Kaan Ekiner
COZEN O'CONNOR
1201 N. Market Street
Suite 1001
Wilmington, DE 19801
(302) 295-2046
kekiner@cozen.com

Attorneys for Defendants Aurobindo Pharma Limited and Aurobindo Pharma U.S.A., Inc.

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

SUPERNUS PHARMACEUTICALS, INC., Plaintiff, v. AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA U.S.A. INC., Defendants.	Civil Action No. 2:25-cv-12186-MEF-MAH

DEFENDANTS AUROBINDO PHARMA LIMITED AND AUROBINDO PHARMA U.S.A., INC.'S ANSWER AND SEPARATE DEFENSES TO PLAINTIFF'S COMPLAINT

Defendants Aurobindo Pharma Limited ("Aurobindo Ltd.") and Aurobindo Pharma U.S.A., Inc. ("Aurobindo USA") (collectively, "Aurobindo"), by and through their undersigned counsel, file this Answer and Separate Defenses to Plaintiff Supernus Pharmaceuticals, Inc.'s ("Supernus" or "Plaintiff") Complaint, and state as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Aurobindo denies all allegations and characterizations in Plaintiff's Complaint except those specifically admitted below. Aurobindo further denies liability for all allegations of patent liability and that Plaintiff is entitled to the relief requested or

any other. In responding to the Complaint, Aurobindo uses the headings employed by Plaintiff strictly as a convenience to the Court, and does not admit any allegation made in, or inference suggested by, such headings. Aurobindo answers the numbered paragraphs of Plaintiff's Complaint as follows:

NATURE OF THE ACTION

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

ANSWER: Aurobindo admits that Plaintiff filed this civil action alleging patent infringement under the patent laws of the United States, Title 35 of the United States Code, involving U.S. Patent Nos. 9,358,204 ("the '204 patent"); 9,603,853 ("the '853 patent"); 9,662,338 ("the '338 patent"); 11,324,753 ("the '753 patent"); 11,458,143 ("the '143 patent"); and 12,121,523 ("the '523 patent") (collectively, the "Patents-in-Suit"). Except as expressly admitted, Aurobindo lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 1, and on that basis denies these allegations.

THE PARTIES

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

ANSWER: Paragraph 2 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, on information and belief, Aurobindo admits that 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. Except as expressly admitted,

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

> 3. Upon information and belief, Aurobindo USA is a corporation organized under the laws of Delaware and operating a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

ANSWER: Admitted.

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

ANSWER: Paragraph 4 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that it develops and manufactures high-quality generic pharmaceutical products that are ultimately used by consumers in the United States. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 4.

> 5. Upon information and belief, Aurobindo USA, either directly or through one or more of its affiliates and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic pharmaceutical products, including in the State of New Jersey.

ANSWER: Paragraph 5 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that it develops and manufactures high-quality generic pharmaceutical products that are ultimately used by consumers in the United States. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 5.

> 6. Upon information and belief, Aurobindo USA is registered as a wholesale drug distributor in the State of New Jersey under Registration Nos. 5003120 and 5006312.

ANSWER: Admitted.

7. Upon information and belief, Aurobindo Ltd. is a corporation organized under the laws of India, having principal places of business at: (i) Galaxy Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Pamkaktha, Ranga Reddy District, Hyderabad, Telangana, India, 500032; (ii) Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Telangana, India; and (iii) Plot No. 11, Survey No. 9, Water Mark Building, Kondapur, Hitech City, Hyderabad 500 084, Telangana, India.

ANSWER: Admitted.

8. Upon information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Ltd.

ANSWER: Admitted.

9. Upon information and belief, Aurobindo USA acts at the direction and for the benefit of Aurobindo Ltd. and is controlled and/or dominated by Aurobindo Ltd.

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 9.

10. Upon information and belief, Aurobindo Ltd. and Aurobindo USA collaborate with respect to the development, regulatory approval, manufacturing, importing, marketing, sale, and/or distribution of pharmaceutical products. Upon information and belief, Aurobindo Ltd. and Aurobindo USA are agents of each other and/or operate in concert as integrated parts of the same business group and enter into agreements with each other that are nearer than arm's length.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 10.

