDA Products.

ANSWER: The allegations in paragraph 15 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the

commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that FDA has sent to Zydus Global a paragraph IV acknowledgement ANDA receipt letter with respect to ANDA No. 220545. Defendants deny all other allegations in paragraph 15.

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

ANSWER: The allegations in paragraph 16 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 220545. Defendants deny all other allegations in paragraph 16.

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

ANSWER: The allegations in paragraph 17 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Defendants in this case and solely as they apply to Zydus Global's Proposed ANDA Product. Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 17.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: The allegations in paragraph 20 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 20.

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

ANSWER: The allegations in paragraph 21 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA is the

U.S. Agent for Zydus Global with respect to ANDA No. 220545. Defendants deny all other allegations in paragraph 21.

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

ANSWER: The allegations in paragraph 22 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court solely for the limited purpose of Plaintiff's claims against Defendants in this case and solely as they apply to Zydus Global's Proposed ANDA Product. Defendants deny all other allegations in paragraph 22.

FACTS COMMON TO ALL COUNTS

23. Upon information and belief, on or about May 27, 2025, Defendants sent a letter pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95) regarding the paragraph IV certification that Defendants submitted in Defendants' ANDA and the patents-in-suit (the "Notice Letter") to Supernus at 9715 Key West Avenue, Rockville, Maryland 20850.

ANSWER: Defendants admit that pursuant to 21 U.S.C. § 355(j), Zydus Global transmitted Zydus Global's Notice Letter, dated May 27, 2025, to Supernus at 8715 Key West Avenue, Rockville, Maryland 20850 notifying Supernus that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus Global's Notice Letter states in part that ANDA No. 220545 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the Patents-in-Suit. Defendants deny all other allegations in paragraph 23.

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

ANSWER: Defendants admit that Zydus Global's Notice Letter contained an Offer of Confidential Access ("OCA") to ANDA No. 220545, pursuant to 21 U.S.C. § 355(j)(5)(C). Defendants deny all other allegations in paragraph 24.

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

ANSWER: Defendants admit that Zydus Global's Notice Letter contained an OCA to ANDA No. 220545, pursuant to 21 U.S.C. § 355(j)(5)(C). Defendants deny the allegations in the second sentence of paragraph 25. Defendants further admit that Supernus and Zydus Global did not reach agreement on the terms of an OCA. Defendants deny all other allegations in paragraph 25.

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

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 220545 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 26.

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

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 220545 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture,

use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus Lifesciences manufactures pharmaceutical products, including generic pharmaceuticals products, sold in the United States. Defendants further admit that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants deny all other allegations in paragraph 27.

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

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 220545 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 220545. Defendants deny all other allegations in paragraph 28.

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

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 220545 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus Lifesciences manufactures pharmaceutical products, including generic pharmaceuticals products, sold in the United States. Defendants further admit that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants deny all other allegations in paragraph 29.

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

ANSWER: Defendants admit that Zydus Lifesciences manufactures pharmaceutical products, including generic pharmaceuticals products, sold in the United States. Defendants further admit that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants deny all other allegations in paragraph 30.

31. Defendants' website states that "[t]he company currently offers more than 500 SKUs to the US market and is ranked the fifth largest unbranded generic corporation in the US based on dispensed prescriptions (IQVIA, NPA Audit, MAT Mar 2023)." *See* https://zydususa.com/overview/ (last visited on June 25, 2025).

ANSWER: Defendants admit that the website, https://zydususa.com/overview/ (last accessed September 22, 2025), states, in part: "[t]he company currently offers more than 500 SKUs to the US market and is ranked the fifth largest unbranded generic corporation in the US based on dispensed prescriptions (IQVIA, NPA Audit, MAT June 2025)." Defendants deny all other allegations in paragraph 31.

32. Defendants' website states that Defendants "are focused on expanding [their] portfolio of complex generics, including modified release solid orals . . . ." *See* https://zydususa.com/overview/ (last visited on June 25, 2025).

ANSWER: Defendants admit that the website, https://zydususa.com/overview/ (last accessed September 22, 2025), states, in part: "[w]e are focused on expanding our portfolio of complex generics, including modified release solid orals, transdermals, injectables, and oral suspensions to further our footprint in the lives of patients." Defendants deny all other allegations in paragraph 32.