11. Upon information and belief, Aurobindo Ltd. and Aurobindo USA are in the business of, among other things, developing, manufacturing, importing, marketing, distributing, and/or selling generic pharmaceutical products throughout the United States (including in the State of New Jersey), and importing generic pharmaceutical products into the United States (including into the State of New Jersey).

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that it develops and manufactures high-quality generic pharmaceutical products that are ultimately used by consumers

in the United States. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 11.

12. Upon information and belief, Aurobindo Ltd. and Aurobindo USA filed Abbreviated New Drug Application ("ANDA") No. 220487 ("Defendants' ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of generic viloxazine extended-release oral capsules, containing 100 mg, 150 mg, and 200 mg of viloxazine ("Defendants' ANDA Products").

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that it filed its Abbreviated New Drug Application ("ANDA") No. 220487 with the U.S. Food and Drug Administration ("FDA") for its viloxazine extended-release oral capsules, containing 100 mg, 150 mg, and 200 mg of viloxazine ("Defendants' ANDA Products"). The content of Aurobindo's ANDA speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 12.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo does not contest subject matter jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 13.

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

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 14.

15. This Court has personal jurisdiction over Aurobindo USA at least because, upon information and belief: (i) Aurobindo USA maintains a principal place of business in New Jersey located at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520; (ii) Aurobindo USA, itself and through related entities and agents, regularly transacts and solicits business, performs work, and contracts to supply goods and services in New Jersey and/or derives substantial revenue from goods or services used or consumed in New Jersey and thus maintains continuous and systematic contacts with this Judicial District; (iii) Aurobindo USA is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (iv) Aurobindo USA has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (v) Aurobindo 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 (FN 1: *See, e.g., Boehringer Ingelheim Pharms., Inc. v. Aurobindo Pharma USA, Inc.*, No. 17-cv-07887, ECF No. 9 (D.N.J.) (not contesting personal jurisdiction and filing counterclaims); *Mitsubishi Tanabe Pharma Corp. v. Aurobindo Pharma USA, Inc.*, No. 17-cv-05005, ECF No. 9 (D.N.J.) (same); *Otsuka Pharma Co. Ltd. v. Aurobindo Pharma Ltd.*, No. 14-cv-03306, ECF No. 10 (D.N.J.) (same).); (vi) Aurobindo USA is registered as a wholesale drug distributor in the State of New Jersey under the Registration Nos. 5003120 and 5006312; and (vii) Aurobindo USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100921223; (viii) Aurobindo USA, itself and through related entities and agents, has purposefully availed itself of the rights, benefits, and privileges of New Jersey's laws by continuously and systematically placing goods in the stream of commerce for importation, use, sale, offer for sale, and/or distribution throughout the United States, including the State of New Jersey; (ix) Aurobindo USA operates a distribution center spanning across 59 acres of land in East Windsor, New Jersey (*see* https://www.aurobindousa.com/news/aurobindo-opens-new-state-art-fully-automated-distribution-center-spanning-across-59-acres-land-east-windsor-nj/ (last visited on June 25, 2025)); (x) Aurobindo USA's contacts with this Judicial District—e.g., the manufacturing, importation, use, sale, offer for sale, and/or distribution of generic pharmaceutical products (including the accused products at issue in this action)—give rise to and/or are related to Plaintiff's claims; (xi) Aurobindo USA, itself and through related entities and agents, has committed, induced, and/or contributed to acts of patent infringement in New Jersey; (xii) if Defendants' ANDA receives final approval, Defendants' ANDA Products will be marketed and distributed by Aurobindo 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 (xiii) Defendants' website admits that "[Aurobindo USA], incorporated in 2004, is the sales and marketing arm of [Aurobindo Ltd.] in the US, distributing oral solid dosages and other products through its network of subsidiaries." See https://www.aurobindo.com/our-business (last visited on June 25, 2025).

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 15.

16. This Court has personal jurisdiction over Aurobindo Ltd. at least because, upon information and belief: (i) Aurobindo Ltd., itself and through its subsidiaries and agents, has purposefully availed itself of the privilege of doing business in the State of New Jersey by continuously and systematically placing goods in the stream of commerce for importation, use, sale, offer for sale, and/or distribution throughout the United States, including the State of New Jersey; (ii) Aurobindo Ltd., itself and through its subsidiaries and agents, regularly transacts or solicits business, performs work, and contracts to supply goods and services in New Jersey and/or derives substantial revenue from goods or services used or consumed in New Jersey; (iii) Aurobindo Ltd., itself and through its subsidiaries and agents, is in the business of developing and manufacturing generic pharmaceutical products for importation, use, sale, offer for sale, and/or distribution throughout the United States, including in the State of New Jersey; (iv) Defendants' website admits that "[Aurobindo USA], incorporated in 2004, is the sales and marketing arm of [Aurobindo Ltd.] in the US, distributing oral solid dosages and other products through its network of subsidiaries" (*see* https://www.aurobindo.com/our-business (last visited on June 25, 2025)); (v) Aurobindo Ltd. has consented and submitted to this Court's jurisdiction in prior civil actions and has invoked the benefits and protections of this Court by asserting counterclaims in prior civil actions (FN 2: *See, e.g., Mitsubishi Tanabe Pharma Corp. v. Aurobindo Pharma USA, Inc.*, No. 17-cv-05005, ECF No. 9 (D.N.J.) (not contesting personal jurisdiction and filing counterclaims); *Otsuka Pharma Co. Ltd. v. Aurobindo Pharma Ltd.*, No. 14-cv-03306, ECF No. 10 (D.N.J.) (same).); (vi) Aurobindo Ltd.'s contacts with this Judicial District—e.g. the manufacturing, importation, use, sale, offer for sale, and/or distribution of generic pharmaceutical products (including the accused products at issue in this action)—give rise to and/or are related to Plaintiff's claims; (vii) Aurobindo Ltd., itself and through its subsidiaries and agents, has committed, induced, and/or contributed to acts of patent infringement in New Jersey; and (viii) if Defendants' ANDA receives final approval, Defendants' ANDA Products will be marketed and distributed by Aurobindo Ltd. in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo does not contest personal jurisdiction

in this Court for the limited purposes of this action only. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 16.

> 17. In the alternative, this Court has jurisdiction over Aurobindo Ltd. under Fed. R. Civ. P. 4(k)(2) because: (i) Supernus's claims arise under federal law; (ii) Aurobindo Ltd. is a foreign defendant not subject to jurisdiction in any state's courts of general jurisdiction; and (iii) Aurobindo Ltd. has sufficient contacts with the United States as a whole—including, but not limited to, preparing and submitting ANDAs to FDA and/or importing, manufacturing, using, selling, offering to sell, and distributing pharmaceutical products throughout the United States—such that this Court's exercise of jurisdiction over Aurobindo Ltd. satisfies due process and is otherwise consistent with the United States Constitution and laws.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo does not contest jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 17.

> 18. Upon information and belief, pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), Defendants have prepared, submitted, and filed with FDA, and FDA has received, Defendants' ANDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Defendants' ANDA Products before the expiration of the patents-in-suit throughout the United States, including in this Judicial District.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that it prepared, submitted, and filed its ANDA No. 220487 with the FDA. The content of Aurobindo's ANDA speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 18.

> 19. Upon information and belief, Defendants acted collaboratively in the preparation and submission of Defendants' ANDA to FDA.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 19.

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

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 20.

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

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo does not contest jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 21.

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

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo does not contest jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 22.

23. Defendants have taken the significant step of applying to FDA for approval to engage in future activities—including the marketing of Defendants' ANDA

Products—which, upon information and belief, will be purposefully directed at this Judicial District.

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo does not contest jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 23.

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

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 24.

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

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo does not contest venue in this Court for the limited purposes of this action only. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 25.

FACTS COMMON TO ALL COUNTS

26. Upon information and belief, on or about May 29, 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: Aurobindo admits that on or about May 29, 2025, Aurobindo sent a Notice Letter to Supernus. The content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 26.