33. Defendants' website states that "[t]o date, Zydus Pharmaceuticals has filed over 129 drug master files (DMFs), received final USFDA approval on 287 Abbreviated New Drug Applications (ANDAs), and has over 85 ANDAs pending approval with the USFDA." *See* https://zydususa.com/overview/ (last visited on June 25, 2025)).

ANSWER: Defendants admit that the website, https://zydususa.com/overview/ (last accessed September 22, 2025), states, in part: "[t]o date, Zydus Pharmaceuticals has filed over 139 drug master files (DMFs), received final USFDA approval on 281 Abbreviated New Drug Applications (ANDAs), and has over 75 ANDAs pending approval with the USFDA." Defendants deny all other allegations in paragraph 33.

34. 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: The allegations in paragraph 34 state legal conclusions to which no answer is required. To the extent that an answer is required, Defendants admit that Zydus's Notice Letter complied with applicable law. Defendants deny all other allegations in paragraph 34.

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

ANSWER: Admitted.

36. Upon information and belief, the Notice Letter does not disclose any invalidity contentions or opinions specifically directed to any claim of the patents-in-suit. Accordingly, upon information and belief, Defendants acknowledge and admit that the patents-in-suit are not invalid.

ANSWER: Defendants deny that the allegations in paragraph 36 accurately and completely recite the statements in Zydus Global's Notice Letter and therefore deny them. Exhibit A to Zydus Global's Notice Letter states in part that "in [Zydus Global's] opinion and to the best of its knowledge, no valid and enforceable claim of [the Patents-in-suit] will be infringed by the manufacture, use, sale, offer to sell within, or importation into, the United States of

[Zydus Global's Proposed ANDA Product]" and "Zydus [Global] does not waive, and expressly reserves, the right to raise additional defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '204, '853, and '338 patents in any ensuing litigation or other proceeding that may result from receipt of this letter. *See Abbott Labs, Inc. v. Apotex Inc.,* 725 F. Supp. 2d 724, 727 (N.D. Ill. 2010) (refusing to strike defense theories not raised in defendant's notice letter because an ANDA filer is 'not limited to the invalidity and noninfringement theories raised in its paragraph IV notice letter.'); *Astra Aktiebolag v. Kremers Urban Dev. Co.,* No. 99 Civ. 8928 (BSJ), 2000 U.S. Dist. LEXIS 2511, at *4 (S.D.N.Y. Mar. 6, 2000) ('There is no language in the relevant statutory provisions, legislative history or cases barring [an ANDA filer] from raising defenses and counterclaims not noticed in [its] ANDA.')." Defendants deny all other allegations in paragraph 36.

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

ANSWER: Defendants deny that the allegations in paragraph 37 accurately and completely recite the statements in Zydus Global's Notice Letter and therefore deny them. Exhibit A of Zydus Global's Notice Letter states in part that "in [Zydus Global's] opinion and to the best of its knowledge, no valid and enforceable claim of [the Patents-in-suit] will be infringed by the manufacture, use, sale, offer to sell within, or importation into, the United States of [Zydus Global's Proposed ANDA Product]" and "Zydus [Global] does not waive, and expressly reserves, the right to raise additional defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '204, '853, and '338 patents in any ensuing litigation or other proceeding that may result from receipt of this letter. *See Abbott Labs, Inc. v. Apotex Inc.,* 725 F. Supp. 2d 724, 727 (N.D. Ill. 2010) (refusing to strike defense theories not raised in defendant's notice letter because an ANDA filer is 'not limited to the invalidity and

noninfringement theories raised in its paragraph IV notice letter.'); *Astra Aktiebolag v. Kremers Urban Dev. Co.,* No. 99 Civ. 8928 (BSJ), 2000 U.S. Dist. LEXIS 2511, at *4 (S.D.N.Y. Mar. 6, 2000) ('There is no language in the relevant statutory provisions, legislative history or cases barring [an ANDA filer] from raising defenses and counterclaims not noticed in [its] ANDA.')."

Defendants deny all other allegations in paragraph 37.

38. 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: Defendants admit that FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists "SUPERNUS PHARMACEUTICALS INC" as Applicant Holder, "QELBREE" as Proprietary Name, "VILOXAZINE HYDROCHLORIDE" as Active Ingredient, "CAPSULE, EXTENDED RELEASE" as Dosage Form, and "EQ 100MG BASE," "EQ 150MG BASE," and "EQ 200MG BASE," as Strengths in connection with New Drug Application ("NDA") No. 211964. Defendants deny all other allegations in paragraph 38.