27. 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: Paragraph 27 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 27.

28. 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: Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that Plaintiff and Aurobindo did not reach agreement on the terms of an Offer of Confidential Access. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 28.

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

ANSWER: Paragraph 29 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 29.

30. The Notice Letter states that **both** Aurobindo USA and Aurobindo Ltd. "are providing Notice" to Plaintiff of the paragraph IV certification that Defendants submitted in Defendants' ANDA.

ANSWER: Paragraph 30 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 30.

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

ANSWER: Paragraph 31 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that it develops and manufactures high-quality generic pharmaceutical products that are ultimately used by consumers in the United States. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 31.

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

ANSWER: Paragraph 32 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 32.

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

ANSWER: Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 33.

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

ANSWER: Paragraph 34 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 34.

35. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a

detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 C.F.R. § 314.95(c)(7) requires that such a letter include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)-(ii).

ANSWER: Paragraph 35 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 35.

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

ANSWER: Paragraph 36 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) were in effect at the time Aurobindo's Notice Letter was filed and that Aurobindo complied with same. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 36.

37. Upon information and belief, the Notice Letter does not disclose any invalidity contentions or opinions specifically directed to: (i) any claims of the '204 patent; (ii) any claims of the '853 patent; (iii) any claims of the '338 patent; or (iv) claims 1-6 and 8-14 of the '523 patent. Accordingly, upon information and belief, Defendants acknowledge and admit that the '204 patent, the '853 patent, the '338 patent, and claims 1-6 and 8-14 of the '523 patent are not invalid.

ANSWER: Paragraph 37 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 37.

38. Upon information and belief, the Notice Letter does not disclose any noninfringement contentions or opinions specifically directed to claims 1-7 of the '143 patent.

ANSWER: Paragraph 38 contains legal conclusions and allegations to which no answer

is required. To the extent an answer is required, the content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 38.

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

ANSWER: Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 39.

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

ANSWER: Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, on information and belief, Aurobindo admits that Supernus's Qelbree® is sold and marketed under 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. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 40.

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

ANSWER: Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, on information and belief, Aurobindo admits that the FDA-approved prescribing information for Qelbree® states that "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." Except as expressly admitted, Aurobindo denies the allegations of Paragraph 41.

42. 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: Paragraph 42 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that Paragraph 42 appears to accurately quote from the "Dosage and Administration" section of the current FDA-approved prescribing information for Qelbree®. Except as expressly admitted, Aurobindo lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 42, and on that basis denies these allegations.

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

ANSWER: Paragraph 43 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that the Patents-in-Suit are listed on FDA's Orange Book in association with NDA No. 211964. Except as expressly admitted, Aurobindo lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 43, and on that basis denies these allegations.

44. 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: Aurobindo admits that the '204 patent is titled "Formulations of Viloxazine," and that the United States Patent and Trademark Office ("USPTO") issued the '204 patent on or about June 7, 2016. Except as expressly admitted, Aurobindo lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 44, and on that basis denies these allegations.

45. 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: Aurobindo admits that the '853 patent is titled "Formulations of Viloxazine," and that the USPTO issued the '853 patent on or about March 28, 2017. Except as expressly admitted, Aurobindo lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 45, and on that basis denies these allegations.

46. 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: Aurobindo admits that the '338 patent is titled "Formulations of Viloxazine," and that the USPTO issued the '338 patent on or about May 30, 2017. Except as expressly admitted, Aurobindo lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 46, and on that basis denies these allegations.

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

ANSWER: Aurobindo admits that the '753 patent is titled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)," and that the USPTO issued the '753 patent on or about May 10, 2022. Except as expressly admitted, Aurobindo lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 47, and on that basis denies these allegations.

> 48. The '143 patent, titled, "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)," was duly and legally issued by the United States Patent and Trademark Office on October 4, 2022, to Supernus upon assignment from inventor Christopher D. Breder. Supernus owns all rights, title, and interest in the '143 patent.

ANSWER: Aurobindo admits that the '143 patent is titled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)," and that the USPTO issued the '143 patent on or about October 4, 2022. Except as expressly admitted, Aurobindo lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 48, and on that basis denies these allegations.

> 49. The '523 patent, titled, "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)," was duly and legally issued by the United States Patent and Trademark Office on October 22, 2024, to Supernus upon assignment from inventor Christopher D. Breder. Supernus owns all rights, title, and interest in the '523 patent.

ANSWER: Aurobindo admits that the '523 patent is titled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)," and that the USPTO issued the '523 patent on or about October 22, 2024. Except as expressly admitted, Aurobindo lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 49, and on that basis denies these allegations.

> 50. 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: Aurobindo admits that NDA No. 211964 is the Reference Listed Drug for Aurobindo's ANDA No. 220487. The content of Aurobindo's ANDA speaks for itself. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 50.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

53. 21 U.S.C. § 355(j)(2)(A)(i) requires that an ANDA contain "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7)." In addition, 21 U.S.C. § 355(j)(2)(A)(v) provides that an ANDA must contain "information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers."

ANSWER: Paragraph 53 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that Plaintiff appears to have accurately quoted from certain sections of 21 U.S.C. § 355 et seq. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 53.

54. 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 25, 2025).

ANSWER: Paragraph 54 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's Notice Letter and ANDA No. 220487 speak for themselves. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 54.

> 55. 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: Paragraph 55 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 55.

> 56. 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: Paragraph 56 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA No. 220487 speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 56.

> 57. 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: Paragraph 57 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA No. 220487 speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 57.

58. 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: Paragraph 58 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA No. 220487 speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 58.

59. 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: Paragraph 59 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA No. 220487 speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 59.

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

ANSWER: Paragraph 60 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA No. 220487 speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 60.

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

ANSWER: Paragraph 61 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA No. 220487 speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 61.

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

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

ANSWER: Aurobindo repeats and re-alleges each of its responses to the foregoing Paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 63 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that it filed its ANDA No. 220487 with the FDA, and that Aurobindo seeks regulatory approval from the FDA for its ANDA. The content of Aurobindo's ANDA speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 63.

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

ANSWER: Paragraph 64 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 64.

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

ANSWER: Paragraph 65 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 65.

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

ANSWER: Paragraph 66 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 66.

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

ANSWER: Paragraph 67 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 67.

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

ANSWER: Paragraph 68 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) were in effect at the time Aurobindo's Notice Letter was filed and that Aurobindo complied with same. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 68.

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

ANSWER: Paragraph 69 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 69.

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

ANSWER: Paragraph 70 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 70.

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

ANSWER: Paragraph 71 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations of Paragraph 71 are wholly speculative, as Aurobindo has not received FDA approval for ANDA No. 220487. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 71.

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

ANSWER: Paragraph 72 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 72.

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

ANSWER: Paragraph 73 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 73.

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

ANSWER: Paragraph 74 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA No. 220487 speaks for itself. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 74.

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

ANSWER: Paragraph 75 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 75.

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

ANSWER: Paragraph 76 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 76.

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

ANSWER: Paragraph 77 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 77.

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

ANSWER: Paragraph 78 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 78.

79. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Defendants' ANDA Products

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

ANSWER: Paragraph 79 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 79.

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

ANSWER: Paragraph 80 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 80.

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

ANSWER: Paragraph 81 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 81.

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

ANSWER: Paragraph 82 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 82.

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

ANSWER: Paragraph 83 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 83.

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

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

ANSWER: Aurobindo repeats and re-alleges each of its responses to the foregoing Paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 85 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that it filed its ANDA No. 220487 with the FDA, and that Aurobindo seeks regulatory approval from the FDA for its ANDA. The content of Aurobindo's ANDA speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 85.

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

ANSWER: Paragraph 86 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 86.

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

ANSWER: Paragraph 87 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 87.

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

ANSWER: Paragraph 88 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 88.

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

ANSWER: Paragraph 89 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 89.

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

ANSWER: Paragraph 90 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) were in effect at the time Aurobindo's Notice Letter was filed and that Aurobindo complied with same. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 90.