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

ANSWER: Defendants admit on information and belief that the prescribing information for Qelbree®, as revised January 23, 2025 and available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/211964s013lbl.pdf (accessed September 22, 2025), states, in part:

> **----------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)

Defendants deny all other allegations in paragraph 39.

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

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

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

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

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

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

ANSWER: Defendants admit on information and belief that the prescribing information for Qelbree®, as revised January 23, 2025 and available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/211964s013lbl.pdf (accessed September 22, 2025), states, in part:

----------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)

Defendants deny all other allegations in paragraph 40.

41. FDA's publication, titled, "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book"), lists six (6) patents—specifically, the three (3) patents-in-suit and United States Patent Nos. 11,324,753 ("the '753

patent"); 11,458,143 ("the '143 patent"); and 12,121,523 ("the '523 patent")—as covering Supernus's Qelbree®. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), the six Orange Book patents were submitted to FDA with or after the approval of NDA No. 211964.

ANSWER: The allegations in paragraph 41 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that FDA's Orange Book lists the '204, '853, and '338 patents and U.S. Patent Nos. 11,324,753 ("the '753 patent"), 11,458,143 ("the '143 patent"), and 12,121,523 ("the '523 patent") under Patent and Exclusivity, "SUPERNUS PHARMACEUTICALS INC" as Applicant Holder, "Apr 2, 2021" as Approval Date, and "QELBREE" as Proprietary Name in connection with NDA No. 211964. Defendants further admit that FDA's Orange Book lists "04/29/2021" as the Submission Date for the '204, '853, and '338 patents, "05/17/2022" as the Submission Date for the '753 patent, "10/07/2022" as the Submission Date for the '143 patent, and "11/21/2024" as the Submission Date for the '523 patent in connection with NDA No. 211964. Defendants deny all other allegations in paragraph 41.

42. The patents-in-suit are listed in the Orange Book as covering Qelbree®.

ANSWER: The allegations in paragraph 42 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that FDA's Orange Book lists the '204, '853, and '338 patents under Patent and Exclusivity and "QELBREE" as Proprietary Name in connection with NDA No. 211964. Defendants deny all other allegations in paragraph 42.

43. 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: The allegations in paragraph 43 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that what purports to be a

copy of the '204 patent is attached to Plaintiff's Complaint as Exhibit A. Defendants further admit that on its face, Exhibit A to Plaintiff's Complaint is titled "Formulations of Viloxazine," the "Date of Patent" is listed as June 7, 2016, and Michael L. Vieira, Austin B. Huang, and Padmanabh P. Bhatt are listed as Inventors. Defendants further admit that according to the United States Patent and Trademark Office's ("USPTO") Patent Assignment Search database, Reel 029795, Frame 0177, the '204 patent is assigned to Supernus Pharmaceuticals, Inc. Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 43 and therefore deny them.

44. 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: The allegations in paragraph 44 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that what purports to be a copy of the '853 patent is attached to Plaintiff's Complaint as Exhibit B. Defendants further admit that on its face, Exhibit B to Plaintiff's Complaint is titled "Formulations of Viloxazine," the "Date of Patent" is listed as March 28, 2017, and Michael L. Vieira, Austin B. Huang, and Padmanabh P. Bhatt are listed as Inventors. Defendants further admit that according to the USPTO Patent Assignment Search database, Reel 029795, Frame 0177, the '853 patent is assigned to Supernus Pharmaceuticals, Inc. Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 44 and therefore deny them.

45. 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: The allegations in paragraph 45 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that what purports to be a

copy of the '338 patent is attached to Plaintiff's Complaint as Exhibit C. Defendants further admit that on its face, Exhibit C to Plaintiff's Complaint is titled "Formulations of Viloxazine," the "Date of Patent" is listed as May 30, 2017, and Michael L. Vieira, Austin B. Huang, and Padmanabh P. Bhatt are listed as Inventors. Defendants further admit that according to the USPTO Patent Assignment Search database, Reel 029795, Frame 0177, the '338 patent is assigned to Supernus Pharmaceuticals, Inc. Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 45 and therefore deny them.

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

ANSWER: Defendants admit that Zydus Global's ANDA No. 220545 identifies Qelbree® viloxazine hydrochloride extended-release capsules, 100 mg, 150 mg, and 200 mg, as the Reference Listed Drug. Defendants deny all other allegations in paragraph 46.

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

ANSWER: Defendants admit that Zydus Global's proposed ANDA product, described in ANDA No. 220545, are viloxazine hydrochloride extended-release capsules, 100 mg, 150 mg, and 200 mg. Defendants deny all other allegations in paragraph 47.

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

ANSWER: Defendants admit that ANDA No. 220545 contains bioequivalence data required by applicable regulations. Defendants deny all other allegations in paragraph 48.

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

ANSWER: The allegations in paragraph 49 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that 21 U.S.C. § 355(j)(2)(A) states, in part:

> (A) An abbreviated application for a new drug shall contain—
>
> > (i) 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) (hereinafter in this subsection referred to as a "listed drug");
> >
> > * * *
> >
> > (v) 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;

Defendants deny all other allegations in paragraph 49.

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

ANSWER: The allegations in paragraph 50 state legal conclusions to which no answer is required. To the extent that an answer is required, Defendants admit that Zydus Global's Notice Letter complied with applicable law. Defendants further admit that the proposed prescribing information for Zydus Global's Proposed ANDA Product will comply with applicable law. Defendants deny all other allegations in paragraph 50.

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

ANSWER: Defendants admit that the proposed prescribing information for Zydus Global's Proposed ANDA Product will comply with applicable law. Defendants deny all other allegations in paragraph 51.

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

ANSWER: Defendants admit that the proposed prescribing information for Zydus Global's Proposed ANDA Product will comply with applicable law. Defendants deny all other allegations in paragraph 52.

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

ANSWER: Defendants admit that the proposed prescribing information for Zydus Global's Proposed ANDA Product will comply with applicable law. Defendants deny all other allegations in paragraph 53.

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

ANSWER: Defendants admit that the proposed prescribing information for Zydus Global's Proposed ANDA Product will comply with applicable law. Defendants deny all other allegations in paragraph 54.

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

ANSWER: Defendants admit that the proposed prescribing information for Zydus Global's Proposed ANDA Product will comply with applicable law. Defendants deny all other allegations in paragraph 55.

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

ANSWER: The allegations in paragraph 56 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 220545. Defendants deny all other allegations in paragraph 56.

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

ANSWER: The allegations in paragraph 57 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA is the

U.S. Agent for Zydus Global with respect to ANDA No. 220545. Defendants deny all other allegations in paragraph 57.

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

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

ANSWER: Defendants restate and reallege their answers to each of the preceding paragraph 1-57 as if fully set forth herein.

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

ANSWER: The allegations in paragraph 59 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Gobal's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 220545 includes a Paragraph IV Certification with respect to the '204 patent. Defendants deny all other allegations in paragraph 59.

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

ANSWER: The allegations in paragraph 60 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed

ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 60.

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

ANSWER: The allegations in paragraph 61 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 61.

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

ANSWER: The allegations in paragraph 62 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 220545. Defendants deny all other allegations in paragraph 62.

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

ANSWER: Denied.

64. Upon information and belief, Defendants submitted Defendants' ANDA with a paragraph IV certification to the '204 patent for the purpose of obtaining FDA approval to

engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Defendants' ANDA Products before the expiration of the '204 patent.

ANSWER: The allegations in paragraph 64 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 220545 includes a Paragraph IV Certification with respect to the '204 patent. Defendants deny all other allegations in paragraph 64.

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

ANSWER: Admitted.

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

ANSWER: Defendants admit that pursuant to 21 U.S.C. § 355(j), Zydus Global transmitted its Notice Letter notifying Supernus that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 66.

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

ANSWER: Denied.

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

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 68.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: The allegations in paragraph 77 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first and fourth sentences of paragraph 77. Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA

Product in or into the United States. Defendants further admit that ANDA No. 220545 includes a Paragraph IV Certification with respect to the Patents-in-Suit, including the '204 patent. Defendants deny all other allegations in paragraph 77.

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

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 220545. Defendants deny all other allegations in paragraph 78.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Defendants restate and reallege their answers to each of the preceding paragraph 1-80 as if fully set forth herein.