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

ANSWER: Paragraph 91 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 91.

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

ANSWER: Paragraph 92 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 92.

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

ANSWER: Paragraph 93 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations of Paragraph 93 are wholly speculative, as Aurobindo has not received FDA approval for ANDA No. 220487. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 93.

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

ANSWER: Paragraph 94 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 94.

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

ANSWER: Paragraph 95 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 95.

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

ANSWER: Paragraph 96 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA No. 220487 speaks for itself. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 96.

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

ANSWER: Paragraph 97 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 97.

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

ANSWER: Paragraph 98 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 98.

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

ANSWER: Paragraph 99 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 99.

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

ANSWER: Paragraph 100 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 100.

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

ANSWER: Paragraph 101 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 101.

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

ANSWER: Paragraph 102 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 102.

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

ANSWER: Paragraph 103 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 103.

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

ANSWER: Paragraph 104 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 104.

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

ANSWER: Paragraph 105 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 105.

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

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

ANSWER: Aurobindo repeats and re-alleges each of its responses to the foregoing Paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 107 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that it filed its ANDA No. 220487 with the FDA, and that Aurobindo seeks regulatory approval from the FDA for its ANDA. The content of Aurobindo's ANDA speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 107.

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

ANSWER: Paragraph 108 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 108.

> 109. Upon information and belief, Aurobindo Ltd. provided, is providing, and will provide material and significant support, advice, aid, instruction, inducement, and encouragement to Aurobindo USA in the preparation, filing, maintenance, and further prosecution of Defendants' ANDA.

ANSWER: Paragraph 109 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 109.

> 110. Upon information and belief, Defendants are jointly and severally liable for Defendants' infringement of one or more claims of the '338 patent.

ANSWER: Paragraph 110 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 110.

> 111. Upon information and belief, Defendants submitted Defendants' ANDA with a paragraph IV certification to the '338 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Defendants' ANDA Products before the expiration of the '338 patent.

ANSWER: Paragraph 111 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 111.

> 112. Upon information and belief, as of the date of the Notice Letter, Defendants were aware of the statutory provisions and regulations in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER: Paragraph 112 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) were in effect at the time Aurobindo's Notice

Letter was filed and that Aurobindo complied with same. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 112.

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

ANSWER: Paragraph 113 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 113.

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

ANSWER: Paragraph 114 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 114.

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

ANSWER: Paragraph 115 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations of Paragraph 115 are wholly speculative, as Aurobindo has not received FDA approval for ANDA No. 220487. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 115.

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

ANSWER: Paragraph 116 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 116.

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

ANSWER: Paragraph 117 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 117.

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

ANSWER: Paragraph 118 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA No. 220487 speaks for itself. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 118.

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

ANSWER: Paragraph 119 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 119.

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

ANSWER: Paragraph 120 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 120.

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

ANSWER: Paragraph 121 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 121.

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

ANSWER: Paragraph 122 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 122.

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

ANSWER: Paragraph 123 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 123.

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

ANSWER: Paragraph 124 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 124.

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

ANSWER: Paragraph 125 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 125.

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

ANSWER: Paragraph 126 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 126.

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: Paragraph 127 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 127.

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

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

ANSWER: Aurobindo repeats and re-alleges each of its responses to the foregoing Paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 129 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that it filed its ANDA No. 220487 with the FDA, and that Aurobindo seeks regulatory approval from the FDA for its ANDA. The content of Aurobindo's ANDA speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 129.

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

ANSWER: Paragraph 130 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 130.

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

ANSWER: Paragraph 131 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 131.

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

ANSWER: Paragraph 132 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 132.

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

ANSWER: Paragraph 133 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 133.

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

ANSWER: Paragraph 134 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) were in effect at the time Aurobindo's Notice Letter was filed and that Aurobindo complied with same. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 134.

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

ANSWER: Paragraph 135 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 135.

136. Under 35 U.S.C. § 271(e)(2)(A), the submission of Defendants' ANDA with a paragraph IV certification to the '753 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Defendants'

ANDA Products before the expiration of the '753 patent is itself an act of infringement of the '753 patent.