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

ANSWER: The allegations in paragraph 82 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted

ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 220545 includes a Paragraph IV Certification with respect to the '853 patent. Defendants deny all other allegations in paragraph 82.

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

ANSWER: The allegations in paragraph 83 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 83.

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

ANSWER: The allegations in paragraph 84 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 84.

85. Upon information and belief, Zydus USA provided, is providing, and will provide material and significant support, advice, aid, instruction, inducement, and encouragement to

Zydus FZE and Zydus Limited in the preparation, filing, maintenance, and further prosecution of Defendants' ANDA.

ANSWER: The allegations in paragraph 85 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 220545. Defendants deny all other allegations in paragraph 85.

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

ANSWER: Denied.

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

ANSWER: The allegations in paragraph 87 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 220545 includes a Paragraph IV Certification with respect to the '853 patent. Defendants deny all other allegations in paragraph 87.

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

ANSWER: Admitted.

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

ANSWER: Defendants admit that pursuant to 21 U.S.C. § 355(j), Zydus Global transmitted its Notice Letter notifying Supernus that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 89.

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

ANSWER: Denied.

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

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 91.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

99. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendants' ANDA Products and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to the infringement of the '853 patent by third parties because: (i) Defendants' ANDA Products constitutes a material part of the methods of treatment claimed in the '853 patent; (ii) Defendants know or should know that Defendants' ANDA Products will be made for uses that directly infringe the methods of treatment claimed in the '853 patent; and (iii) Defendants' ANDA

Products are not staple articles or commodities of commerce suitable for substantial noninfringing uses.

ANSWER: Denied.

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

ANSWER: The allegations in paragraph 100 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first and last sentences of paragraph 100. Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 220545 includes a Paragraph IV Certification with respect to the Patents-in-Suit, including the '853 patent. Defendants deny all other allegations in paragraph 100.

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

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 220545. Defendants deny all other allegations in paragraph 101.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Defendants restate and reallege their answers to each of the preceding paragraph 1-103 as if fully set forth herein.

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

ANSWER: The allegations in paragraph 105 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 220545 includes a Paragraph IV Certification with respect to the '338 patent. Defendants deny all other allegations in paragraph 105.

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

ANSWER: The allegations in paragraph 106 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in

the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 106.

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

ANSWER: The allegations in paragraph 107 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 107.

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

ANSWER: The allegations in paragraph 108 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 220545. Defendants deny all other allegations in paragraph 108.

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

ANSWER: Denied.

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

ANSWER: The allegations in paragraph 110 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 220545 includes a Paragraph IV Certification with respect to the '338 patent. Defendants deny all other allegations in paragraph 110.

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

ANSWER: Admitted.

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

ANSWER: Defendants admit that pursuant to 21 U.S.C. § 355(j), Zydus Global transmitted its Notice Letter notifying Supernus that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 112.

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

ANSWER: Denied.

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

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 114.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: The allegations in paragraph 123 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first and last sentences of paragraph 123. Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial

manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 220545 includes a Paragraph IV Certification with respect to the Patents-in-Suit, including the '338 patent. Defendants deny all other allegations in paragraph 123.

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

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 220545. Defendants deny all other allegations in paragraph 124.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

PRAYER FOR RELIEF

Defendants specifically deny that Plaintiff is entitled to the general or specific relief requested against Defendants, or to any relief whatsoever, and pray for judgment in favor of Defendants dismissing this action with prejudice, and awarding Defendants their reasonable

attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in their Answer and without admitting any allegations of the Complaint not otherwise admitted, Defendants aver and assert the following Affirmative Defenses to Plaintiff's Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 9,358,204)

Plaintiff will not and cannot meet the burden of proof required to show that the submission of Zydus Global's ANDA No. 220545 and/or the commercial importation, manufacture, use, offer to sell, and/or sale of Zydus Global's Proposed ANDA Product in or into the United States will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '204 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,358,204)

Upon information and belief, the claims of the '204 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

THIRD AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 9,603,853)

Plaintiff will not and cannot meet the burden of proof required to show that the submission of Zydus Global's ANDA No. 220545 and/or the commercial importation, manufacture, use, offer to sell, and/or sale of Zydus Global's Proposed ANDA Product in or into the United States will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '853 patent.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,603,853)

Upon information and belief, the claims of the '853 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

FIFTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 9,662,338)

Plaintiff will not and cannot meet the burden of proof required to show that the submission of Zydus Global's ANDA No. 220545 and/or the commercial importation, manufacture, use, offer to sell, and/or sale of Zydus Global's Proposed ANDA Product in or into the United States will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '338 patent.

SIXTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,662,338)

Upon information and belief, the claims of the '338 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

RESERVATION OF DEFENSES

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

COUNTERCLAIMS

Zydus Lifesciences Global FZE ("Zydus Global"), Zydus Pharmaceuticals (USA) Inc. ("Zydus USA"), and Zydus Lifesciences Limited ("Zydus Lifesciences") (collectively,

"Counterclaimants") by their attorneys, allege the following counterclaims against Plaintiff/Counterclaim Defendant Supernus Pharmaceuticals, Inc. ("Supernus" or "Counterclaim Defendant").

PARTIES

1. Zydus Global is an entity organized and existing under the laws of Dubai, United Arab Emirates with its principal place of business at FZJO B2601, Jebel Ali Free Zone Dubai, Dubai, United Arab Emirates.

2. Zydus USA is an entity organized and existing under the laws of the State of New Jersey with its primary place of business at 73 Route 31 North, Pennington, New Jersey 08534.

3. Zydus Lifesciences is an entity organized and existing under the laws of India, with its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad 382481, India.

4. Upon information and belief, Counterclaim Defendant is a corporation organized and existing under the laws of Delaware, having a place of business at 9715 Key West Avenue, Rockville, Maryland 20850.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, 35 U.S.C. § 1 *et seq*., 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5).

6. This Court has personal jurisdiction over the Counterclaim Defendant because the Counterclaim Defendant commenced and continues to maintain this action against Counterclaimants in this judicial district.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), 21 U.S.C. § 355(j)(5)(C)(i)(II) and because Counterclaim Defendant commenced and continues to maintain this action against Counterclaimants in this judicial district.

REGULATORY FRAMEWORK

8. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271), a pharmaceutical company seeking approval from the U.S. Food and Drug Administration ("FDA") to sell a new drug must file a New Drug Application ("NDA"), which includes specific data concerning the safety and effectiveness of the drug referenced in the NDA, i.e., the reference-listed drug or RLD.

9. The Hatch-Waxman Act provides that NDA holders shall submit to FDA the patent number and expiration date of any patent that the NDA holder believes "claims the drug for which the applicant submitted the [NDA] . . . which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). FDA lists the patent number(s) and expiration date(s) in its publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book").

ORANGE BOOK LISTED PATENTS FOR QELBREE®

10. Upon information and belief, Counterclaim Defendant is the holder of NDA No. 211964 for Qelbree®, viloxazine hydrochloride extended-release capsules, 100 mg, 150 mg, and 200 mg.

11. United States Patent No. 9,358,204 ("the '204 patent"), titled "Formulations of Viloxazine"—a copy of which Counterclaim Defendant purported to attach to its Complaint as Exhibit A—was issued on June 7, 2016. According to the United States Patent and Trademark Office's ("USPTO") Patent Assignment Search database, Reel 029795, Frame 0177, the '204 patent is assigned to Counterclaim Defendant. FDA's Orange Book lists the expiration date of the '204 patent as February 7, 2033.

12. Upon information and belief, Counterclaim Defendant submitted the '204 patent to FDA for listing in FDA's Orange Book concerning NDA No. 211964 for Qelbree®, viloxazine hydrochloride extended-release capsules, 100 mg, 150 mg, and 200 mg. Accordingly, Counterclaim Defendant maintains and has affirmatively represented that the '204 patent claims the approved drug viloxazine hydrochloride extended-release capsules or a method of using that drug. Therefore, any ANDA applicant, including Zydus Global, attempting to sell viloxazine extended-release capsules before the expiration of the '204 patent has a reasonable apprehension of suit with respect to the '204 patent.

13. United States Patent No. 9,603,853 ("the '853 patent"), titled "Formulations of Viloxazine"—a copy of which Counterclaim Defendant purported to attach to its Complaint as Exhibit B—was issued on March 28, 2017. According to the face of the patent, the '853 patent is assigned to Counterclaim Defendant. FDA's Orange Book lists the expiration date of the '853 patent as February 7, 2033.

14. Upon information and belief, Counterclaim Defendant submitted the '853 patent to FDA for listing in FDA's Orange Book concerning NDA No. 211964 for Qelbree®, viloxazine hydrochloride extended-release capsules, 100 mg, 150 mg, and 200 mg. Accordingly, Counterclaim Defendant maintains and has affirmatively represented that the '853 patent claims the approved drug viloxazine hydrochloride extended-release capsules or a method of using that drug. Therefore, any ANDA applicant, including Zydus Global, attempting to sell viloxazine extended-release capsules before the expiration of the '853 patent has a reasonable apprehension of suit with respect to the '853 patent.

15. United States Patent No. 9,662,338 ("the '338 patent"), titled "Formulations of Viloxazine"—a copy of which Counterclaim Defendant purported to attach to its Complaint as Exhibit C—was issued on May 30, 2017. According to the face of the patent, the '338 patent is assigned to Counterclaim Defendant. FDA's Orange Book lists the expiration date of the '338 patent as April 2, 2035.

16. Upon information and belief, Counterclaim Defendant submitted the '338 patent to FDA for listing in FDA's Orange Book concerning NDA No. 211964 for Qelbree®, viloxazine hydrochloride extended-release capsules, 100 mg, 150 mg, and 200 mg. Accordingly, Counterclaim Defendant Supernus maintains and has affirmatively represented that the '338 patent claims the approved drug viloxazine hydrochloride extended-release capsules or a method of using that drug. Therefore, any ANDA applicant, including Zydus Global, attempting to sell viloxazine extended-release capsules before the expiration of the '338 patent has a reasonable apprehension of suit with respect to the '338 patent.

ZYDUS GLOBAL'S ANDA

17. On April 2, 2025, Zydus Global submitted ANDA No. 220545 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of viloxazine extended-release capsules, 100 mg, 150 mg, and 200 mg.

18. Because Zydus Global seeks FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the proposed products described in ANDA No. 220545 ("Zydus Global's Proposed ANDA Product") before the expiration of the '204, '853, and '338 patents, ANDA No. 220545 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the '204, '853, and '338 patents.

19. Zydus Global sent a letter dated May 27, 2025, notifying Supernus that Zydus Global submitted ANDA No. 218568 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus Global's Proposed ANDA Product and that ANDA No. 220545 includes a Paragraph IV Certification with respect to the '204, '853, and '338 patents ("Zydus Global's Notice Letter").

20. Zydus Global's Notice Letter includes a statement of the factual and legal bases in support of Zydus Global's Paragraph IV Certification for the '204, '853, and '338 patents.

COUNT I
(Declaratory Judgment of Noninfringement of U.S. Patent No. 9,358,204)

21. Counterclaimants repeat and reallege the allegations in paragraphs 1-20 above as though fully set forth herein.

22. By asserting its claim against Counterclaimants for infringement of the '204 patent, Counterclaim Defendant has created a case or controversy regarding the noninfringement of the '204 patent.

23. The submission of Zydus Global's ANDA No. 220545 and/or the commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of Zydus Global's Proposed ANDA Product would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '204 patent.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 9,358,204)

24. Counterclaimants repeat and reallege the allegations in paragraphs 1-23 above as though fully set forth herein.

25. By asserting its claim against Counterclaimants for infringement of the '204 patent, Counterclaim Defendant has created a case or controversy regarding the validity of the '204 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

26. The claims of the '204 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

COUNT III
(Declaratory Judgment of Noninfringement of U.S. Patent No. 9,603,853)

27. Counterclaimants repeat and reallege the allegations in paragraphs 1-26 above as though fully set forth herein.

28. By asserting its claim against Counterclaimants for infringement of the '853 patent, Counterclaim Defendant has created a case or controversy regarding the noninfringement of the '853 patent.

29. The submission of Zydus Global's ANDA No. 220545 and/or the commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of Zydus

Global's Proposed ANDA Product would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '853 patent.

COUNT IV
(Declaratory Judgment of Invalidity of U.S. Patent No. 9,603,853)

30. Counterclaimants repeat and reallege the allegations in paragraphs 1-29 above as though fully set forth herein.

31. By asserting its claim against Counterclaimants for infringement of the '853 patent, Counterclaim Defendant has created a case or controversy regarding the validity of the '853 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

32. The claims of the '853 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

COUNT V
(Declaratory Judgment of Noninfringement of U.S. Patent No. 9,662,338)

33. Counterclaimants repeat and reallege the allegations in paragraphs 1-32 above as though fully set forth herein.

34. By asserting its claim against Counterclaimants for infringement of the '338 patent, Counterclaim Defendant has created a case or controversy regarding the noninfringement of the '338 patent.