ANSWER: Paragraph 136 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 136.

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

ANSWER: Paragraph 137 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations of Paragraph 137 are wholly speculative, as Aurobindo has not received FDA approval for ANDA No. 220487. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 137.

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

ANSWER: Paragraph 138 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 138.

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

ANSWER: Paragraph 139 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 139.

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

ANSWER: Paragraph 140 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA No. 220487 speaks for itself. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 140.

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

ANSWER: Paragraph 141 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 141.

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

ANSWER: Paragraph 142 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 142.

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

ANSWER: Paragraph 143 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 143.

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

ANSWER: Paragraph 144 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 144.

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

ANSWER: Paragraph 145 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 145.

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

ANSWER: Paragraph 146 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 146.

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

ANSWER: Paragraph 147 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 147.

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

ANSWER: Paragraph 148 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 148.

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

ANSWER: Paragraph 149 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 149.

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

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

ANSWER: Aurobindo repeats and re-alleges each of its responses to the foregoing Paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 151 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that it filed its ANDA

No. 220487 with the FDA, and that Aurobindo seeks regulatory approval from the FDA for its ANDA. The content of Aurobindo's ANDA speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 151.

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

ANSWER: Paragraph 152 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 152.

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

ANSWER: Paragraph 153 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 153.

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

ANSWER: Paragraph 154 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 154.

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

ANSWER: Paragraph 155 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 155.

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

ANSWER: Paragraph 156 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) were in effect at the time Aurobindo's Notice Letter was filed and that Aurobindo complied with same. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 156.

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

ANSWER: Paragraph 157 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 157.

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

ANSWER: Paragraph 158 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 158.

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

ANSWER: Paragraph 159 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations of Paragraph 159 are wholly speculative, as Aurobindo has not received FDA approval for ANDA No. 220487. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 159.

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

ANSWER: Paragraph 160 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 160.

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

ANSWER: Paragraph 161 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 161.

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

ANSWER: Paragraph 162 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA No. 220487 speaks for itself. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 162.

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

ANSWER: Paragraph 163 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 163.

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

ANSWER: Paragraph 164 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 164.

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

ANSWER: Paragraph 165 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 165.

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

ANSWER: Paragraph 166 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 166.

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

ANSWER: Paragraph 167 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 167.

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

ANSWER: Paragraph 168 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 168.

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

ANSWER: Paragraph 169 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 169.

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

ANSWER: Paragraph 170 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 170.

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

ANSWER: Paragraph 171 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 171.

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

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

ANSWER: Aurobindo repeats and re-alleges each of its responses to the foregoing Paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 173 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that it filed its ANDA No. 220487 with the FDA, and that Aurobindo seeks regulatory approval from the FDA for its ANDA. The content of Aurobindo's ANDA speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 173.

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

ANSWER: Paragraph 174 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 174.

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

ANSWER: Paragraph 175 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 175.

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

ANSWER: Paragraph 176 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 176.

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

ANSWER: Paragraph 177 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 177.

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

ANSWER: Paragraph 178 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo admits that 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7) were in effect at the time Aurobindo's Notice

Letter was filed and that Aurobindo complied with same. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 178.

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

ANSWER: Paragraph 179 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's Notice Letter speaks for itself. Except as expressly admitted, Aurobindo denies the allegations of Paragraph 179.

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

ANSWER: Paragraph 180 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 180.

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

ANSWER: Paragraph 181 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the allegations of Paragraph 181 are wholly speculative, as Aurobindo has not received FDA approval for ANDA No. 220487. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 181.

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

ANSWER: Paragraph 182 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 182.

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

ANSWER: Paragraph 183 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 183.

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

ANSWER: Paragraph 184 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Aurobindo's ANDA No. 220487 speaks for itself. Except as expressly admitted, Aurobindo denies the remaining allegations of Paragraph 184.

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

ANSWER: Paragraph 185 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 185.

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

ANSWER: Paragraph 186 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 186.

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

ANSWER: Paragraph 187 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 187.

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

ANSWER: Paragraph 188 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 188.

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

ANSWER: Paragraph 189 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 189.

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

ANSWER: Paragraph 190 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 190.

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

ANSWER: Paragraph 191 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 191.

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

ANSWER: Paragraph 192 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 192.

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

ANSWER: Paragraph 193 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Aurobindo denies the allegations of Paragraph 193.

PLAINTIFF'S PRAYER FOR RELIEF

All allegations in Plaintiff's Complaint that are not expressly admitted by Aurobindo are denied. Aurobindo denies that Plaintiff is entitled to any of the relief sought in its Prayer for Relief.

AUROBINDO'S SEPARATE DEFENSES

Without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not expressly admitted, Aurobindo asserts the following Separate Defenses to Plaintiff's Complaint without assuming the burden of proof on any defense that would otherwise rest on Plaintiff. Aurobindo reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

FIRST SEPARATE DEFENSE
(No Infringement of U.S. Patent No. 9,358,204)

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Aurobindo's ANDA No. 220487 has not infringed, do not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '204 patent.

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

The '204 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101 *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

THIRD SEPARATE DEFENSE
(No Infringement of U.S. Patent No. 9,603,853)

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Aurobindo's ANDA No. 220487 has not infringed, do not infringe, and would not, if

marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '853 patent.

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

The '853 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101 *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

FIFTH SEPARATE DEFENSE
(No Infringement of U.S. Patent No. 9,662,338)

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Aurobindo's ANDA No. 220487 has not infringed, do not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '338 patent.

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

The '338 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101 *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

SEVENTH SEPARATE DEFENSE
(No Infringement of U.S. Patent No. 11,324,753)

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Aurobindo's ANDA No. 220487 has not infringed, do not infringe, and would not, if

marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '753 patent.

EIGHTH SEPARATE DEFENSE
(Invalidity of U.S. Patent No. 11,324,753)

The '753 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101 *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

NINTH SEPARATE DEFENSE
(No Infringement of U.S. Patent No. 11,458,143)

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Aurobindo's ANDA No. 220487 has not infringed, do not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '143 patent.

TENTH SEPARATE DEFENSE
(Invalidity of U.S. Patent No. 11,458,143)

The '143 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101 *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

ELEVENTH FIRST SEPARATE DEFENSE
(No Infringement of U.S. Patent No. 12,121,523)

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Aurobindo's ANDA No. 220487 has not infringed, do not infringe, and would not, if

marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '523 patent.

TWELFTH SEPARATE DEFENSE
(Invalidity of U.S. Patent No. 12,121,523)

The '523 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101 *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

THIRTEENTH SEPARATE DEFENSE
(Failure to State a Claim for Exceptional Case)

Plaintiff's Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285. Aurobindo's actions in defending this case do not give rise to an exceptional case.

RESERVATION OF DEFENSES

Aurobindo reserves any and all defenses 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.

Dated: August 29, 2025

Respectfully submitted,

s/ Kaan Ekiner

Kaan Ekiner
COZEN O'CONNOR
1201 N. Market Street
Suite 1001
Wilmington, DE 19801
(302) 295-2046
kekiner@cozen.com

Attorneys for Defendants Aurobindo Pharma Limited and Aurobindo Pharma U.S.A., Inc.

OF COUNSEL:

W. Blake Coblentz
Aaron S. Lukas
COZEN O'CONNOR
2001 M Street, NW, Suite 500
Washington, DC 20036
(202) 912-4800
wcoblentz@cozen.com
alukas@cozen.com

Keri L. Schaubert
COZEN O'CONNOR
3 WTC, 175 Greenwich Street, 55th Floor
New York, NY 10007
(212) 509-9400
kschaubert@cozen.com

CERTIFICATE OF SERVICE

I hereby certify that on August 29, 2025, a true and correct copy of the foregoing **DEFENDANTS AUROBINDO PHARMA LIMITED AND AUROBINDO PHARMA U.S.A., INC.'S ANSWER AND SEPARATE DEFENSES TO PLAINTIFF'S COMPLAINT** was filed electronically with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

s/ Kaan Ekiner
Kaan Ekiner