35. The submission of Zydus Global's ANDA No. 220545 and/or the commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of Zydus Global's Proposed ANDA Product would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '338 patent.

COUNT VI
(Declaratory Judgment of Invalidity of U.S. Patent No. 9,662,338)

36. Counterclaimants repeat and reallege the allegations in paragraphs 1-35 above as though fully set forth herein.

37. By asserting its claim against Counterclaimants for infringement of the '338 patent, Counterclaim Defendant has created a case or controversy regarding the validity of the '338 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

38. The claims of the '338 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

PRAYER FOR RELIEF

WHEREFORE, Counterclaimants respectfully request that the Court enter judgment against Counterclaim Defendant as follows:

A. A declaration that Counterclaimants have not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '204, '853, and '338 patents.

B. A declaration that the claims of the '204, '853, and '338 patents are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;

C. A declaration that Counterclaim Defendant takes nothing by its Complaint;

D. A dismissal of Counterclaim Defendant's Complaint with prejudice;

E. An award to Counterclaimants of their reasonable costs and attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285; and

F. An award of any other and further relief that this Court may deem just and proper.

Dated: September 22, 2025

By: *s/ Theodora McCormick*

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Attorneys for Zydus Lifesciences Global FZE, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, except that the same Plaintiff has asserted at least some of the patents-in-suit in this case in the following pending matters in this Judicial District: *Supernus Pharmaceuticals, Inc. v. Aurobindo Pharma Limited et al.*, C.A. No. 2:25-cv-12186 (D.N.J.), *Supernus Pharmaceuticals, Inc. v. Apotex Inc.*, C.A. No. 2:25-cv-12184 (D.N.J.), *Supernus Pharmaceuticals, Inc. v. Appco Pharma LLC et al.*, C.A. No. 2:25-cv-12183 (D.N.J.), *Supernus Pharmaceuticals, Inc. v. Zenara Pharma Private Limited et al.*, C.A. No. 2:25-cv-13207 (D.N.J.), *Supernus Pharmaceuticals, Inc. v. MSN Pharmaceuticals, Inc.*, C.A. No. 2:25-cv-13204 (D.N.J.), *Supernus Pharmaceuticals, Inc. v. Creekwood Pharmaceuticals LLC*, C.A. No. 2:25-cv-13201 (D.N.J.) and *Supernus Pharmaceuticals, Inc. v. Macleods Pharmaceuticals Limited et al.*, C.A. No. 2:25-cv-15399 (D.N.J.). Plaintiff has also asserted at least some of the patents-in-suit in this case in the following pending matters in another judicial district: *Supernus Pharmaceuticals, Inc. v. Aurobindo Pharma Limited*, C.A. No. 1:25-cv-00808 (D. Del.), *Supernus Pharmaceuticals, Inc. v. Appco Pharma LLC*, C.A. No. 1:25-cv-00807 (D. Del.), *Supernus Pharmaceuticals, Inc. v. Creekwood Pharmaceuticals LLC*, C.A. No. 1:25-cv-00880 (D. Del.), *Supernus Pharmaceuticals, Inc. v. MSN Pharmaceuticals, Inc.*, C.A. No. 1:25-cv-00879 (D. Del.), and *Supernus Pharmaceuticals, Inc. v. Macleods Pharmaceuticals Limited et al.*, C.A. No. 1:25-cv-01446 (D. Del.). Defendants are not aware of any other action pending in any court or any pending arbitration or administrative proceeding related to this matter.

Dated: September 22, 2025

By: *s/ Theodora McCormick*
Theodora McCormick

LOCAL CIVIL RULE 201.1 CERTIFICATION

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

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

Dated: September 22, 2025

By: *s/ Theodora McCormick*
Theodora McCormick

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Zydus Lifesciences Global FZE, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited's Answer, Affirmative Defenses, and Counterclaims to Plaintiff's Complaint was filed via ECF and served on all counsel of record via ECF and by electronic mail on September 22, 2025.

Dated: September 22, 2025

By: *s/ Theodora McCormick*
Theodora McCormick